HEALTH CARE LAW-MAKING IN CENTRAL AND EASTERN EUROPE

SOCIAL EUROPE SERIES, Volume 3

HEALTH CARE LAW-MAKING IN CENTRAL AND EASTERN EUROPE

REVIEW OF A LEGAL-THEORETICAL MODEL

André Pieter DEN EXTER

Intersentia
Antwerp – Oxford – New York

Distribution for the UK:
Hart Publishing
Salter's Boat Yard
Folly Bridge
Abingdon Road
Oxford OX1 4LB
UK
Tel: + 44 1865 24 55 33
Fax: + 44 1865 79 48 82

Distribution for North America:
Transnational Publishers
410 Saw Mill River Road
Ardsley
New York 10502-2615
USA
Tel: + 1 914 693 5100
Fax: + 1 914 693 4430

Distribution for Switzerland and Germany:
Schulthess Verlag
Zwingliplatz 2
CH-8022 Zürich
Switzerland
Tel: + 41 1 251 93 36
Fax: + 41 1 261 63 94

Distribution for other countries:
Intersentia Publishers
Churchilllaan 108
2900 Schoten
Belgium
Tel: + 32 3 680 15 50
Fax: + 32 3 658 71 21

Health Care Law-making in Central and Eastern Europe
Review of a Legal-Theoretical Model

André Pieter den Exter

© 2002 Intersentia
Antwerp – Oxford – New York
http://www.intersentia.com

ISBN 90-5095-253-4
D/2002/7849/46
NUR 825

No part of this book may be reproduced in any form, by print, photoprint, microfilm or any other means, without written permission form the publisher.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

This volume is the product of PhD research on health legislation in several Central and Eastern European countries. It directly emanates from a previous PHARE project supporting the Albanian Ministry of Health in revising the legal framework of health care law in Albania. The magnitude and complexity of legislative reforms aroused the author's scientific interest and encouraged him to extend his research to other countries in the Eastern hemisphere. The author has become familiar with all the countries discussed in the present volume, as well as their health care legislation and organisation, not only through this research but also through personal contacts spanning a number of years, albeit with occasional interruptions.

In order to increase the accuracy of the information gathered, several interviews have been conducted. Those interviewed included university colleagues, key figures in the legislative and policy departments of Ministries of Health, staff members of social health insurance funds and health professional organisations, constitutional judges and ombudsmen. To all those persons who so generously gave their time for these interviews, I wish to extend my most sincere gratitude.

To review the intermediate outcomes, the findings have been presented at seminars and colloquia including the Interdisciplinary Centre for Ethics of the European University Viandrina Frankfurt (Oder); the School of Public Health, Charles University Prague; the Law Schools of the Universities of Warsaw, Eötvös Loránd, and Turku; the Constitutional Courts in the Czech Republic, Hungary and Poland; the World Conference on Medical Law, Balaton Hungary, and the World Health Organization Regional Office Copenhagen, Denmark. The results of the research have subsequently been published in various European (legal) journals describing health legislative successes and shortcomings. The colleagues who read and commented upon articles, drafts and sections of this book have helped me greatly in improving this work and their support I gratefully acknowledge. They particularly include Eva Baginska, Marianna Fazekas, Danuta Gajdus, Ágnes Horváth, Lukas Prudil, Marek Safjan, Judit Sándor, Jana Silhanová, Árpád Skrabski, András Tamás, Katarzyna Tymowska and Petr Tröster. Whilst a scarcity of translated legal materials was a major limitation, this obstacle has been overcome by conducting extensive interviews with key figures. The author is therefore confident that the examination of health care legislation presented here is an accurate reflection of the situation as it existed up until 2001.

The author is also indebted to a large number of individuals who supported him throughout the course of this research. It has been a

particular pleasure to work with my promotor Johan Legemaate. Special thanks also to all the members of the doctoral committee.

I offer my gratitude and respect to my supervisor Bert Hermans. With his broad knowledge and experience in the field of health care law, he played a key role in the completion of this research. He supervised this dissertation with great understanding, personal interest and endless encouragement.

I reserve my special thanks for my colleagues Martin Buijsen and Ernst Hulst, whose solidarity, spirit and humour were constant sources of inspiration to me.

Last, but not least, I would like to express my gratitude to my family, and in particular to my parents, for the encouragement and enduring support they offered during the completion of this work.

Rotterdam, April 2002

ABBREVIATIONS

ABH	Constitutional Court Hungary
AJH	Acta Juridica Hungarica
ARSP	Archiv für Rechts- und Sozialphilosophie
CEE	Central and Eastern Europe
Coll.	Collection of Laws (Official Journal of the Czech Republic)
COM	Commission Document
CMJ	Croatian Medical Journal
CMLR	Common Market Law Review
DRGs	Diagnosis Related Groups
Dz.U.	Dziennik Ustaw (Official Journal of Poland)
EA	Europe Agreement
EC	European Community
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms
ECtHR	European Court of Human Rights
ECJ	European Court of Justice
ECR	European Court Reports
EEA	European Economic Association
EEC	European Economic Community
EECR	East European Constitutional Review
EFTA	European Free Trade Association
EJHL	European Journal of Health Law
EJLE	European Journal of Law and Economics
EJPH	European Journal of Public Health
ESC	European Social Charter
ETS	European Treaty Series
EU	European Union
GC	General Comment
GP	General practitioner
HIF	Health Insurance Fund
HRQ	Human Rights Quarterly
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
ILO	International Labour Organization
MK	Magyar Közlöny (Official Hungarian Law Gazette)
NERA	National Economic Research Associates
NHS	National Health Service

NIS	Newly Independent States
NPAA	National Programme for the Adoption of the Acquis
NTER	Nederlands Tijdschrift voor Europees Recht (Dutch J. of European Law)
OECD	Organisation for Economic Co-operation and Development
OTK	Orzecznictwo Trybunalu Konstytucyjnego (Rulings of the Polish Constitutional Tribunal)
PHARE	*P*oland and *H*ungary: *A*ssistance to the *R*econstruction of the *E*conomy
Rev. CEE Law	Review of Central and East European Law
RPO	Rzeznik Praw Obywatelskich (Polish Ombudsman)
Series A	Publications of the European Court of Human Rights; Judgements and Decisions
TEU	Treaty on European Union
UN	United Nations
WHO	World Health Organization
ZaöRV	Zeitschrift für ausländisches öffentliches Recht und Völkerrecht

TABLE OF CASES

European Court of Justice

Albany	Case C-67/96 [1999] ECR I-5751
Ambulanz Glöckner	Case C-475/99 [2001] ECR I-8089
Babahenini	Case C-113/97 [1998] ECR I-183
Barkoci	Case C-257/99 [2001] ECR I-6557
Bond van Adverteerders	Case C-352/85 [1988] ECR 2085
Brentjens	Joined Cases C-115/97 C-116/97 and C-117/97 [1999] ECR 1999 I-6025
Dassonville	Case C-8/74 [1974] ECR 837
Decker	Case C-120/95 [1998] ECR I-1831
Deliuige	Joined Cases C-51/96 and C-191/97 [2000] ECR I-2549
Germany	Case C-376/98 [2000] ECR I-8419
Gloszczuk	Case C-63/99 [2001] ECR I-6369
Féderation Française	Case T-106/95 [1997] ECR 1997 II-229
Ferlini	Case C-411/98 [2000] ECR I-8081
Grogan	Case C-159/90 [1991] ECR I-4685
Gül	Case C-131/85 [1986] ECR I-573
Jany	Case C-268/99 [2001] ECR I-8615
Kohll	Case C-158/96 [1998] ECR I-1931
Kondova	Case C-235/99 [2001] ECR I-6427
Max.mobil	Case T-54/99 [2002] ECR I-000
Müller-Fauré/Van Riet	Case C-385/99
Kziber	Case C-18/90 [1991] ECR I-199
Demirel	Case C-12/86 [1987] ECR 3719
Pavlov	Joined Cases C-180/98 to C-184/98 [2000] ECR I-6451
Pierik II	Case C-182/78 [1979] ECR 1977
Polydor	Case C-270/80 [1982] ECR 329
Poucet and Pistre	Joined Cases C-159/91 and C-160/91 [1993] ECR I-637
Racke	Case C-162/96 [1998] ECR I-3655
Reyners	Case C-2/74 [1974] ECR 631
Royer	Case C-48/75 [1976] ECR 497
Smits/Peerbooms	Case C-157/99 [2001] ECR I-5473
Titanium dioxide	Case C-300/89 [1991] ECR I-2867
Tögel	Case C-76/97 [1998] ECR I-5357
Twomey	Case C-215/90 [1992] ECR I-1823

Vanbraekel	Case C-368/98 [2001] ECR I-5363
Vereniging van Samenwerkende Prijsregelende Organisaties in de Bouwnijverheid	T-29/92 [1995] ECR II-289

European Court of Human Rights

Airey	9 October 1979 series A 32
Guerra	19 February 1998 Reports 1998-I
Karara	29 May 1998 series A 40900/98
L.C.B.	9 June 1998 (14/1997/798/1001)
López Ostra	9 december 1994, 41/1993/436/515
Marckx	1 June 1979, series A 6833/74
Osman	17 May 1996 series A 23452/94
Tavares	12 september 1991 series A 16593/90

Hungarian Constitutional Court

2/1990 (II.18) ABH
11/1990 (V.1.) ABH
20/1990 (X.4) ABH
15/1991 (IV.13.) ABH
4/1997 (I.22) AB, ABH 1997, 41 [49]

Czech Constitutional Court

Pl US 35/93
Pl 49/1994 Sb
Pl US 35/95
Pl US 337/97

Polish Constitutional Tribunal

K. 1/88, 94
K. 7/90, 55
K. 6/91, 62
K. 14/91, 132
K. 14/92, 330 – 331
W 12/94, OTK 1996
U 3/95, 245
K 7/95, 414

K 15/95, OTK 1996
K 25/95, 501
K 8/96, 275
K 10/98

CHAPTER 1: INTRODUCTION

> "*Health care reforms can often be compared with teenage sex. Everybody is talking about it while no one knows who is doing it. And when it happens it is often under lousy circumstances.*"[1]

Most of the European countries are confronted with health care system reforms. In Central and Eastern Europe, however, the countries face specific challenges. Whereas "socialist" governments traditionally have been deeply involved in all facets of health care, the general process of initiated market-oriented reforms has also affected the nature and scope of government intervention in health care. Stimulated by the successes of concepts such as decentralisation, deregulation, and privatisation in order to create a more flexible market economy, policy-makers also began to apply such notions to the health care sector. The experiences in the early 1990s however, revealed certain devastating effects of transposing the general concept of market competition to the field of health care. One valuable lesson of those developments was that liberalising relations in health care necessitates a certain degree of government intervention. Furthermore, the nature and scope of Central and Eastern European health care reforms differed from country to country with no uniform "blueprint" for reform, derived from emulating Western European experiences, being readily available. Nevertheless, previous experiences in reforming health care may provide us with valuable lessons. Their significance needs, nonetheless, to be reviewed in accordance with specific national setting.

1. THE HEALTH CARE SYSTEM

The urgency of implemented reforms in the early 1990s had largely motivated by economic considerations. Due to the worsening socio-economic situation governments opted for drastic reforms such as a shift from a tax revenue-based health care scheme to a system based on (premium) contributions. The idea was to create additional and/or supplementary resources in order to secure the financing of increasing health care expenditures. Owing to the decrease in taxrevenues, government contributions to finance health care services had also decreased dramatically. The general belief was that a premium-based health insurance

[1] In: The Right to Health Care in several European countries. A.P. den Exter, H.E.G.M. Hermans (eds). Kluwer Law International, The Hague, 1999: 2.

system would enable the funds necessary to finance basic health care facilities to be increased. To change the financing structure, as well as the organisation of the present health care system would, however, necessitate legal, and in particular legislative "backup". (Re)developing such a legislative scheme has to be considered within the framework of the fundamental obligations and functions that influence the relationship of government *vis-à-vis* society. En route to transition, it is important to reconsider the position and function of the (national) authorities of Central and Eastern European countries, particularly in the field of health care. A belief in proiritising and reshaping or developing new regulation – including (non-) legislative rules – is on the increase. The process of regulation has to be considered within the framework of fundamental social concepts and objectives. Enshrined in international treaties and national constitutions, these legal norms contain practical criteria to operationalise and review various policy objectives. Simultaneously, these parameters function as boundaries in limiting the accessibility, quality, structure and financing of care. Non-membership of the relevant treaties and a lack of adequate health care legislation exclude such a direct review in most Central and Eastern European countries, at least for the moment. Nevertheless, treaty obligations should be considered as absolute norms that will commit Central and Eastern European countries in the not too distant future. Comparing national legislation to such legal-theoretical parameters may have consequences to the modalities and content of legislation. The term "legal-theoretical" refers in this context to the development and assessment of an analytical model that aims at structuring a not *a priori* structured process.

With reference to health care, the meaning of legal-theoretical criteria becomes manifest in the legislative or law-making process on public health, the organisation of health care services, quality of care, the financing of care and patients' rights. In view of the risk of *ad hoc* and uncontrolled drafted legislation without preceding elaborated or specified criteria, policy objectives or priorities, the necessity to structure this activity increases. As such, a circular model of law-making may provide an adequate formal legal framework to rationalise this process, in compliance with the historical setting of Central and Eastern European countries.

2. LAW, LAW-MAKING AND POLICY

From a legal-theoretical perspective, it is important that the intended changes in Central and Eastern Europe meet with the substantive normative framework of international law. Furthermore, such normative criteria can be considered as underlying principles in drafting national legislation. Previous research revealed that substantive legal norms could be linked

to actual developments in a formal framework in order to structure and review the health care legislative process.[2]

Since economic developments dominate the health policy-agenda, it is crucial to examine to what extent existing health care laws, notably in the field of organisation and financing, correspond with the policy priorities. Contrariwise, the direct or self-executing effect of international treaty provisions may impose substantial amendments of legislation. Particularly in financing health care potential conflicts might occur with respect to individual formulated entitlements of the insured. In view of the current legislative system, it is questionable whether the unrestricted introduction of market elements will provide an answer to current problems in Central and Eastern European health care. The debate on the development and introduction of "regulated or managed competition" appears to be a striking example of the possibilities and problems to which Central and Eastern European countries could be confronted.[3] A problem with this type of research is the fact that developments in a specific Central and Eastern European setting are not generally comparable to those in other countries. This is even more so with regard to legislation. Nonetheless, based on the understanding derived from the law-making doctrine, it is possible to review certain legislative developments within the framework of a formal legal-theoretical model of law-making (the circular model of law-making). In the health care legislative setting, such a model is related to health policy developments such as the introduction of market elements, notably in the field of the provision and financing of health care. Previous outcomes of research enable a first review of the process of legislative changes in health care in Central and Eastern Europe based upon this developed model.

3. THE FORMULATION OF THE PROBLEM, STRUCTURE, METHODOLOGY AND LIMITATIONS

Formulation of the problem and central questions

The introduction of a "Bismarckian" based health insurance model in most Central and Eastern European countries necessitates a revision of existing legislation, based on a more "Western"-oriented approach. Such a

---

2 A.P. den Exter, H.E.G.M. Hermans, E.H. Hulst. Health Care Legislation in Central and Eastern Europe. A Problem-Oriented Method of Legal Analysis of Health Care Systems in Central and Eastern Europe. The Albanian Example. *Rev. CEE Law* 1997, Iss. 2: 117-132.

3 The notion of "regulated or managed competition" was originally developed and subsequently elaborated by A.C. Enthoven. Theory and Practice of Managed Competition in Health Care Finance. North-Holland, Amsterdam, 1988.

"Europeanization" of the internal legal order can be observed in most countries in Central and Eastern European. Its underlying notion is the democratic experiences and structure of Western countries and societies. Simultaneously, the requirements of supranational legal orders such as the European Union and the Council of Europe have made it necessary to adapt legislation.

The absence of an adequate normative framework causes conflicts between actual developments and legal norms and regulation. In the health care legal doctrine various functions of law or "law-jobs" can be discerned, *viz*, the guarantee, the conflict regulating and the planning or allocative function of health care law. Of importance within the framework of this research are the guarantee and allocation functions of law. Health care legislative or law-making policy is determined by these functions of health care law. For instance, in order to guarantee access to basic health care, the legislature will have to define a social security scheme whereas in an early stage, policy choices have to be made. Such choices notably *reflect* the guarantee function of health care law. Alternatively, the defined legal norms *express* policy choices such as the choice to introduce market competition in health care. The debate on the implementation of these functions is of relevance to Eastern Europe particularly since most Eastern European countries are faced with omissions and inadequacies in reforming health care legislation.

From a legal perspective, the introduction of market elements in the organisation and financing of health care may invoke unintended side-effects, contrary to actual and normative starting points of law-making. The guarantee and regulative function enable the review of such developments and the formulation of legislative limitation to such experiences. As would be expected, in this respect the national authorities will focus on the constitutional or legislative tasks formulated or derived from the constitution, such as the promotion of public health and the protection of the rights of individual patients. But it is also likely that, given the allocation and guarantee function of the law, national authorities have a substantial role in regulating the financing and provision of the health care system.[4] Absence of government intervention in the organisation and financing of health care could invoke inefficiencies and equality conflicts in the allocation of scarce resources.

The relevant normative parameters are found in the international and European health legal literature, described notably by Roemer, McKray and Longley.[5] With respect to the development of a substantive legal-

---

4 R. Roemer. Law and Health Policy in: R. Roemer and G. MacKray (eds). Legal Aspects of Health Policy. Issues and Trends. Greenwood Press Westport, 1980: 439.

5 Roemer *o.c.* 439; D. Longley. Health Care Constitutions. Cavendish Publishing, 1996.

theoretical framework, research should enclose health legal principles and legal norms, including those norms entrenched in (supra)national legal orders. Various scholars have confirmed the importance of international norms to health care, notably European Community law.[6]

In order to analyse the current legal reforms of Central and Eastern European health care systems, a conceptual model of health care law-making will be developed. Such a model should reflect general substantive norms of international law as well as specific national legal norms relevant to health care. By applying such a model to law-making practise and by reviewing existing legal norms in light of the model's underlying principles, the model may contribute to the rationalisation of the legislative activity in these countries. In the context of EU enlargement, the analytical model should ameliorate the understanding of the legal consequences of incorporating *acquis communautaire* to the process and content of health legislation in Central and Eastern European candidate countries. Augmentation of such insights is necessary since the contemporary discussion seems largely to be dominated by economic considerations. These assumptions have led to the following problem formulation: *Whether a legal-theoretical model of law-making can contribute towards the review of the process and content of legislative reforms in Central and Eastern European health care systems. And, if possible, by what means this may be achieved.* The elaboration of this thesis has necessitated the formulation of the following central questions:

The first question, dealt with in part one, examines whether it is possible to develop a conceptual model of health care law-making. Such a model aims to review both the process and content of legislative reforms in Central and Eastern European health care systems. The theoretical model to be developed will be found upon the doctrine of law-making, the method of law-making and recent understanding of a circular approach to law-making.[7] The underlying assumption is to structure and systematise the law-

---

6 *Cf. e.g.*, Chr. Altenstetter. The Effect of European Policies on Health an Health Care: An Agenda for the Future in: Health Care in Europe after 1992. H.E.G.M. Hermans *et al* (eds) Dartmouth publishing. Aldershot 1992. J. Montgomery. Health Care Law. Oxford University Press 1997. H.J.J. Leenen The Right to Health Care in the Netherlands in: The right to health care in several European countries. A.P. den Exter, H.E.G.M. Hermans (eds), Kluwer Law International, The Hague 1999; H. Nys. Patiënt en Europa op zoek naar een Europees geneeskundig dienstverleningsrecht (Patient and Europe in pursuit of a European medical provision right), Inaugural lecture University Maastricht 2000; H.D.C. Roscam Abbing. Patient in Europe of the 21st century: a health legal consideration in: The future of European integration (in Dutch). Ars Aequi 2001, Iss. 50: 72-80.

7 The law-making doctrine as understood by legal theorists such as Peter Noll. Gesetzgebungslehre. Hamburg 1973; Burkhardt Krems Grundfragen der Gesetzgebungslehre erörtert anhand neuerer Gesetzgebungsvorhaben insbesondere der Neuregelung des Bergschadenrechts. Duncker und Humblot, Berlin 1979; Jerzy Wróblewski. Einführung in die Gesetzgebungstheorie. Wien 1984; W.G. van der Velden. De ontwikkeling van de wetgevingsweten-

making activity by means of a simplified model. These understanding will be addressed to a specific field of law-making, *i.e.* health care law-making. Consequently, the underlying principles of health care law have to be examined since they function as benchmarks in the formulation and operationalisation of the normative role and functions ("law-jobs") of the legislature in health care. Its relevance to Central and Eastern Europe concerns the synthesis of the dynamic process of law-making with the qualities of health care law. Such a circular model stresses the importance of health policy by correlating incremental policy-reforms with health care law-making. The concomitant gradual legislative changes should enable the legislature to structure and systematise health care system reforms in a more controlled manner.

The second question, dealt with in part two, is whether such an analytical model of health care law-making is applicable to legislative practise in several countries. To verify this thesis, three case studies will be discribed that focus on current law-making practise in selected Central and Eastern European countries. Such a global analysis enables the comparison of both the process and content of health care law-making with the theoretically discerned stages and clusters of health care law-making. The outcomes of research, *i.e.* any possible similarities and differences between the two, may confirm the relevance of such a theoretical model to a broader Central-Eastern setting. As such, the application of this theoretical model may enable the identification, definition and likely anticipation of (potential) legalistic problems in legislative decision-making in the field of health care. In this stage of research, elements of the legislative model will be examined for their comprehensiveness and effectiveness. In addition, a comparison of the country studies will enable the identification of similarities and differences in the application of the model *between* the countries. This will consequently enable the identification of the country most successful in applying the model. However, explaning this is not a legal matter *per se.*

In part three the final question to be examined is whether and in what respect the model could contribute to the EC approximation of laws process. This third question examines the relevance of the model through an in-depth analysis of a specific theme, namely, the approximation of national law to Community law. Since the ratification of the Europe agreements, Community law and the underlying *communautaire* principles became an additional and, most likely, dominant source of law. Future

---

schap, een rechtstheoretisch onderzoek (The development of the science of legislation: A legal theoretical inquiry). Koninklijke Vermande, Lelystad 1988; H.B. Winter. Evaluatie in het wetgevingsforum. Een onderzoek naar de relatie tussen evaluatie en kwaliteit van wetgeving (Evaluation in the legislative forum). Kluwer, Deventer 1996.

accession to the European Union requires candidate countries to adopt the *acquis communautaire*, i.e. the approximation of their national law to EC legal standards. This requirement has raised concerns about the "compatibility" of national health (care) legislation with supra-national law. Both the magnitude and complexity of the acquis complicate its incorporation into national law. This research will also examine whether, and by what means, the model is able to contribute to the analysis and assessment of the "approximation of laws" process in a more rational manner. The application of a modified circular model of law-making in this field should confirm the relevance of this model to EC law harmonisation and its ability to predict events. Put in more general terms, its ability to verify the basic assumption of the legal-theoretical model, *i.e.* rationalisation of the process and content of health care law-making.

Structure of this study

In order to answer these central questions, this research has been divided into three parts. Part one sets out the conceptual framework for this research and is related to question one. In the first chapter, a legal-theoretical model of law-making is described based on the doctrinal debate on the method of law-making. The underlying assumption of such a method is the structuring and systematisation of law-making activity. Moreover, such activity could be expressed by means of a simplified model. To generalise a model of health care law-making in Central and Eastern Europe, the research commences with an analysis of a general law-making model as derived from legal-theoretical doctrine. The primary question to be answered is "in what respect does current law-making theory confirm the notion of a general model of law-making"? The introductory chapter will therefore discuss several prominent Continental legal commentators, starting with Peter Noll ("*Gesetzgebungslehre*"), Burkhardt Krems ("*Grundfragen der Gesetzgebungslehre*") and Jerzi Wróblewski ("*Einführung in die Gesetzgebungstheorie*"). More recent theorists have subscribed to the underlying circular approach of law-making. The next chapter addresses a normative framework of health care law. Substantive principles such as the right to health care and patient autonomy function as primordial values in operationalising the role and function of national authorities in health care ("law-jobs"). Transposed to the general notion of a legal-theoretical model of law-making, these health care "law-jobs" play a crucial role. The final chapter of part one describes the synthesis of a tentative circular model of health care law-making and its relevance to health policy in Central and Eastern Europe. Coping with rapid and profound changes, legislative measures are often not planned in advance and go hand in hand with lack of systematics. Therefore, the main question in the Central and

Eastern European reform debate is related to the amelioration of consistency and coherency in health care law-making. Seen from this perspective, it is questionable whether the application of a rudimentary theoretical law-making model, combined with a framework of substantive parameters of health care law, may improve the current situation.

Part two addresses the second question regarding the relevance of the model of health care law-making in Central-Eastern Europe by examining three selected countries. Since the initiated reforms, health care legislation has become a major issue in the current reform debate in Central and Eastern Europe. The subsequent chapters therefore examine the most important legal changes in the countries concerned. These changes focus, *inter alia*, on regulating the privatisation and decentralisation of health care facilities and services, introduced in a non-structured manner without sufficient consideration and evaluation of (un)intended (side-)effects. Particularly in the field of health care financing, legal reforms introduced rashly have caused major problems in the selected countries. What lessons could be drawn from such omissions, notably with respect to health care law-making? An alternative approach might be the circular model of law-making as developed in part one. In order to assess its relevance, the comprehensiveness and effectiveness of the model is examined in part two. The central question concerns the relationship between law-making practise in several Central and Eastern European countries and the theoretical model, or: how does the legislature cope with law-making practise, in the light of the theoretically discerned stages and clusters of law-making? In consequence, what are the main problems that occur in law-making practise? It is argued that a comparative analysis may reveal possible (un)intended (side) effects of newly initiated legal reforms. By structuring and systematizing the law-making process, the law-making model could increase the rationality of law-making in the health care sector. Case-study research of illustrative legal changes is the first step in verifying this assumption.

Part three includes a more in-depth review of the practical value of the circular model of law-making, the third question of this research. Therefore, the research focuses on one specific theme, the approximation to EC law. The first experiences in the law approximation process revealed major deficiencies, notably the (in)direct implications of the internal market acquis to national health care legislation. The methodological approach of the circular model suggests a strengthening of this law approximation process by analysing and reviewing both the health acquis, and the domestic legal norms incorporating EC law more systematically. Subsequent omissions or shortcomings in the transformation process would enable the adjustment of the domestic approximation objectives and necessary strategy in more detail. It will appear, however, that the original model requires

further modification, in particular the inclusion of Community legal principles. It is argued that a modified theoretical model is feasible in rationalising the approximation of laws process. Examination of the transposition process, in terms of the analytical model enables the verification of the relevance of a developed legal-theoretical method of health care law-making. The final chapter constitutes the concluding part of this research. Conclusions are drawn with regard to the results of the present study.

Methodology

The objective of research is to draft a legal-theoretical model of law-making in the field of health law in Central and Eastern Europe and, subsequently to examine the relevance to legislative practice. The selected method must therefore first describe and analyse the doctrinal debate concerning the law-making method *sui generis*. Consequently, the analysis applies the dynamic notion of law-making to a specific legal setting, that of health care law. On the basis of literature research, it is questioned whether, from a theoretical point of view, such an method of law-making can be of relevance to the legislative reform process in Central and Eastern Europe. The sources referred to in answering this question were found at academic institutions in various countries and largely available in English or German. The subsequently developed theoretical framework enabled an examination of the value of this analytical method. The methodology applied included a comparison of existing national legal norms and the legislative activity to the circular notion on health (care) law-making. The outcomes, both the content and the process, enabled the verification of the relevance of the underlying theoretical notion on law-making in the selected legal orders. Finally, by applying this analytical method to the transposition of EC law, the rationality of the theoretical approach is argued in terms of the law-approximation process. Relevant legal sources discussed include, *inter alia*, national legislation (Acts of Parliament), international treaties and covenants, legal principles, and relevant court rulings. In addition, various policy documents from the Ministries of Health and other health care institutions were examined to identify and discuss major legislative reforms issues. It is recognised that the scarce availability of translated legal materials presented major limitations. In order to compensate for this deficiency and increase the accuracy of the information gathered, several interviews were conducted. Those interviewed included university colleagues, key figures at the legislative and policy departments at the Ministries of Health, staff members of social health insurance funds and health professional organisations, and the judiciary. They are mentioned by name in the text, as well as their function at the moment of being

interviewed. The author feels confident that his examination accurately presents the main features of health legislation up until 2001. To review the intermediate outcomes, the findings were presented at (inter) national seminars and colloquia, and published in several European journals describing health legislative successes and shortcomings.

Limitations

The analysis of a law-making model has several restrictions. For instance, it does not include the controversial autonomous legislative or law-making science versus legislative or law-making doctrine. In view of the lack of consensus, this part of research is restricted to a singular aspect of the law-making doctrine, the law-making *method* ("*Gesetzgebungsmethode*"), reflected by a simplified model. Nevertheless, in order to define and to position the object of research, an introductory overview of the status quo considering the law-making science will be necessary.

Secondly, the technique of law-making ("*Technik der Gesetzgebung*"), as a separate part of the law-making doctrine is not a research issue. This subject will be strictly interpreted as the systematics and the formulation of regulation to which proper law-making should answer. As yet, causality and mutual interference between the technique and the method of law-making do not seem likely, albeit it is not excluded. In case the technique of law-making seriously influences the scheme or contents of the law-making method, further examination of this aspect is required.

Thirdly, the research is limited to the formal legislature in view of the statute law tradition in Continental Europe, which differs from the Anglo-Saxon countries. Even there, however, statute law-making gains more importance. Nevertheless, the influence of case law in the legislative process should not be disregarded; as far as possible, this aspect will also be considered.

Fourthly, as far as the application of the traditional theoretical methods of law-making are concerned, the debate is primarily focused on the absence of the interdisciplinary (economic and public administrative sciences). In practise, law-making is a complex political process in which several actors participate and in which several disciplines mutually are involved. This implies a continuous political "struggle" that occurs in a political arena focused on formulating social problems, legal analysis, and transformation into legal regulation, realisation and evaluation. However, in spite of the admitted importance of an interdisciplinary approach, an analytical legal point of view may, to a certain extent, explain the results of law-making (possible results, (un) known side-effects, the coherency between several stages of lawmaking, *et cetera.*) in order to rationalise the process of law-making. Although law-making is primarily a legal affair, the

relevance of related (sub)disciplines has indeed been acknowledged. Hereafter, political, social and economical influences will be described in general terms as far as necessary, in order to increase the value of the method. Obviously, the limited knowledge of non-legal sciences results in a restricted understanding of the reality of law-making.

A further restriction concerns the selection of four major clusters in health care legislation, *viz*, public health, the organisation of health services, financing, and patients' rights since EU accession and the introduction of market forces in health care particularly affects legislation in these fields. The emphasis on primary care, decentralising and privatising health services, the shift from a tax-based health care system towards a mixture of sources of funding, and the reinforcement of patients' rights characterise the main developments in these selected areas. These developments have appeared in various Central and Eastern European countries although each country adopted different mechanisms to regulate the transition with subsequent different outcomes. The diversity of occurring problems resulted in varying agendas of the legal reforms. Nonetheless, the general topics of legal dilemmas the countries face show some similarity.

Finally, the country analysis focused on three selected countries, *viz*, Hungary, the Czech Republic, and Poland. These countries are "in the first wave" of accessing to the European Union. Consequently, these candidate Member States will have to approximate national legislation to EC law in an early stage. Moreover, they appeared to have a leading role in initiating health care reforms, notably the introduction of a more market-based health care system. The manifested legal problems, while more urgent in these countries, are nevertheless illustrative to less developed countries in the region.

Part One

Generalising a theoretical model of health care law-making

CHAPTER 2: A MODEL OF LAW-MAKING

1 INTRODUCTION

In the contemporary legislative-theoretical discourse, the subject of a law-making method has been frequently discussed. A new impulse in this debate has come from the development of a circular model of law-making, reflecting the method of law-making.[1] Such a simplified approach reflects the discerned elements of the law-making activity by means of a series of stages (event, analysis, draft, enforcement, evaluation, adaptation, *et cetera*). The consecutive sequence enables an analysis of the legal aspects of each single stage, whereas the circular approach provides for to modification of obsolete or ineffective regulation. In view of the classical functional concept of law-making, the philosophy of applying such a model is to systematise and rationalise the law-making practise, an activity often characterised by ambiguous, inconsistent motives and objectives. Generally, application of such a model, based on a theoretically justified analysis, may increase the understanding of the law-making activity. This assumption of the law-making process, reflected by a simplified model, and related with the inherent functional concept of law-making has been criticised both in legal-theory as well as by related administrative and public sciences. The main aspects of this debate concern the analytical rationality-concept of law-making and the political arena in which the law-making process occurs. The restrictions of the omnipotent law-maker and the fiction of law-making as a directive instrument to procure social changes, put in perspective the idea of rationalising the legal decision-making process. Nonetheless, given these constraints, the assumption of a law-making method, reflected by a legal-theoretical model could, to a certain extent, be useful to enhance legal decision-making.

The relevance of referring the legal-theoretical debate of a law-making model concerns the importance to the Central and Eastern European law-making reforms. As is well known, most Central and Eastern European countries, as well as newly emerged Baltic states, are reforming their political, economic and social systems based on a more liberal-oriented concept of a (social) market economy. Legislation has been an indispensable instrument in initiating and regulating these reforms. Simultaneously, the comprehensive reforms also affect the legislative system, as well as the legislative or law-making practise. With the renewed interest in concepts

---

[1] Peter Noll Gesetzgebungslehre. Hamburg. 1973.

such as the *rule of law*, constitutional democracy, and deregulation of legislation has emerged a strong aversion to the "socialist" law-making tradition.[2]

Previous experiences in restructuring social relations by means of "shock-therapy" have caused economic depression and hardship.[3] Therefore, as far as law-making is concerned, a gradual approach of introducing reforms seems socially and politically more desirable and acceptable. In the perspective of directing a gradual transition process by means of legislation, (the possibility of) "xeroxing" foreign legislation has been exchanged for developing "home-made" legislation, adjusted to the specific circumstances and possibilities. It is questionable to what extent such an approach can be realised by means of a rational law-making model and within the framework of a previously determined legislative strategy. If that is the case, law-making activity may occur according to a rather rational accountable method, whereas the systematic approach of law-making could enable the legislature to anticipate future changes, instead of constantly being confronted with *ad hoc* questions. In view of the scope and complexity of reforms in Central and Eastern European countries, this is of paramount importance.

Recent understanding from both the legal and public sciences emphasises the non-legal aspects of law-making, notably political motives. Rationalisation of legislation in a Central and Eastern European setting should therefore take into consideration these non-legal aspects. In these countries, the fragile basis of newly constitutional democracies interferes with the rationalisation process of legislation. For instance, constitutional conflicts between legislative and executive powers, combined with a hostile political competition with opposition parties complicate consensual solutions. Decisions of this type largely characterise the legal decision-making process. In order to develop a model of law-making that is applicable in the "Eastern European" setting, non-legal aspects may necessitate modifying contemporary theories on law-making. Nonetheless, this study is primarily focused on *legal* aspects of a law-making model.

The assumption of a non-strictly legal circular concept of law-making has been developed in the German legal literature. A main representative of this tradition was the Swiss legal scholar Peter Noll, who started a discussion on the "dynamic" concept of rational law-making. In view of this assumption, law-making activity can be presented as a continuous process

---

2 In fact, a single "socialist-approach" of law-making does not exist; law-making in the former Eastern bloc differs, as it must, to Western Europe where, for instance Roman law and Common law traditions resulted in various differentiations in law-making.

3 S. Frankowski and P.B. Stephan. Legal reforms in post-communist Europe: the view from within. Martinus Nijhoff, Dordrecht 1995: 2.

of modifying norms, initiated by changed circumstances and taking into account non-legal aspects of the law-making environment that are relevant to the outcome. In the Central and Eastern European legal doctrine the Polish scholar Jerzy Wróblewski elaborated a more or less similar methodological concept of law-making, although both approaches differ substantially.[4] More recently, the legal-theoretical notion of a regulative period of law-making has been adhered by, *inter alia*, Eijlander and Winter.[5]

Analysis of both law-making concepts, combined with more recent studies increase the understanding on this subject and may confirm the validity of a tentative legal-theoretical model of law-making that is feasible in the Central and Eastern European setting. The ultimate relevance of such a model concerns its relation with health care law-making and will be discussed extensively in the following chapters. But first, to position the object of research, this chapter will begin with a brief overview of several legal-theoretical aspects of both the law-making *doctrine*, which is defined as the science, and studying the law-making practise (section 2.2). Secondly, a more extensive discussion has been included on the characteristics of the law-making *method* that constitutes a part of the law-making doctrine (section 2.3). Accordingly, this section will focus on the methodologies formulated by Peter Noll and Jerzy Wróblewski. Both legal theorists had a major impact on the rationality discussion on law-making. Although it is not intended to provide a duplication of the legislative theories, such an exposition is, however, necessary to understand the subsequent discussion on the assumptions and content of a law-making method (section 2.4–2.6).

2. LEGAL-THEORETICAL BACKGROUNDS: CHARACTERISTICS OF THE LAW-MAKING DOCTRINE

The contemporary law-making practise is characterised by an increased volume and extended complexity of legislation. This tendency has been observed in most European legal systems, started after World War Two.[6]

---

4 Jerzy Wróblewski. Einführung in die Gesetzgebungstheorie. Wien 1984.

5 Ph. Eijlander. De wet stellen. Beschouwingen over onderwerpen van wetgeving (To position the law). W.E.J. Tjeenk Willink Zwolle 1993; H.B. Winter. Evaluatie in het wetgevingsforum. Een onderzoek naar de relatie tussen evaluatie en kwaliteit van wetgeving (Evaluation in the legislative forum). Kluwer, Deventer 1996.

6 T. Öhlinger. Methodik der Gesetzgebung: Legistische Richtlinien in Theorie und Praxis. Springer Verlag, Wien 1982: 21-2; J. Wróblewski. Einführung in die Gesetzgebungstheorie. Wien 1984: 35; P. Noll. Gesetzgebungslehre. Hamburg 1973: 9; W. Schreckenberger. Krise der Gesetzgebung? in: Gesetzgebungslehre: Grundlagen-Zugänge-Anwendung. Kohlhammer Studienbücher. Rechtswissenschaft. Stuttgart 1986: 21-37; U. Karpen. Gesetzgebungs-, Verwaltungs-, und Rechtssprechungslehre. Beiträge zur Entwicklung einer Regelungstheorie. Baden Baden: Nomos Verlag 1989: 13-14; H. Schäffer, A. Rácz. Quantitative Analysis of Law: A comparative empirical study. Sources of Law in Eastern and Western Europe. Akadémiai

The shift towards a "socialist" or a "welfare state" imposed intensive government involvement, notably through legislation. Simultaneously, socialisation of human relations and technological innovations also contributed to the continuously changing flood of (complex) legislation. In the legal-theoretical literature, the increased size and complexity of law-making have been debated for several decades.[7] The growing academic interest concerns law-making activity; an activity, historically characterised as a professional skill, learned by practise without a scientific setting. The Swiss legal scholar, Peter Noll gave new impulse to the legal discourse about the necessity of an autonomous law-making discipline, called the legislative or law-making doctrine ("*Gesetzgebungslehre*").[8] With the rationalisation of the law-making activity as his leading motive, Noll described the law-making doctrine as *"eine Lehre, und nicht als Kunst, die Form und Inhalt der Rechtsnormen mit dem Ziel untersucht, Kriterien, Richtlinien und Anleitungen zur rationalen Normgebung und Normgestaltung zu erarbeiten' an"*.[9] Whereas the object of research has been defined by two questions:
– *"how should the law optimally be formed as regards to its contents", and*
– *"how, or by what means, can legislative norms influence social situations in an intended direction"*.[10]

Such a description of the object of research and its objectives, emphasises the normative-functional character of the law-making doctrine. Nonetheless, the functional aspect dominates in Noll's approach. In view of Noll's rationality concept of law-making this should come as no surprise.

Kiadó. Budapest 1990; Z. Péteri. Anmerkungen zur parlamentarischen Gesetzgebung in Ungarn in: Gesetzgebungsverfahren und Gesetzgebungsqualität. H. Schäffer (ed.) Manz. Vienna 1992: 29-30; K. Kulcsár. Modernization and Law. Budapest 1992: 196, 198-99; P. Sarnecki. Gesetzgebungsqualität und Gesetzgebungsverfahren in Polen in: Gesetzgebungsverfahren und Gesetzgebungsqualität *o.c.*: 37-40; H. Szurgacz. Entwicklungen im Polnischen Sozialrecht unter besonderer Berücksichtigung der Krankenversicherung und der Sozialhilfe in: Rechtsberatung und Verwaltungsförderung in Mittel- und Osteuropa: Vorträge und Diskussionen im Zweiten Werkstattsgespräch zur Verwaltungs förderung der Hochschule für Verwaltungswissenschaften Speyer, München 1994: 174-5

7 Quoted by Noll. In the legal history, Savigny already noted the implications of extensive codification of legal positivism. C.F. von Savigny. Vom Beruf unserer Zeit für Gesetzgebung und Rechtswissenschaft. Heidelberg 1814.

8 P. Noll. Gesetzgebungslehre. Hamburg 1973.

9 Noll *o.c.*: 15.

10 "Wie sollte Recht inhaltlich optimal gestaltet werden", *o.c.*: 25 and "wie können mit gesetzlichen Normen sociale Zustände in einem erwünschten Sinne beeinflußt werden" *o.c.*: 63.

2.1 Rationality of law-making

The rationality concept of law-making describes Noll as one of the leading principles of "Rechtsstaatliche" democracy.[11] According to democratic norms, with the public as the ultimate legislator, the content and the realisation of laws have to be generally accessible, generally understandable and rationally controllable; implying a rational aspect of axiology. Postulated as a scientific resolvable activity, *"hat es* [the law-making doctrine] *die Aufgabe, die Gesetzgebungspraxis zu beraten"*. Ergo, the law-making doctrine is summarised as a *"wissenschaftlich fundierte Handlungsanleitung zur rationalen Gesetzgebung"*.[12] Ruiter adheres to the analytical character of such a doctrine as "a coherent and rational law-making concept, based on reflection and as an abstraction of practical knowledge, with the ultimate objective to improve the law-making practise.[13]

In sum, the rationality concept of law-making is characterised as a "scientifically-determined" activity, implying both an educational aspect (obtaining knowledge) and an analytical element (generalising and applying this obtained knowledge in comparable circumstances), legitimised by its inherent democratic character.

2.2 The normative and functional aspects of law-making

The notion of law includes two dimensions, *viz*, the instrumental and normative dimension. Despite the predominant role of the instrumental-functional perception ("*Machttechnologie*"), Noll's assumption of law-making also contains a normative (axiological) element: a consideration of interests, i.e. an evaluation of priorities ("*Machtkritik*"). Noll's argumentation is that the selection and definition of a social problem to which law-making assists, itself includes a normative element. The premise of a

---

11 *O.c.*, 15. The German concept "*Rechtsstaat*" can be compared to the Anglo-Saxon *rule of law* principle although they are not identical (*infra* note 94). Generally, the "*Rechtsstaat*" is described as: the government, subject to the law, and able to exercise its power only in accordance with general laws, and the intervention with liberty and property must be predictable and verifiable.

12 According to Krems, Noll did not succeed in such a "Handlungsanleitung". Noll failed to address the actors and specific situations to which he referred. Nonetheless, his law-making doctrine should be understood as: "a useful collection of data and preliminary studies, related to this theme" B. Krems. Grundfragen der Gesetzgebungslehre. Duncker und Humblot Berlin 1979: 29-31.

13 D.W.P. Ruiter. *Wetgevingswetenschap of wetgevingsleer* (law-making science or doctrine) in: *Nederlands Juristenblad* (NJB) 1988: 978-9. However, Ruiter's (strictly legal or "static") concept of a law-making doctrine differs from Noll's process approach which is not primarily legal (or "dynamic" law-making, discussed in section 2.2.2(c). With regards to rationality, Ruiter subscribes the aspect of (scientific) controllability and systematization. Bestuursrechtelijke wetgevingsleer (Administrative legislative science) Assen Van Gorcum, 1987: 38.

normative question (*"wertfrage des richtigen Recht"*) is also the result of the interpretation of the concept of law, the result of a critical reflection above power.[14]

Nevertheless, the functional perception of law-making evokes several questions, for instance, (a) the aspect of identification of the norm subject (*"Normadressat"*) of the law-making doctrine, to whom the law-making doctrine is addressed; (b), if there are several norm subjects, to what extent is it applicable to all the actors; and (c), the premise of rationality of law-making.[15] Questions, caused not only by vagueness in defining the law-making concept but also by the abstraction of certain political realities. A further analysis of these aspects is necessary before commenting upon Noll's theory.

a. Norm subject

In general, the norm subject of the law-making doctrine is defined as the legislature. According to the "Model der indivuduellen vollbewusten Handlung", Noll describes the law-making activity as a consideration of the emulated objectives of legislation by the legislator; once chosen an objective, the legislator searches for an appropriate means and finally chooses the most optimal option, with a minimum of negative side-effects.[16] Obviously, this assumption of decision-making as an individual, fully informed and rational activity is hardly likely in law-making practise. For instance, the fiction of an individual legislator is rather a complex composition of several acting actors (parliament, government, *et cetera*), each emulating its own objectives. Given the varying perspectives, their objectives of law-making may also differ or might even conflict. Noll describes the law-maker as a multiform composition and law-making as a social process, a procedure characterised by the separation of powers, influenced by various actors with formal and informal competencies.[17]

With its constrains, this concept of "indivuduellen vollbewusten Handlung" is restricted to a metaphorical use of the structure of the law-making activity. Despite this restriction, which has been confirmed by Noll, he presumes the legislator as an individual actor, without drawing conclusions to the structure of the law-making model.

In view of the fiction of a monolithic legislator, the subsequent question raised is how to define the law-maker? Noll refers to the formal legislator as norm subject of the law-making doctrine, as *"diejenigen Instanzen, ohne*

---

14 Noll *o.c.*: 63.
15 Krems, *o.c.*: 29-30.
16 Noll *o.c.*: 72.
17 *L..c.*: 72.

deren ausdrücklichen oder stillschweigende Zustimmung ein rechtlicher Erlass keine formelle Geltung erlangt".[18] The implicit consent discerns the informal law-maker from the formal legislator. Krems criticised this strict formal interpretation. He claimed that "all the persons influencing the law-making procedure, forced to take into account the common interest", may be defined as the law-maker.[19] Different from Noll, this description of the norm subject is not restricted to the formal law-maker and more realistic. Since most bills are initiated and drafted by the national government or ministries, initiative draft laws by members of parliament are rare.[20] As a consequence, civil servants, elaborating legal drafts at the ministry, have a considerable influence on the law-making process. Private interest groups are excluded as norm subject, since their interest cannot be considered as common interest. Nevertheless, it cannot be denied that private interests (*e.g.*, the pharmaceutical industry, professional organisations, labour unions) are influential lobbyists in order to convince policy-makers. The law-making practise cannot exclude this reality.

The diversity of norm subjects, and the magnitude of (in)formal legislators, each with their differing interests, under different circumstances, must have consequences for law-making doctrine and thus for the method of law-making. Therefore, Krems differentiates norm subjects according to their role and function in the law-making procedure.[21] The necessity of this differentiation between norm subjects has been questioned

---

18 *O.c.*: 44.

19 Krems *o.c.*: 43.

20 U. Rosenthal, M.P.C.M. van Schendelen, A.B. Ringeling. Openbaar Bestuur: organisatie, politieke omgeving en beleid (Public Administration: organisation, political environment and policy). Samsom Tjeenk Willink 1987: 239-40. At least, this has been observed in the Netherlands. Similar experiences in other Western European countries have not been confirmed, although there is no reason to believe that the situation in other countries would be any different. As far as Central and Eastern Europe is concerned, since the recent reforms started in the late eighties, there is no clear picture of current practise. In at least in three countries the incidental character of parliamentary law-making has been confirmed, *viz.* Hungary, the Czech Republic and Poland. Péteri (Hungary), Sarnecki (Poland), *supra* note 6 and J. Reschová and J. Syllová (Czech Republic). The Legislature of the Czech Republic in: The New Parliaments of Central and Eastern Europe. D.M. Olson and P. Norton (eds) Frank Cass London 1996: 96. Also, SIGMA Support for Improvement in Governance and Management in Central and Eastern European Countries: Czech Republic, p.7. During the first democratically elected government period the percentage of initiated draft laws and resolutions by the government was respectively 63 percent, 22 percent initiated by individual members and 15 percent by Committees. I. Soltész. The Committee System of the National Assembly Functioning of the Committees and their Role in Legislation (1990-1994) in: Hatékonysági Összetevők a Parlamenti Munkában, Center for Public Affairs Studies. Budapest 1994: 144. In an interesting article László Kiss confirmed the dominant role and überpolitisiertheit' of the executive power in drafting law-making in Hungary. L. Kiss. Einige Fragen der Rechtsstaatlichkeit und der Gesetzgebung in Ungarn. *Osteuroparecht* 1990, Iss. 1: 12-22.

21 Krems *o.c.*: 29-30.

by Van der Velden: He poses that at best an actor-specific model could function as an additional, instead than an alternative, model to the general method of law-making.[22]

b. Degree of influence

In view of the tenability of a general model, although complied with an additional actor-specific model as suggested by Van der Velden, the question of the degree of influence, cannot be answered. Even Krems' assumption of a differentiated actor-model cannot clarify this aspect. It is likely that no model of law-making is able to specify the degree of applicability to different actors.

c. Notion of rationality

Given the assumption of a multiform legislator, does this affect the notion of rational law-making, and if so, to what extent? The rationality concept was characterised as a central theme of post-World War Two law-making theory. Recent understanding, mainly originated from the public and political sciences, has criticised that concept. The general criticism is the relative significance of the analytical concept to law-making; an assumption, explicable from a rather limited functional point of view.[23]

Apart from the legal-functional notion of law-making, law-making also has important normative and political functions that affect the notion of law-making. Nollkaemper is one of the recent theorists who has subscribed to the limitations of a strict legal approach.[24] He alleges that the assumption of law-making as a rational and controllable process, limits the feasibility of a distracted law-making method. Rational law-making is more a legal fiction, than a political reality. Nevertheless, the endeavour of a certain degree of rationalisation and controllability of the law-making process is legitimated, although it has its restrictions.[25]

---

22 W.G. van der Velden. De ontwikkeling van de wetgevingswetenschap, een rechtstheoretisch onderzoek (The development of the science of legislation: A legal theoretical inquiry). Koninklijke Vermande, Lelystad 1988: 219.

23 *Cf. e.g.* H.A. Simon. Administrative behaviour. New York, 1965. D. Braybrooke and C.E. Lindblom. A strategy of decision: Policy Evaluation as a Social Process. New York, 1963: 66-9. Lindblom CE. The science of muddling through in: *Publ. Adm. Review* 1959;19: 79-88. Lindblom CE. Still muddling, not yet through in: *Publ. Adm. Review* 1979:517-26. Etzioni, A. Mixed scanning. A "third" approach in decision-making. *Publ. Adm. Review* 1967;27: 385-397.

24 P.A. Nollkaemper. De grenzen van een juridische wetgevingsleer (the limitations of a legal law-making doctrine) in: *NJB* 1988;8;27: 966-70. His appeal to put into perspective the rationality concept is based on the political perspective of law-making. *cf.* A. Görlitz. Die politische Funktionen des Rechtes Wiesbaden. 1976 and Krems *o.c.* 1979.

25 *O.c.*: 968.

The inherent political character is expressed by the balances of power and the influence of actors in the law-making process, which necessitates to compromise on results and can interfere with the analytical notion of law-making. In order to ameliorate this situation, the rationality concept was introduced. However, the subsistent political character determines the extent in which the process can be controllable.[26] Review of (parts of) the law-making process is a relative data, the extent to which it is possible being determined by the implications of the political process of law-making.[27] Focused on optimising the quality of legal texts, these implications are, *inter alia*:

- drafting a well-defined text might be limited where the political objectives have not yet crystallised. Without clear objectives, to perfect the reproduction of this content is less relevant;
- unclear editing may be necessary to achieve political consensus. Usually, vagueness of the text serves the objective of political agreement, rather than legal security;
- besides its instrumental function, "symbolic legislation" is not primarily focused on effectuating legislative rules. Other functions call for other demands on formulation and content of legislation.[28]

In view of the diversity of legislators and the inherent political character, the rationality concept in legal decision-making has be put into perspective. Generally speaking, statements concerning the extent to which non-rational, contextually conditioned aspects influence rational law-making, cannot be given. Nonetheless, awareness of and revealing non-legal functional motives can, to some extent, contribute optimising well-considered, empirically based decision-making.

The assumption of the relative significance of rational law-making and the influence of non-legal aspects in the law-making process is characteristic of the so-called "dynamic" or non-exclusive legal approach of law-making.[29] In this perspective, the law-making doctrine is directed towards the entire

---

26 *L.c.*: 968.

27 *L.c.*: 968.

28 *O.c.* Görlitz en Krems. Görlitz makes the following differentiation of the political functions of law: Stabilisierung, Konsolidierung, Integration, Neutralisierung, Sozialisation, Regulation, Rationalisierung, Sanktionierung, Legitimierung, Innovation, Reflexivität, Görlitz: 60-134. Krems: besides to optimize rational legislation, a law-making doctrine should also take into account the political functions: 34-35.

29 *Cf. e.g.*, Rödig, J. Gesetzgebungstheorie als praxisorientierte rechtswissenschaftliche Disziplin auf rechtstheoretischer Grundlage, in: Vorstudien zu eigner Theorie der Gesetzgebung. J. Rödig, E. Baden, H. Kindermann (eds) Bonn 1975: 11-18; H. Kindermann. Plan und Methode det Gesetzgebungstheorie *Rechtstheorie*, 1978, Heft 2: 229-235.

process of law-making and contrary to the "static" approach that concerns a single aspect, the definition of legal documents.

Generally speaking, the static-approach is limited to a strict legal approach of law-making, since drafting legislation is primarily a legal affair. Given the political influence on law-making, the assumption of a strict legal activity is rather questionable.[30] The "dynamic" approach of law-making refers to the diverse character of the law-making doctrine, although in the legal literature, there is no consensus on the origin of approach (mono-, multi- or interdisciplinary).[31] In this respect, Noll's interpretation of interdisciplinary can be described as a non-exclusively legal oriented discipline, in contrast to traditional legal scholars. The role of other related sub-disciplines is emphasized by such phrases as:
[...] (the law-making doctrine, *AdE*) "should define its range and boundaries of competencies principally and systematically in order to facilitate the expertise of related sciences",[32] and [...] "the development and elaboration of a general method of law-making (as part of law-making doctrine) is a matter of legal science, without conflicting with the interdisciplinary approach".[33] According to Noll, the integrated approach of law-making does not contradict the primary legal origin. To illustrate this, he uses the analogy with medicine. In medical science, instead of debating their various type of knowledge, the contribution of various sub-medical disciplines is taken into account to reach the right diagnosis and treatment.[34] Analogous to law-making, the complexity and size of issues subjected to law-making, necessitates the legal sciences to co-operate with related sub-disciplines. "Without discussing the origin (discipline) of knowledge, it will be used if the knowledge is suitable for justifying recommendations about the law-making practise", and "coherence between the results of the involved disciplines is already sufficient".[35] Nonetheless,

---

30 Nollkaemper *o.c.*: 967-8.

31 Therefore, the author refers to legal theorists such as Kindermann, 1978: 230, Krems 1979, Rödig 1975: 11-18; W. Maihofer. "Gesetzgebungswissenschaft" in: Gesetzgebung: kritische Überlegungen zur Gesetzgebungslehre und zur Gesetzgebungstechnik. G. Winkler, B. Schilcher (eds) Springer Verlag 1981: 12, 18, 33; W. Hugger. Gesetze, ihre Vorbereitung, Abfassung und Prüfung: ein Handbuch fuer Praxis und Studium. Baden-Baden, Nomos 1983: 32; Van der Velden 1989: 78. Since this debate refers to the legal-theoretical discussion of the law-making doctrine as an autonomous science, this aspect is outside the scope of this research.

32 Noll *o.c.*: 69.

33 *O.c.*: 71.

34 *O.c.*: 66 the debate between empirical-analytical (therapy) versus normative science (diagnosis).

35 Ruiter *o.c.*: 38-39.

legal science will have a co-ordinating task, without questioning the parataxis of sub-disciplines.[36]

In sum, the law-making doctrine can be characterised as a scientifically reflected activity, focusing on the law-making practise without denying certain aspects of tradition, intuition and individual talent,[37] whereas the law-making concept may be interpreted as a desirable rational and controllable activity, represented by a dynamic process. The phrase "desirable" refers to the intention of full rationality, which is rather unlikely.[38] In order to develop optimal legislation, the awareness of the inherently political background of law-making should be included as far as necessary and possible. Nonetheless, any unforeseeable circumstances which influence the law-making process puts this rationality into perspective.

3 METHODS OF LAW-MAKING

In view of its restrictions, the rationality-concept of law-making enables one to reflect on law-making activity through the various stages of law-making. It concerns the method of law-making, as an element of law-making doctrine. Generally speaking, the law-making doctrine can be divided into three elements, a. the method, b. the technique of law-making, and c., the procedure of law-making. Whereas the technique of law-making is primarily concerned with the formulation of a legal document, the procedure of law-making includes the formal (constitutional) process of law-making.

Within the framework of this research, normative statements on the content of law-making activity and thus law-making method is the object of research. Given the circular-approach of law-making, reflected by the various stages, a review of this legal process could result in normative conclusions on the rationality, effectiveness and (internal and external) coherence of the final legal text. Such conclusions may necessitate adapting a legal document. Moreover, such an instrument could also have consequences for law-making policy, since law-making policy and law-making are mutually related (see chapter four).

In Continental law-making theory, both Noll and Wróblewski elaborated a method of law-making in order to describe and analyse the development

---

[36] A fragment of that debate concerns Noll's definition of interdisciplinarity. Krems especially reproaches Noll inconsistency by describing law-making ultimately as a legal discipline despite his inter-disciplinary argument, Noll *o.c.*: 9, 58, 64, 70-72 (as quoted by Ruiter). Though Krems seems to be right about the interpretation of a primary legal activity, Ruiter assumes that Noll's inconsistency is not determined in advance and refers to the mentioned analogy (Ruiter *o.c.*: 39).

[37] Ruiter 1987 *o.c.*: 43.

[38] Karpen *o.c.*: 50.

of legal documents and deduce normative conclusions. In this research setting, method has been defined as: "a collection of well-ordered and specified activities and possibly other instruments, in order to achieve a particular aim or aims, in a particular field and under particular conditions".[39] In terms of law-making, the aim or objective of the method is to rationalise the law-making process. A model can reflect the law-making method, defined as "a system of elements and relations between those elements, which resembles as much as possible the system of which it is a model; simplified and therefore easier to handle".[40] A model as an instrument to help us understand reality. In view of its descriptive function, a model should, in a non-complex way, describe reality. Therefore, such a model should contain the relevant elements (i.e. the stages of law-making) and their mutual relations. The correlation is reflected by the consecutive stages of the law-making process. Related to its descriptive character, a model has also a predictive function. In this case, based on a model of law-making, it should (as far as) possible predict and direct the law-making process. This assumption on the predictive and directive function of law-making by means of a theoretical model has been discussed in the legal-theoretical literature. Hereafter, two prominent theories will be discussed.

3.1 Noll's method of law-making

In "Gesetzgebungslehre" Noll gave a new impulse to the European Continental debate on law-making theory. The method he described of law-making can be characterised by the circular approach of the law-making process. Reflected by a model that includes various stages, the main consequence of his theory was the dynamic and not primarily legal approach of the law-making activity.[41] The analytically elaborated model can function as an attempt to optimise rational law-making. Noll's method of law-making includes the following elements, which will be discussed successively:[42]

- Problem impulse ("*Problemimpulse*")
- Problem definition ("*Problemdefinition*")
- Definition of concept objectives ("*Entwurf von Zielvorstellungen*")
- Data analysis ("*Tatsachenanalyse*")

---

39 Van der Velden *o.c.*: 192.

40 P.G. Swanborn. Methoden van sociaal-wetenschappelijk onderzoek; inleiding in ontwerpstrategieën (Methods of social-scientific research). Boom, Meppel 1984: 159.

41 The stages of law-making do not include an unconditionally linear progress. On the contrary, the iterative character is rather a theoretical construction than a reality.

42 Noll discerns the stages without explicitly defining the law-making concept.

- Actual and normative relations (*"Faktische unf Normative Bindungen der Gesetzgebung"*)
- Plan of Alternatives (*"Entwurf von Alternativen"*)
- Criticism (*"Kritik der Entwürfe"*)
- Control (*"Nachkontrolle"*)
- Adjustment (*"Korrektur"*)

Stage 1: Problem impulse

Originally, the reconstruction of the elements of law-making was based on the theory of the individual final activity (*"das individuelle finale Handeln"*): the legislature considers emulated objectives, selects an objective, searches for appropriate means in order to accomplish the objective and selects the optimal means able to attain the objective with the least possible negative effects. Noll admits this model of an individual, omniscient, and omnipotent actor is not realistic in the law-making concept.[43] The legislator is not identical with one actor; it is a multiform creation and law-making itself is a social process; an activity, based on the separation of powers, participated by various actors with different opinions and different (in)formal competencies. The assumption of "das individuelle finale Handeln" can only be maintained metaphorically.[44] The consequence to the law-making structure is to substitute the individual motive for problem impulse, defined by Noll as: "all those reasons, that induce legislative authorities to a normative activity".[45] The distinction between origin, content and the effect of problemimpulse is practically untenable. Generally speaking, the prestage of problem impulse will be erected by the resemblance of a collective consciousness, abstracted from individual insights. In a democratic society, the danger of a problem impulse, started by individual interests has little chance unless it is broadly based. Nevertheless, the influence of media in initiating impulses should not be underestimated. The monopoly position of a government-controlled media in most former less developed countries strengthen the role of government in this stage.

The exposure to external problem impulses places the legislator in a dilemma: law-making meant as an active, conscious, and legitimacy-oriented guiding of society and its developments; legislation is simultaneously a product of social institutions.[46] This mutual influence seems an unsolvable contradiction. Given the exposure to external problem impulses, the extent of influence is not clear. It is obvious that certain problem impulses have

---

43 *O.c.*: 72.
44 *L.c.*: 72.
45 *O.c.*: 73.
46 *O.c.*: 74.

been prioritised in the law-making process as a result of intensive lobbying of social or private interest groups (trade unions, patients, physician associations, industry, *et cetera*).

An instrument that to a certain extent prioritises law-making more objectively are government statements or party programmes. However, these programmes have a rather declamatory character and have no direct and verifiable influence on daily law-making practise.[47]

In order to create a more transparent law-making process, in which problem impulses are indeed social priorities, Noll suggests an important first step is to reveal and formulate problem impulses, which will open the order to ranking discussion. As a result, problem impulses are less subject of unverifiable democratic powers.[48] The simple statement of defining the problem seems to be a rather easy solution; without further consequences, it is doubtful if it will increase transparency in prioritising problem impulses. Revealing and defining all the problem impulses implies the assumption of the omniscient government; in fact, this is often not the case.

Generally speaking, the ranking of problemimpulses should be related to the contents; urgent and/or socially unacceptable situations should be prevented or solved, if necessary, through regulation. Legal science, and therefore law-making, is pre-eminently a normative science. Legislative normative values are based on social interests or ideology. For the law-making practise, these values are important, but more or less considered as data.

According to Noll, law-making can be generally considered as an "experiment"; a modification of current values instead of developing a complete new concept. The Constitution, Civil law, Penal law are examples of such existing value systems,[49] used as impetus of legal changes. As a consequence, the problem impulse is often determined by previous legal institutions. Instead of opting for non-regulative alternatives, the regulative (legal) concept is almost automatically chosen for problem-solving, where non-legal solutions are to be preferred (prevention and information versus enforced commitments, unemployment control versus penal law, *et cetera*).

Stage 2: Problem definition

Functioning as a methodical point of reference to problem-solving, a survey of present problems is necessary before possible solution (s) can be handed over. Such a problem-definition includes, from a legislative perspective, both a normative and an analytical component. To define a situation or

47 *O.c.*: 75.
48 *L.c.*: 75.
49 *O.c.*: 77.

activity as unsatisfactory assumes a normative judgement, whereas the analytical aspect concerns an empirical description of the character and extent of the problem-object.[50] A frequent difficulty is that a problem-analysis that does not contain the essence of the problem; limited research or problem-analysis exclusively focused on judicial aspects could narrow the discussion, miss real causes and therefore create a doubtful solution. Although not always the case, in complex and far-reaching issues, a thoroughly diverse analysis of the situation is necessary in revealing normative motives and the essence of the problem.

Stage 3: Definition of concept objectives

The next stage after analysis of an imperfect situation is to draft the objective(s) for solving the problem. However, in the law-making practise the (ultimate) objective of drafting legislation is not always clear. The possibility of adjustment of the objective during the law-making process is quite likely since prospects of the attained potential objective are limited. Besides, interim (and unforeseen) developments also require adaptation of the previous objective.

Instead of one objective, a number of objectives or several additional objectives is more probable. These objectives might interfere with each other and affect the implementation of the legal document(s). As a consequence, adjustment of the objectives and/or legal documents is again necessary.

Noll indicates another reason why the "definition of objectives" needs further attention. The normative aspect of law-making practise influences the problem impulse, the definition of the problem and therefore the definition of the objective in order to solve the problem.[51] For that reason, definition of the objective is rather relative. More important is the lack of a precise idea for formulating the objective; unforeseen circumstances or social tendencies could result in rashly and vaguely defined objectives on the basis of which measures will be taken. By putting into perspective the possibility of defining objectives, represented by a "dynamic process" of constant re-defining objectives, the value of defining objectives is also put into perspective. For example, the objective of penal law is not to eliminate crime or to effectuate a crime-less society: more realistic is the assignment of crime-fighting.[52]

The proposition of law-making as a linear process, ending with a finale solution for solving a problem can be considered a fiction. Problems

---

50 *O.c.*: 81.
51 *O.c.*: 83.
52 *O.c.*: 85.

continuously change in nature and intensity, new developments require modification of objectives and instruments to realise these objectives. Nevertheless, to a certain extent the presumption of the linear character of law-making by means of defining objectives and adequate measures to solve the problem is indeed feasible. Short-term and rather simple objectives, *e.g.* the construction of a new school-building or airport, can be easily realised, without continuous redefining the objective.[53] However, a long term objective such as realising access to basic health care services requires generalisation from concrete cases, constant feedback with newly evoked problems, objectives, instruments, *et cetera*. Although a more strict description of the abstract objective might be helpful, certain generalisation of objectives is (practically and/or politically) inevitable and therefore a restricted but necessary element in the law-making procedure.

Stage 4: Data analysis

According to Noll, the objective of law-making is to a certain extent not focused on solving a problem, but more or less focused on reducing the negative consequences of the arisen situation. In the penal context, the legislator expects and hopes to minimise the negative consequences of certain type of crime by symptom control.[54] For instance, crime and unemployment are to a certain extent interrelated. Instead of solving social causes (employment-promoting measures), de-legalising crime is hardly discussible. However, by penalising norm-violating behaviour, to some extent the government restricts penal offences, without solving the ultimate cause. According to Noll to develop such "competitive acts" is to a certain extent the primary objective of law-making. Legislation can not eliminate crime, however it can restrict or decrease crime.[55]

What are the consequences to data analysis? A proper data analysis is focused on a restricted research object, as defined by the problem definition and it should describe the possible effects of legislative interference. According to Noll, data analysis will be more effective, where it focuses on explaining the mutually competitive causes of legislative intervention and initiated counter-forces.[56]

Based on data analysis, the subject of research that necessitates legislation might include social, political, economical and other relevant aspects. Therefore, the normative consequences of these aspects should be considered in the analysis, as well as the normative implications of

---

53 *L.c.*: 85.
54 *O.c.*: 88.
55 *L.c.*: 88.
56 *L.c.*: 88.

existing legislation on the research object. Scientific analyses could function as a useful instrument. However, thorough theoretical research requires time and the theoretical character of possible results limits their feasible use in practise.

As a result of the restricted possibilities of data analysis, legal decision-making contains a certain degree of uncertainty. Nevertheless, legal decision-making is frequently based on insufficiently controlled analysis considering (un)known effects. Although the results of an elaborated analysis do not guarantee optimal decision-making itself, the outcomes could positively influence the decision-making process. The lack of a detailed data analysis is a common issue that concerns various sectors of decision-making. Illustrative is the legislative approval of highly developed medical technologies without sufficiently examining possible ethical, legal, and social aspects (artificial insemination, in vitro fertilisation, *et cetera*)

In default of proper data analysis about possible future effects, the danger of interest or ideology-based decision-making is not inconceivable. Improper motives, unverifiable and subjective motives endanger the transparency and rationality of legal decision-making. Nevertheless, law-making is frequently the consequence of an urgent problem situation that requires direct legislative interference. In such cases, a thorough scientific analysis is practically impossible. As a result, *ad hoc* measures do not show always show themselves to be qualitatively thought through. Often, the lack of a well-considered long-term legislative policy underlies these problems. The sudden and drastic politico-legal reforms in most of the Central and Eastern European countries confirm this statement. Rashly considered concepts of market-economy and a re-constitutionalisation are often characterised by a lack of a coherent and long-term strategy, which accelerated social disintegration.[57]

Stage 5: Actual and normative relations

Here, Noll means the interdependency between legislative norms and actual developments that is based on the basic notion of the "Natur der Sachen". Although actual circumstances or developments have a certain impact on legislation,[58] Noll emphasises the directive function of legislation, without abstracting the established actual structures.[59] Normative relations concern the relation with existing legal regulation (*positivrecht*), such as

---

57 S. Frankowski, P.B. Stephan. Legal reforms in post-communist Europe: The view from within. Martinus Nijhoff, Dordrecht 1995: 482.

58 For instance the influence of new medical technologies upon legislation; newly developed technologies might frustrate health (legislation) policy (planning, cost containment, *et cetera*).

59 *O.c.*: 98-9.

constitutional and treaty provisions, acts, as well as the judicial rulings. For this moment, the importance of consistency and harmony within the legal framework is noticed.

Stage 6: Plan of alternatives

Where parliament is the legislature, various options can be presented to solve a problem. These options generally mean legislative intervention. In practise, however, most of the draft texts are prepared at the ministry, whereas parliament considers the presented option.[60] In the optimal decision-making, various (non-)legislative alternatives should be submitted to be deliberated on by parliament. Obviously, the occurrence of alternatives does not automatically guarantee the strengthening of the quality of the final decision, but it would improve the quality of the decision-making process. Consideration of several (legal) options, necessitate reflecting on the original objectives in order to review the means proposed. Noll emphasises the legislative alternatives, although non-legislative considerations such as self-regulation, or subsidies could to a degree also be a possible option. This concerns the discussion of legislation *vis-à-vis* other types of regulation.

Stage 7: Comment on the drafts

Noll identifies the empirical and normative perspective when commenting on suggested (legislative) drafts.[61] The empirical observation concerns the question of possible effects (if the underlying and predicted facts have been realised), whereas the normative aspect concerns a value judgement of the suggested relation objective-legislative instrument.

Possible instruments to carry out an actual analysis of proposed data are "Simulation" and "Planspiel".[62] These quantitative analyses are derived from the science of economics; both instruments are prognostic devices based on the interpretation of empirical data, in order to deduce future tendencies of economical developments. Similar application in the law-making setting, could foresee future (side-)effects of legislative measures. Although it is emphasized that prognosis is characterised by a degree of uncertainty. One of the factors that offers a perspective on the function of prognosis is the rash introduction of various alternatives. A sufficient

---

60 *O.c.*: 107.

61 *O.c.*: 120.

62 Both techniques are characterized by a model-approach of a social problem. Simulation is a model of reality, "ein Ersatz für das Realexperiment", whereas in "Planspiel" the most extreme scenarios are tested ("Labor auf die Bühne") *o.c.*: 120-4.

prognosis of different types is therefore hardly possible and, besides, shifting social situations complicate its predictive capacities.

The normative aspect concerns a qualitative review of different alternatives, from a normative perspective. It is generally understood that a comparison of objectives of several options is hardly possible. The political setting of law-making affects the choice of certain preferences. Since political (short-term) objectives do not necessarily correspond with the (scientific) optimal preference, the quality of the outcome is questionable. Besides, phenomena such as a lack of (financial) means and human capacities restrict alternatives, necessitate the balance of normative priorities ("*Kollisionen zwischen Werten*").[63]

Stage 8: Control

The question of effectiveness refers to what extent norm subjects comply with or are applicable to the legal norm ("*faktische Wirksamkeit*"). Norm-conforming behaviour is strongly related to the type of offence (in penal and administrative law), the risk of being caught and consequences (in civil, disciplinary law). Depending on these circumstances, norm conformity is predominantly a balance of interests.

Apart from the "faktische Wirksamkeit", Noll discerns the "soziale Wirksamkeit". This "social effectiveness", primarily expresses a normative judgement on the appropriateness of achieving the law-making objectives from the perspective of the legislator,[64] which refers to the side-effects of implementing a legal norm. Serious unintentional and undesirable side-effects threaten the "soziale Wirksamkeit"; examples of social ineffectiveness are where the norm does not achieve its originally objective since it appears to be incapable of bringing about a certain situation; conflicting effects of stimulating and preventive sanctions; harmful consequences in other social relations, and fourth, acts which lack an actual function, such as symbolic acts.[65] Symbolic regulation is socially ineffective, since the principal intended objective of the legislator (the enactment of a general norm) differs from the possible actual effects (realisation and application of the general norm). Nonetheless, symbolic acts have a (political) function. Its compromising character indicates varying political convictions. A vague definition enables a multi-interpretable act and therefore consensus on a controversial subject.

---

63 *O.c.*: 137.
64 *O.c.*: 156.
65 *O.c.*: 156-7.

Stage 9: Correction

In view of the fact that a perfect law does not exist, continuous adjustment or adjusting legislation will be necessary. Historically, diverse actors, *viz*, politicians, scientists have initiated the reaction of the legislator to those defects, the judiciary, interest-groups, *et cetera*. In spite of this situation, Noll urges the necessity of a more permanent review of current and future legal documents, initiated by the legislator itself. A systematised, structural surveillance of the use and effects of legislation, related to a feedback from a central institution preparing legal drafts would increase the quality and effectiveness of legislation. Even more important, such an approach could mean a substantial decrease of the large volume of modifications ("*Änderungs-gesetze*")[66] which, when frequently accumulated modifications, could ultimately jeopardise legal security.

The aspect of review mentioned above, and the subsequent amendment of possible defects, would ultimately result in less changed, durable acts. Since this kind of review is not restricted to the final stage of the law-making process, but occurs continuously, the notion of a well-considered, more rational and consequent decision-making would be more plausible.

In conclusion, Noll's methodological approach discernes several stages of law-making activity. The infinite "experimental" approach implies a continuous, circular notion of law-making. Moreover, the analytical approach of the described stages enables a more rational review of (not primarily) legal arguments.

Since Noll's law-making method is based on a more "Western", notably German oriented legal tradition, it is questionable whether this approach is applicable to an "Eastern" European setting. In order to verify this thesis, Noll's approach will be compared with the law-making method of a prominent Polish scholar Jerzy Wróblewski, who confirmed the theoretical methodological approach of law-making by means of a model. As a leading representative of the Eastern European periphery, his theory is illustrative to a degree of current thinking. *Grosso modo*, he recognises the phased model of law-making and the significance of the non-legal effects of law-making. The similarities between both legal theorists strengthens the notion of a universal law-making method.

[66] *O.c.*: 160.

3.2 Wróblewski's method of law-making

The tradition of Polish methodological concepts has initiated important impulses to European legal thinking. Jerzy Wróblewski was a prominent representative of that Polish legal philosophy and legal theory. His method of law-making confirmed the general concept of law-making as formulated by Noll[67] although the temporary thesis of a tenable uniform law-making method has yet to be confirmed. Wróblewski, however, confirms the hypothesis of the intention of rational law-making, reflected by a model that discerns several elements. From Wróblewski's analysis, it is conceivable that the abstract model of the law-making activity has a tradition in Poland. In the legal literature, commentators from other Central and Eastern European countries confirmed the importance of the rationality-concept in legal decision-making.[68] Nevertheless, political influence and mutual differences cannot be ignored. The heritage of the socialist tradition (*e.g.*, ideology, fragile newly developed democracies and limited countervailing powers) considerably affects the law-making activity. Due to the diversity of recent political reforms in Central and Eastern Europe, relevant consequences of current law-making practise need further discussion.

Wróblewski defined the law-making activity in statutory law systems as an enactment of general norms by the legislature and he assumed the context of a contemporary system of statutory law, working within an ideology of

---

[67] J. Wróblewski. Meaning and Truth in Judicial Decision. Helsinki 1983. J. Wróblewski. Einführung in die Gesetzgebungstheorie. Wien 1984. J. Wróblewski. Contemporary Models of the Legal Sciences. Wroclaw 1989.

[68] *Supra* note 7: 20; T. Sárközy. The present state and the future work of Hungarian economic legislation, *Acta Juridica Hungarica*, 1993, Iss. 1-2: 21-26; V. Knapp. Current issues and Problems of Legislation in Czechoslovakia in: Legislation in European Countries. U. Karpen (ed.) European Association of Legislation. Nomos Verlaggesellschaft Baden-Baden 1996: 119-123, advocating better law-making including elements from the rationality notion, by writing that "legal science has no institutional place in the legislative process" and "a continuous problem is the fact that neither the legal science not the legal practise has succeeded so far in finding a reliable method of ascertainment of the effectiveness of legal rules, that there is no reliable feedback between the effect of the legal rule and the legislative authority which has adopted it." Idem Wronkowska and Gwizdz "it would be more reasonable to make use of various opportunities to rationalize the legislative process offered by different forms of post-legislative research starting from research commissioned by scientific institutions up to obligating state organs to submit to the parliament periodical reports on the functioning of enacted statutes" *o.c.*: 343.

rational and legal decision-making.[69,70] Similar to Noll, he presented the problem of decision-making based on an analysis of a theoretical model thought of as a rational activity. Not as a generalised description but rather a scientific creation, singling out the essential problems the decision-maker has to solve for legitimising decisions in a sufficiently complex decisional setting. Wróblewski characterised rational law-making by five elements. They are:[71]

- the determination of an objective of law-making (normative activity);
- the determination of empirical relations between the type of situation the assumed purpose belongs to, and the type of phenomena as potential consequences (determination of potential means to the assumed objective);
- the selection of potential means to the objective which can be used as legal instrument (the determination of potential *legal* means to the assumed objective);
- to develop a legal norm as an instrument to achieve the considered objective, i.e. the choice of a concrete legal means, and
- the enactment of a general legal rule.

Explanation of the elements of law-making, as discerned by Wróblewski:
1. Normative activity. The objectives of law-making are determined by normative values, accepted by the legislature. Wróblewski refers to more complicated cases, in which the law-maker actively participates in formulating the normative system in question, considering the potential means.[72] Hence, the choice of objective is normatively conditioned. The degree of conditionality differs, depending on the characteristics of objectives and the feature of the concerned normative system.[73] Practically, the choice is also determined by the legislator's knowledge concerning the possibility of realisation of the objective; rational law-makers do not strive for something that cannot be realised.[74] Wróblewski confirms the theoretical situation of a single objective (monotelism). In fact, frequent objectives (politelism), that may be even conflicting, is more realistic. Classification of the objectives by means of priorities, and a clear strategy to implement

---

69 Wróblewski discerned two methods of law-making, *viz.* by enactment of general norms (LGN), and by decision of the case (LDM). Law-making by enactment of general norms is most explicit by the statutory law system, whereas the second reflects the common law system. Hereafter, the research will be restricted to law-making by general norms due to the primarily statutory law tradition in Continental Europe.

70 Wróblewski 1983 *o.c.*: 51.

71 Wróblewski. 1983 *o.c.*: 57-58.

72 Wróblewski 1989 *o.c.*: 38.

73 *L.c.*: 38.

74 *L.c.*: 38.

these objectives can function as a useful instrument in minimising the conflicting interests.[75]
2. Determination of potential means. According to Wróblewski, this stage concerns the empirical basis of law-making supplied by science and common experience. The data constitute the necessary elements to formulate statements concerning the relation means and objective.[76] Generally, an empirical relation between input and output can be rendered by a standard formula:
C (cause) ⇒ E (effect)

In science, this model is transformed to the instrumental concept of decision-making as:
M (means) ⇒ P (purpose)

This may be read as: "to achieve P one ought to use M".[77] However, in practise there are different instruments M to fulfil the objective P. Besides the intended effect, the applied instrument M provides also side-effects (SE), which are known SE_k or unknown SE_{uk}. Hence, the formula will be:
$M_n \Rightarrow P + SE_k + SE_{uk}$,

This may be read as: "for realising P one ought to use M_n considering the known side-effects SE_k and the risk of unknown side-effects SE_{uk}".[78] Several hypothetical means can be used to realise P. They differ in the side-effect SE_k, which are "costs". The factor SE_{uk} is by definition an unknown data and means an inherent risk in any action if there is no complete knowledge of the results; this is the standard situation of any social action in the present state of knowledge.[79]
3. Determination of potential legal means. The selection of the potential legal means, used as a legal instrument. To map all the possible means, the legislator uses his knowledge according to the formula: $M \Rightarrow P + SE_k$. Since the SE_{uk} are the unknown consequences, the decision to act is determined by the costs SE_k. To quantify the costs SE_k, and therefore the choice of the selected means, Wróblewski discerns two types of criteria, *viz*, instrumental or functional and non-instrumental criteria. Functional criteria review the

---

75 Implicitly, Wróblewski refers to a structural approach of law-making instead of the "problemimpulse and definition", as mentioned by Noll. The confirmation of the variety of (possibly conflicting) objectives, requires to prioritize them. Moreover, to elaborate a procedure for a coherent framework that includes related law-making objectives (section 5).

76 *O.c.*: 36.

77 *O.c.*: 39.

78 *L.c.*: 39.

79 *L.c.*: 39.

effectiveness of the intended means. They refer to "costs" or "time" required to obtain P by using a particular M. Functional values may be contradictive to non-instrumental values, accepted by the normative system. In such a situation the selected means is the result of balancing the costs SE_k and non-functional values,[80] or subsequently, the relation between the potential legal norm and the normative framework of government objectives.

In summary, the relevant questions are successively: (i) "whether legal rules are proper means from an instrumental point of view"; (ii) "whether legal rules are proper means from the viewpoint of the functional values which the law-maker treats as binding him"; and, (iii) "what is the relation of legal rules to other instruments of the social policy if used for the same objective as these rules". The answers to the mentioned questions determine the selected legal means.

4. Definition of the legal norm. To draft a legal norm includes corollary questions such as the type of selected norm (civil, penal, or administrative) and the hierarchical level (form) of enacted norms. Although technical and functional problems are decisively, normative aspects in this stage are related to the characteristics of law, the legal system and the current social-political context it operates in.
5. Enactment of a general rule as the result of the law-making activity.

In sum, the legal decision-making can be described by a simplified mathematical manner: Legal norm N is enacted by provisions $p_1 \ldots p_n$, as means to achieve purpose G, that is chosen according to (non) instrumental evaluations $v_1 \ldots v_n$ determined by the normative system SA, considering scientific statements $s_1 \ldots s_n$ describing the regularities of relevant empirical phenomena.[81] The mathematical approach of Wróblewski method of law-making discerns several elements of the law-making activity that reflect law-making as a finite activity. Its relevance to the methodological approach is the inherent notion of law-making activity reflected as a regulative process and the rationality concept of law-making. Similar as Noll's Gesetzgebungslehre, Wróblewski's systematic approach has a highly theoretical character. For instance, Wróblewski's assumption of the normative conditioned choice of objectives, and the (presumed) knowledge of the legislature about the (effects of) alternatives.

---

80 *L.c.*: 39.

81 Wróblewski 1983 *o.c.*: 59.

4 ANALOGIES NOLL AND WRÓBLEWSKI

Comparison of both concepts of law-making reveals certain similarities that strengthen the notion of a universal method of law-making. These analogies will be discussed more extensively and concern underlying assumptions such as the process of law-making, the rationality-concept, law-making considered as political process, the diversity of the law-making actors, the temporary sequence and the universal character.

Process of law-making
Generally speaking, both theorists consider the law-making activity as a (ongoing) process, subject of research of the law-making method. In order to describe that process, the law-making activity is represented by means of a model that reflects the relevant elements of decision-making. These elements are considered as stages of the law-making process, although the iterative character does not necessarily imply the actual sequence of the law-making stages. Actually, the law-making stages show a rather inconsistent sequence, in which the stages interfere and manifest a certain overlap. This complicates a strict theoretical classification. Nonetheless, the theoretical concept of a model can describe the essential elements of the law-making process. Based on such a description, statements concerning the relation objective-means can be deduced and evaluated by the consequences.

Notably Noll emphasized the circular character of the model by the "experimental character" of law-making; control, feedback and renewed impulses express the continuity of law-making. Wróblewski on the other hand, does not seem to link these elements in his model of law-making. His strictly defined model of law-making does not include control and feedback as entities of the law-making process.

Rationality-concept
In the law-making literature the rationality-concept of both models is criticised by its rather theoretical approach. This reproach concerns the rather simplistic perception of the law-making activity.[82] Both authors recognise to a certain extent the restrictions of the rationality-concept in

[82] Van der Velden reproaches both Noll and Wróblewski neglecting the discussions in decision-making science concerning the fiction of rationality. He argues that both models were inspired by "primitive" concepts of decision-making. New understanding from the administrative sciences roughly identify three major models of decision-making: the "rational-comprehensive" model, "incremental" and "mixed-scanning model". As a consequence of this differentiation, the assumption of full rationality, interpreted as "Zweckrationalität", is rather obsolete, Van der Velden, *o.c.*: 203. That may be the case, but that conclusion does not reject the intention of rationality, given its restrictions.

law-making. Noll puts into perspective the notion of "das individuelle finale Handeln" by emphasising the metaphorical character of the objective-means relation, whereas Wróblewski discerns the functional and non-functional (normative and socially-determined) aspects of potential means in proper law-making. Despite these observations, the expectations of scientifically justified decision-making are often too high. Frequently, decision-making occurs in uncertain circumstances such as the (long-term) consequences of certain regulative instruments. Moreover, political motives do not necessarily correspond with rational-scientific motives in decision-making. Illustrative to the maxim of rationality is Wróblewski's remark: "rational decision-makers do not strive for something that cannot be realised."[83] Nonetheless, as a consequence, the restricted rationality-concept does not necessarily affect the structure of the law-making model since the circular approach already implies this notion, through its continuous evaluation and possible adjustment of legal norms. Criticism on the rather simplistic concept of law-making is not justified as far as the "legal determined" output of the decision-making process is oncerned. According to Van der Velden, both Noll and Wróblewski assumed the ultimate legislative character of the outcome of the law-making activity.[84] However, both theorists observed the alternatives for law-making interference by means of several potential (non-)legislative instruments. The assumption of different means M_n in order to answer the problem P, results in dividing the alternative stage into several potential options, of which the most optimal regulative alternative(s) is(are) chosen.

Law-making as political process

Nollkaemper already differentiated the objective of the law-making doctrine as an attempt to optimise decision-making, without the intention of full rationality. This restriction put into perspective the function of the law-making model and expresses a more realistic approach, given the political background in which law-making occurs. In the political arena, motives and objectives do not necessarily correspond with legal motives and objectives. Also Noll, contrary to Wróblewski, confirmed the possible discrepancies between the legal and political perspective without further consequences to the course of the model. These differences in perspective (non-functional and political motives) and the degree of uncertainty in decision-making impel to a restricted value of the rationality-concept in law-making rather than revising the course of the model. Consideration of the non-strictly legal aspects in the decision-making process, insofar as possible and necessary, would contribute towards increasing the value of

[83] Wróblewski 1989 *o.c.*: 38.

[84] Van der Velden *o.c.*: 220-3.

deduced statements. Since political philosophy and culture vary from country to country, statements on this aspect of the law-making process are socio-politically determined. As regards to Central and Eastern Europe, the recent political reforms changed the decision-making process drastically. Specific aspects that are characteristic for this region are the relatively new dualistic approach of law-making in a parliamentary tradition, the multiform party-system and the lack of political co-operation, and consensus-policy.

Diversity of the law-making actors

Noll is criticised for the assumption of the law-maker represented as a single norm subject; in fact, the fiction of a singular actor consists of a variety of actors, each with their own interests. Interests, which do not necessarily correspond, might even conflict. As a consequence, the model needs adjustment, since the multi-actor model affects the elements of the model. Krems differentiated the model by various actors and their position in the law-making process; an "actor-specified-model".[85] Wróblewski also assumed a single-actor during the formulation of the objectives and thereafter.[86] Nonetheless, the fiction of a monolithic actor does not have to be rejected out of hand. In view of the political setting of the law-making activity, it is based on consensus. The balanced choices of objectives, means, and alternatives are justified ultimately by agreement between the related actors concerning controversial values.[87] As a consequence, the validity of the single-actor model does not have to be rejected, in its entirety. More important is to consider the situation of a multitude of participating actors, instead of developing an actor-specific model.[88] Nonetheless, the proposed differentiation by means of an actor-specified model is not contradictory to the general (abstract) model of law-making, it could have an additional function.[89]

Temporal sequence

A main difference between Noll and Wróblewski concerns the circular, respectively linear approach of law-making. Whereas Noll emphasized the circular aspect of law-making, Wróblewski's description of five elements of law-making suggests a finite series of activity.

---

85 Krems *o.c.*: 29-30.

86 Wróblewski 1983, *o.c.*: 57. The determination of the objectives is based on consensus concerning the normative system (AS), and justified by agreement.

87 *O.c.*: 57.

88 Van der Velden *o.c.*: 219.

89 *L.c.*: 219.

The stages control and feedback as described by Noll, express the experimental and thus temporary character of law-making. Given the law-maker's restrictions, negative side-effects influence the effectiveness of the legal norm. In order to nullify or decrease these effects, modification of the existing norm is necessary, which subsequently initiates new problem impulses whereas, according to Wróblewski, the enactment of the legal norm is the end of the sequence. The circular or linear character should not be interpreted as a strict consecutive course of the law-making activity. It represents an artificial methodical series of consideration, in order to explicate the complexity of the law-making process. Each of these stages or elements can question the previous phase, which subsequently necessitates interim adaptation. Nonetheless such a (partly) a-temporal course does not exclude the iterative character of the entities.[90] For instance, after criticism on a draft text, reformulating alternatives is possible.

Universality

Despite the circular or linear approach, as far as the strict sense of decision-making is concerned, both models are largely identical in defining the relevant elements (objectives, data analysis, potential means, selection of alternatives, draft of legal norm, enactment). In view of these similarities, it is plausible to assume a universal theoretical model of law-making, at least in the strict sense and considering the unique situational law-making aspects. If, and to what extent a circular law-making model in the Central and Eastern European setting is likely, cannot yet be answered. Nonetheless, the necessity of rationalising law-making has generally been confirmed by Central and Eastern European theorists.[91] Planning, prioritising, and reliable data analyses are major prerequisites, while the fiction of an omniscient, omnipotent legislator (known and unknown side-effects), implies law-making as an infinite process which frequently necessitates the modification of current regulation. A controllable and accountable evaluation is therefore essential before any substantial and structural change may be executed. In view of these considerations, the circular approach in the Central and Eastern European context seems quite likely.

In summary, from a legal-theoretical perspective, the tenability of a uniform model of law-making is quite likely. At least in a strict sense, in the Central and Eastern European literature there are several indications that confirm to dynamic, more circular concept of law-making. Nevertheless, the fragile state of the newly emerged or transformed political systems substantially influences the content of law-making. Political aspects such as the diversity

---

90 *O.c.*: 200

91 Wronkowska and Gwizdz, *supra* note 68.

of political controversies and tendencies of nationalism complicate rational law-making, but this does not detract the proposed elements of a tentative theoretical method. To construct such a uniform model of law-making, the analogies impose several changes of Noll's original concept on law-making.

5 ADAPTATION OF NOLL'S LAW-MAKING MODEL

The assumption of a general theoretical model of law-making impel certain changes of the original model as developed by Noll. This section will discuss these changes and its reasoning. The analogies between the previously discussed notions of law-making and additional annotations concerning the law-making theory necessitate, first of all, some textual changes. More important, however, are the consequences for the structure and content of the model. Necessary changes concern the underlying notions concerning the "pre" and "post" legislative stages of law-making. Analysis of the following considerations enables to construct the ultimate model.

Circular model and policy

Strictly considered, both Noll and Wróblewski have developed a comparable general model of law-making. Whereas Wróblewski's approach of law-making can be characterised as static, Noll's circular approach, on the other hand, includes the stages "control" and "correction" of the legal norm. The temporary character of law-making necessitates assessment of the legal norm, including a review of the original objectives of law-making. As a consequence, this circular approach could impose modification or even withdrawal of the legal norm. In any case, more important still is the relationship with law-making policy.

Ideally, law-making objectives correspond with the legislator's policy plan that formulates the legislative policy objectives. An amendment of a legal norm seems likely in case of diversity between the objectives and ultimate outcome of legislation. Apart from amending the individual legal norm, it may even be necessary to adjust the underlying policy plan, for instance in case of fundamental inconsistencies between the legal norm and underlying policy plan. Due to the interrelationship between legislative policy and law-making, changes in policy invoke changes in legislation.

The assumption of the circular approach of law-making can therefore have consequences to the decision-making at policy level. Such an approach impels policy-makers to develop and elaborate a coherent framework of short and long-term policy objectives, transformed into law-making objectives. To a certain extent this approach could prevent *ad hoc* law-making, mostly rashly developed which increases the risks of deficiencies and inconsistencies to the law-making programme. In view of previous experiences with rather unstructured reforms of the legal framework,

Central and Eastern Europe policy makers subscribe to the need for such a consistent approach.

Functions of law-making

In order to rationalise law-making; a primary requisite is an elaborated strategy based on a framework of law-making objectives. This presumption is based on the legal-theoretical functions of law-making. Traditionally, the normative function has been emphasized in the legal literature. However, in the contemporary law-making tradition, also the functional approach of law-making can be discerned. These functions have a guarantee function derived from the "*Rechtsstaat*" principle and an instrumental policy function, which considers law-making as an instrument in order to achieve certain policy objectives.

The guarantee function of law-making is a rather abstract idea, it is conceptualised by principles such as legal security, legal equality and democracy, since legal norms are supposed to maintain these principles. This assumption refers to the legality-principle, *viz*, legal norms determined by law. Since parliament is the ultimate legislature, government intervention is restricted by competencies given by the parliament. Therefore, the competencies of the executive power are generally in accordance with the democratic notions of decision-making of the freely elected parliament.[92] Besides, the restraints of the executive power to the law create legal security to the citizens, i.e. the legislature determines in which cases and according to what procedures the executive power may act. Therefore, citizens know what to expect from the executive power. Finally, legal equality will be served by the legality-principle. Since the legislature stipulates general norms of behaviour, to be complied by the executive power, discriminatory treatment of similar cases is not allowed.[93] It should be taken into account that such an interpretation of the guarantee function is based on a Western liberal notion of the "*Rechtsstaat*".[94] According to this approach, the "*Rechtsstaat*" is considered as the ultimate ideal epitome of the Western legal tradition. Whereas the assumption of the "*Rechtsstaat*" as a multi-interpretable concept, subjected to the historical and cultural circumstances, would place the guarantee function of law-making in a different

---

92 Winter *o.c.*: 13.

93 *O.c.*: 14.

94 The Anglo-Saxon synonym for "Rechtsstaat" is often described as the *rule of law*. However, these concepts at nor identical. Although there are some corresponding elements *e.g.*, "in accordance with the law", differences mainly concern the different perspectives of groups of "consumers". Moreover, the interpretation of both concepts is a product of time. As a consequence, the general *Rechtsstaat* is a (partially) contested concept M.A.P. Bovens, W. Derksen, W.J. Witteveen (eds). Rechtsstaat en sturing (Rechtsstaat and steering). Tjeenk Willink, Zwolle 1987: 15.

perspective.[95] Despite the emerged problems, generally, a classical Western interpretation has generally been formally codified in most Central and Eastern European constitutions. A tendency, strengthened by economic and political co-operation with the European Union and statements by the European Commission that "before either disbursing (financial) aid or concluding Europe agreements, the Community must be satisfied that the Central and Eastern European countries had made firm commitments to five fundamental objectives, *viz*, the *rule of law*, respect for human rights, the establishment of a multiparty system, the holding of free and fair elections, and economic liberalisation with a view of introducing a market economy.[96] One of the consequences of the direct correlation between the Community's economic power has allowed it to dictate the agenda for reform in Central and Eastern Europe. Once the Community had decided to establish a clear link between human rights, democratisation and the extension of aid, the Central and Eastern European states had little practical choice but to accept the community's prescription for reforming their legal and political systems.[97]

According to these considerations, the intent of the guarantee function of law-making, as considered in a liberal "Rechtsstaat" approach, has generally been confirmed by Central and Eastern European legislators and Constitutional Courts rulings, despite possible consequences with regard to long-term policy objectives. As far as the current practise of safeguarding individual rights is concerned, the principal acceptance of the guarantee

---

95 H.R. van Gunsteren. Rechtsstaat of juridische traditie? (The "Rechtsstaat" or legal tradition), in Bovens *o.c.*: 175. Implications of transposing a Western "Rechtsstaat"-concept have been concretized by various judicial statements of the Hungarian and Polish Constitutional Court. The realization of social reforms has been seriously frustrated by a strict and unfeasible interpretation of the Rechtsstaat. In the long run, such an obstructive attitude, can damage the whole reform-process in these countries. *Cf. e.g.*, A. Sajó. How the rule of law killed Hungarian welfare reform. *EECR* 1996, Winter: 31-41; A. Arato. The constitution-making endgame in Hungary. *EECR* 1996, Fall: 31-39; J. Hellman. Constitutions and economic reform in the Post-communist transitions. *EECR* 1996, Winter: 46-56.

96 European Commission. n. 52, p. 3. EC, "The development of the Community's relations with the countries of Central and Eastern Europe", p. 3, 18 April 1990. SEC (90) 717. EC, "Association agreements with the countries of Central and Eastern Europe: a general outline", p. 2, 27 August 1990, COM (90) 398; referred in the preamble of the Europe Agreement European Community and the republic Hungary, L 347/2, 31.12.1993; Europe Agreement European Community and the republic Poland, L 348/2, 31.12.93 whereas the second generation EAs codified this principle, for instance article 6 EA with Czech Republic (1994) L 341/14. Other important indications are the ratification of both the European Convention on Human Rights (ECHR) and the European Social Charter (ESC) by several CEE-countries. As such these countries confirm their commitment to a constitutional order based on a (social) democracy, rule of law, and respect for individual rights and freedoms.

97 T. King. The European Community and human rights in Eastern Europe, in: *Legal issues of European integration*. 1996 (2): 125.

function reveals serious deficiencies.[98] The distorted market economy has a major impact on the meaning of human rights. Many legal rules remain under-enforced and the administration of justice is unable to guarantee the enforcement.[99] It is questionable to define these shortcomings as "growing pains" or to consider them as structural deficits.

Apart from the "rechtsstaatliche" approach guaranteeing fundamental legal principles, the functional approach of law-making considers law-making as an instrument in order to realise certain policy objectives (*e.g.*, to plan and structure relations, the allocation of financial and physical means or services, to encourage and discourage certain behaviour, *et cetera*). In view of the legality-principle, policy objectives can be realised by means of legislation. Here, law-making is considered as a – legitimised – instrument to achieve policy objectives.[100] From an administrative perspective, the functional aspect of law-making has been emphasised although the legal-technical notion of rationalism and functionalism in law-making has been put into perspective both in the Western and Central-Eastern European literature.[101] Less high expectations of the concept of "social engineering" by means of legal instruments resulted in a more realistic approach. Nonetheless, the notion of legal norms based on the guarantee and functional perspective will be maintained. To a certain extent this assumption can conceptualise the complications occurring in the law-making process.

The previous discussion concerning the functions of law-making was necessary in order to clarify the objective determined-approach of law-making. Both Noll as Wróblewski identify the notion of "problem impulse" or objective as the initiating element of a regulative process. Noll's definition of "problem impulse" as "all those reasons, which induce a normative activity", reflects law-making as a non-structural rather intangible activity, despite his reference to a (declamatory) government or party programme. In view of the unforeseeable and continuous changing social relations or circumstances, that might be partly the case. However, given

---

98 A. Sajó. On Old and new Battles: obstacles to the rule of law in Eastern Europe. *Inquiry* 1995 March: 97-104.

99 *O.c.*: 100.

100 Another assumption of law-making as an instrument concerns policy considered as realized positive law-making. As a consequence, policy itself has no independent base: E.H.M. Hirsch Ballin. Publiek recht en beleid (administrative law and policy). Alphen a/d Rijn, 1979. Between the objective-instrument approach and realized law-making, various hybrid forms are possible.

101 *E.g.*, K. Kulcsár. The role of the political system and state in social transformation in East Central Europe in: The role of the state in social transformation under the impact of the world crisis: the case of East Central Europe, Budapest 1986: 50.

the traditional functions of law-making, law-making also has a relatively controllable character. In this respect, Wróblewski's distinction between both the normative and functional objectives, besides short and long-term objectives of law-making is more attractive. In case actual non-structural problem impulses are considered as short-term objectives, Wróblewski's distinction of objectives corresponds to Noll's definition of problem impulses. In view of the assumption of rationalising the law-making activity, the author prefers Wróblewski's approach of normative and functional objectives including short and long-term objectives. Realising the possibility of conflicting objectives, Wróblewski emphasises the necessity of co-ordination and establishing priorities between both types of objectives.[102]

Given the political dimension of defining law-making objectives and its functions, differentiation of these functions in the policy stage, could increase a more systematic approach of the law-making activity. Elaboration of a framework of coherent law-making would, to a certain extent, decrease the *ad hoc* character of law-making.

Obviously, an objective-determined approach of law-making cannot be considered as a panacea to rationalise law-making. Nonetheless, it has certain advantages, in particular in the Central and Eastern European setting, where priorities and the extent of far-reaching reforms require a clear strategy of law-making policy to direct these changes.[103]

General or "actor-specific" model

In the previous paragraph, the diversity of law-making actors did not result in the prior rejecting the single-actor model in advance. A differentiated actor-specific model was suggested as additional, not contradictory to a general model. Such a differentiation, if possible and necessary could concern various formal and informal law-making actors, with their own motives and objectives. Complications concern the temporary character of motives, which are not considered as constant, may possibly change during a certain time, and may be conflicting to other motives (*e.g.*, guarantee *vis-à-vis* efficiency). Besides, obscured motives complicate the real intention of actors. To a certain extent, further elucidation of the motives could be helpful rationalising and prioritising certain motives. Revealing law-making motives can increase the understanding of the law-

---

102 Wróblewski 1984 *o.c.*: 19.

103 To a certain degree this was the case just after the collapse of communism in Central and Eastern Europe. After a period of euphoria in many CEE-countries, ambitious reform programmes concerning the introduction of a market economy have frequently been postponed. Given the social consequences of "shock-therapy", the reform programmes have been adjusted into a more gradual and a more realistic approach by modifying policy and law-making objectives.

making perspective. Subsequently, reviewing different motives and therefore legitimising law-making will be more important in case the diversity of law-making actors increases.

Control and correction vs. implementation and evaluation

As mentioned earlier, a main difference between Noll and Wróblewski concern the stages of control and feedback, which are absent at Wróblewski. Although Wróblewski confirmed the relevance of monitoring legislative effects, he did not include an explicit stage of evaluation in his model. The reason is his strict interpretation of law-making, the enactment of a legal norm is considered as the final step of the decision-making cycles. Control and feedback, although of importance, are not included into his linear approach.

In both the contemporary Western and also Central and Eastern European literature, a more circular concept, including a re-assessment of the effectiveness of enacted legal norms, is more or less accepted.[104] Criticism upon the omnipotent law-maker, imposed a more moderate approach, in which continuous control of the effectiveness and feedback to the original objectives constitutes necessary elements of the law-making process, reflected by the model. As a consequence, Noll, who used a less strict definition of the law-making process, included the stage control and correction after the enactment of the legal norm. Nonetheless, his definition of the control and correction-stages is rather restricted. As far as the systematic and institutional review of the effectiveness of a legal norm concerns, the review is not restricted to a certain stage of the law-making process. This assumption is not disputed in the contemporary literature.

However, Noll's restricted interpretation of control and correction concerned the effectiveness of the single legal norm, despite his referral to the relation with the legal structure in general. Although he mentions the "Interdependenz von Einzelregelungen im Gesamt der Rechtsordnung", this concerns more the systematics of the law-making technique, than the method.[105] As a consequence, the correction is also primary restricted to the individual legal norm, instead of including possible effects to the law-making policy. Since the realisation of law-making policy occurs in a political arena, derived law-making objectives, and

---

104 *Supra* notes 5 and 6, in particular Eijlander, Winter, Öhlinger, and König (in: Schreckenberger) emphasized the relevance of feedback (evaluation) of enacted legal norms. Conform U. Karpen (ed.) Legislation in European Countries. Nomos Verlagsgesellschaft Baden-Baden 1996: 485, S. Wronkowska, A. Gwizdz. Current Problems of Legislation in Poland in: Karpen *o.c.*: 343; L. Kiss. *supra* note 20 and Zweig, *infra* note 109.

105 K. König. Evaluation als Kontrolle der Gesetzgebung in: Gesetzgebungslehre: Grundlagen, Zugänge, Anwendung. W. Schreckenberger, K. König W. Zeh (eds) Stuttgart Kohlhammer 1986: 106.

therefore the definition of legislative documents, are determined by political influences. In this perspective, the term "control" as used by Noll is too restricted. Instead, the phrase "implementation" is more appropriate, although this concept does not correspond entirely with Noll's meaning of control. Viewing from the aspect of evaluation, both concepts correlate to control and correction. Nonetheless the combination implementation-evaluation has additional advantages and will be used hereafter.

Implementation

When appearances are considered from a purely normative perspective, the detailed circumstances and conditions of the application are generally left out of consideration. Where implementation is examined, they constitute part of the picture. In other words, the study of implementation broadens the perspective and steers interest beyond the mere execution of laws towards the conditions for the law to act as a means of shaping policy.[106] Implementation is generally considered as "realisation or application of laws and other action programmes produced in the process of policy development".[107] In addition to administrative enforcement, implementation also depends on the attitude of the relevant target groups. Moreover, since it is an element on its own in a political process, it cannot reasonably be isolated from the processes that precede it, particularly programme development. Considering these aspects, implementation will be accordingly oriented primarily towards the programme concerned, the specific nature of the implementing authority and the features of the target and addressee groups.[108]

Evaluation

Originally, evaluation of legislation has a predominant American tradition.[109] Nonetheless, in the contemporary (Western) European law-

---

106 J. Schwarze, U. Becker, C. Pollak. The implementation of community law. Studies in the legislative and administrative policies of the European Community and its member states. Nomos Verlagsgesellschaft Baden-Baden 1994: 12-13.

107 R. Mayntz. Die Implementation politischer Programme: Theoretische Überlegungen zu einem neuen Forschungsgebiet in: Implementation politischer Programme. R. Mayntz. Verlagsgruppe Athenäum 1980: 236.

108 *O.c.*: 239-40.

109 See, for instance, the "Sunset-legislation" concept, i.e. legislation with a limited period of validity and which mandates the legislature to systematic utilization of evaluative research. F. M. Zweig. Evaluation in Legislation. Sage Publications Beverly Hills 1979. For a more extensive commentary on Sunset legislation in the German setting, P. Langner. Zero-Base Budgeting und Sunset Legislation. Instrumente zur Rückgewinnung öffentlicher Handlungsspielräume? Nomos Verlaggesellschaft Baden-Baden 1983.

making practise, evaluation is also accepted as part of the decision-making processes.[110]

Legislative evaluation is aimed at the analysis and review of a legal norm. It concerns an assessment of the content, application and effects of the legal norm against a number of predetermined criteria.[111] Such an (institutionalised) evaluation concerns both legal criteria (derived from the legislative technique, legal system and the guarantee function) as well as policy functional criteria (goal attainment, effectiveness and efficiency) and could contribute to increase the quality of law-making. Besides the "*rechtsstaatliche*" function of guaranteeing legal-security and equality, the policy aspect concerns the norm conformity (compliance with and enforcement of the law, i.e. the effects). More important is the effectiveness of the legal norm. If, and to what extent is compliance with or enforcement of the law based on the legal norm or due to external (legal) aspects (causality aspect). Secondly, what are possible (un) foreseeable side-effects. These questions correspond to evaluation of policy, in which the main question concerns the realisation of policy objectives. In this respect, legislation is also considered as a policy instrument in order to achieve certain policy objectives.[112] The policy objective is a main function of contemporary law-making but not exclusively. Ideally, legislative evaluation includes an analysis of both functions, operationalised by specific criteria. Nonetheless, practically, policy-determined criteria frequently dominate in the evaluation process.

In the literature, one can find various types or forms of evaluation that can be distinguished.[113] In order to optimise evaluation, Winter introduces a systematic evaluation of law-making.[114] From an analytical perspective, such an evaluation includes primarily a reviewable collection and analysis of data. These data should therefore answer validity, reliability and representativeness criteria. Secondly, these criteria need further explanation. As far as the methodology is concerned, the chosen method can vary in approach as in type of analysis.[115] The methodological concepts should

---

110 *C.f., e.g., Recht en Regelmaat* 2000, Iss. 5 (special issue), which provides an overview of various legal contributions concerning legislative policy, notably the impact of evaluation of legislation studies in several European Union member states.

111 Winter *o.c.*: 4, 34.

112 Winter *o.c.*: 33-34.

113 The most common types of evaluation are *ex ante* and *ex post* evaluation of legal norms. *Ex ante* evaluation will be initiated before a legal norm has became effective, whereas *ex post* evaluations are the most frequently used type and occur after enactment of a law.

114 Winter *o.c.*: 21 *e.s.*

115 Roughly speaking, the methodological approaches can be discerned to the effects (goal-attainment), and effectiveness (to what extent is intervention successful). Types of analyses can be classified as qualitative and quantitative (experimental) methods, which refers to the introduction of external variables as an explanatory factor.

enable the deduction of statements concerning the extent of success of regulative interventions to an observed change. Once the method of evaluation has been selected and motivated, the next step to rationalise evaluation is elucidation of the selected criteria by means of elaborating the guarantee and instrumental policy objectives of law-making. The variety of perspectives and agendas to review government intervention, affects the process of evaluation. Generally speaking, official policy objectives function as a framework of evaluation criteria since its democratic realisation legitimised this perspective. A second reason is that evaluative information will be submitted to policymakers, on the basis of this information, they may reconsider possible modification.[116] Nonetheless, the functioning of official policy objectives as evaluation criteria has its restrictions. For instance, vagueness of policy objectives increases exposure to external influence since unclear objectives need to be operationalised, contradictive objectives, and changes in policy objectives decided.[117] Despite these constraints, it can be considered as an attempt to rationalise evaluation. In a systematic evaluation, awareness of these dilemmas should impel the explication of the applied criteria. Furthermore, they should account for the origin of the review criteria in order to enhance the controllability and understanding in evaluation and the applied criteria.[118] Until now, such a systematic evaluation has primarily been focussed on the policy functional dimension. The guarantee objectives refer to more abstract aspects of law-making. The referred guarantee functions were identified as safeguarding legal equality and enhancing legal security. From that perspective, explication into policy objectives depends on clarification of the evaluative criteria and their accountability. Besides the possibility of the mutual contradictive characters of guarantee objectives, a further complicating factor is the relation with policy functional objectives. It is generally understood that the guarantee and directive function can serve conflicting interests. Whereas the policy functional perspective concern possible statements on effects and effectiveness of (legal) intervention, the guarantee character of law-making is focused on the legal-technical character of the defined norm, internal and external coherence to the legal system, including general legal principles, codified provisions in acts, constitutions or treaties. Referred to these criteria, the specific character of legislative evaluation therefore also includes a guarantee component.

---

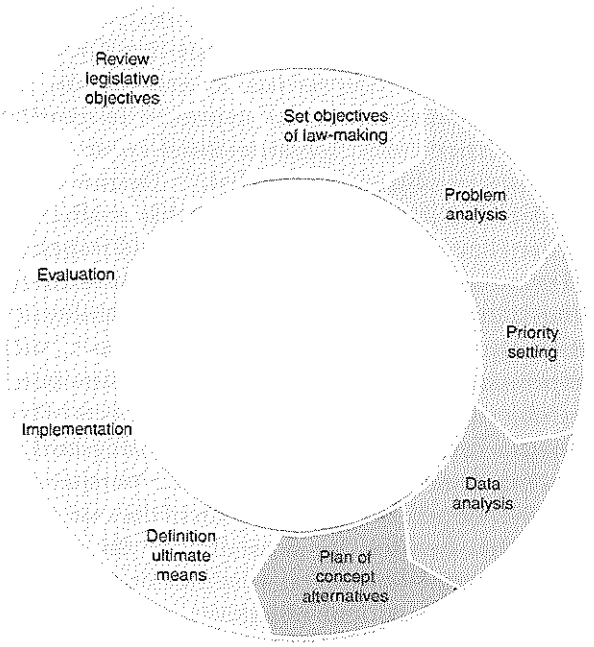
116 Winter *o.c.*: 26.

117 M. Herweijer. De dynamiek van doeltreffend gedrag: een struikenblok bij evaluatie (The dynamics of effective behaviour: an obstacle at evaluation) in: *Bestuurswetenschappen* 1981, Iss. 5: 348-366.

118 Winter *o.c.*: 27.

More specifically, an analysis and concluding statements concerning the extent of effectiveness of guarantee objectives.[119]

To conclude, in view of the suggested modifications, the law-making activity can be reflected by means of the stages of law-making as described by Noll. The suggested changes concern the objective-determined approach, and the introduction of the element "implementation" and "evaluation". Graphically, the adapted model of law-making reads as follows:



The circle emphasises the circular approach of the legislative activity as a continuing process. In view of the assumption of a comparable interpretation of both Noll's and Wróblewski's notion on law-making, in a strict sense, the ultimate model includes the following elements:

- Objectives of law-making
- Problem analysis
- Priorities
- Data analysis
- Plan of concept alternatives
- Definition of ultimate (legal) means

[119] *O.c.*: 30-33.

- Implementation
- Evaluation
- Modification of law-making and (objectives of) law-making policy.

Systematic and judicial evaluation of legislation may impose on the legislature to review and reconsider the original objectives of law-making. Eventually, this review may call for the amendment of the present legal norm. Since the process of drafting legislation is, *ideally*, part and parcel of the underlying legislative policy, modification of the legal norm may also affect policy decision-making (chapter four). To emphasize this interdependence between legislation and policy, this element has been lifted out of the circle. In general, the proposed systematic and analytical approach is based on an operationalised framework of consecutive elements. The application of this approach can increase the transparency and controllability of the legal decision-making. Awareness and reference to non-specific legal aspects in the decision-making process, if possible and necessary, would increase the practical feasibility of this analytical concept. Such an approach refers to the "dynamic" approach of legislative decision-making as described in the German legal literature on rationalising the law-making activity.

6 CONCLUSIONS

Legal decision-making, notably drafting legislation in transition countries has been criticised for a lack of rationality. As an attempt to rationalise the law-making activity in a Central and Eastern European setting, this chapter described a legal-theoretical method of law-making in general. This method is derived from influential theorists such as Noll and Wróblewski. The method may be reflected by means of an analytical model, simplifying the legislative activity in terms of consecutive stages. Apart from underlying legal-theoretical notions, the developed analytical model includes more recent insights derived from related disciplines. For instance, instead of a static, purely legal approach, the legislative activity is considered as a dynamic activity, that includes, as far as necessary, correlative sciences. It appeared that stages such as implementation and evaluation of legal norms are crucial to effectuate the enacted legal norm. The subsequent outcomes of evaluative research may give raise to reconsider existing legal norms and/or underlying policy. Such a circular notion of law-making enables an increase in understanding in legislative decision-making in a more rational manner. In the following chapters, it is argued that such an approach can be applied to a specific field of legislation, *viz*, health (care) legislation. Particularly since health care systems in transition countries are in a "state of flux", rational decision-making on necessary legal reforms could contribute to reduce the negative experiences these countries have

faced in transforming their health care legal framework. In order to understand the specific relevance of the analytical model to health care law, the following chapter examines the functions of health care law.

CHAPTER 3: A NORMATIVE FRAMEWORK OF HEALTH CARE LAW[1]

1 INTRODUCTION

The general notion of a model of law-making can be applied to a specific field of law, *viz*, health care law. Such a model then reflects the basic norms of health care law. The relevance of such a specific model is to rationalise health care law-making. Since the law-making activity is based on the underlying notions of law, such a model should reflect these basic values. More specifically, the notions of health care law. Therefore, this chapter begins by identifying and operationalising the basic values of health care law. The definition of such a normative framework of health care law raises the question of its unique underlying values ("conceptual unity"). Therefore, in section 2 the specific basic values of health care law are discussed, *viz*, the right to health care and patient autonomy. Implicitly, such an analysis acknowledges the unique nature of health care law as a separate field of law.[2] Whether or not such principles are universally acceptable, and thus applicable in another, in this case, Central and Eastern

---

1 Different definitions have been used in the legal literature to describe this field of law (Medical law, health law, health care law, droit sanitaire, Arztrecht, *et cetera*). Within the scope of this research the phrase "health care law" will be used (or simply abbreviated to "health law). Health care law includes first and foremost the more traditional (individual) aspects in the physician-patient relationship. Due to the increased social dimension of health care, health care law has a broader scope and also encompasses the delivery of other health care services and facilities by others than doctors, including public health services. In view of the more institutionalised notion of health care, the object of research of health care law has extended to the other relations within the triangular model physician-patient-purchaser. Simultaneously, the identified clusters constitute separate relationships with the legislature/government. Consequently, the object of health care law also covers the organisation, planning and financing of health care.

2 In legal doctrine, various theorists have contributed to the debate on legitimising the existence of a separate legal discipline. Since that debate is outside the scope of this research, the author refers to the legal arguments contributed by various theorists, *cf., e.g.*, H. Nys. Medical law and health law: from co-existence to symbiosis?; F.P. Grad. Public health law: its form, function, future, and ethical parameters; H.J.J. Leenen. Health law and health legislation: possibilities and limits. H.D.C. Roscam Abbing. Health, human rights, and health law: the move towards internationalization, with special emphasis on Europe in: Health Legislation at the Dawn of the XXI[st] Century. *International Digest of Health Legislation*. World Health Organization. Special Issue 1998, Iss. 1; J. Montgomery. Health Care Law. Oxford University Press 1997; E. Deutsch. Arztrecht und Arzneimittelrecht. Springer Verlag Berlin, 1983. Contrary to the notion of a separate legal (sub) discipline, the opposite has also been defended. Ergo, a mere part of civil, penal and administrative law. For instance, B.. Sluyters. Geknipt Verband ("Die zersplitterte Zusammenhänge"), inaugural lecture, Leiden University, Kluwer Deventer 1985: 18-25.

legal setting is subject of this research. In the following section, section 3, the modalities of health care law as discerned by legal theorists is examined. These qualities of health care law operationalise the conceptual framework of health care law, i.e. they transform the underlying standards into more concrete normative commitments to the national legislature. The conceptual framework of health care law is based on its underlying principles and the modalities of health care law as established in (inter)national law. Particularly international sources of law include common normative standards of health care law in terms of equal access to scarce resources, the solidarity principle and respect for individual human rights and freedoms in health care. In section 4 a *tour d'horizon* of relevant international sources of law that formulate and substantiate these concepts of health care law is given.

2 PRINCIPLES OF HEALTH CARE LAW

Given the diversity among theorists on the object of study, there is no consensus on the underlying principles of health care law.[3] *Grosso modo*, two pivotal principles have been discerned, *viz*, the right to health care and respect for (patient) autonomy.[4] Apart from these principles it is questionable whether other rights such as the right to life or corollary concepts, namely the right to physical integrity and the right to dignity are sufficiently specific to function as underlying principles of health law. Molinari answered this question affirmatively.[5] The author is, however, of the

---

3 *Cf. e.g.*, G.J. Annas. The rights of patients. Southern Illinois University Press, 1989: 3; H.J.J. Leenen, J.K.M. Gevers, G. Pinet. The rights of patients in Europe: a comparative study. Deventer Kluwer Law and Taxation Publishers 1993: 1; I. Kennedy, A. Grubb. Medical Law. London, Buttersworth 1994: 3; P.A. Molinari. The right to health: From the solemnity of declarations to the challenges of the practise. *supra* note 2, H.D.C. Roscam Abbing. International organizations in Europe and the right to health care. Kluwer Deventer 1979; T. Birmontiene. The Development of a Health Law Doctrine in Lithuania. *Medicine and Law* 1999, Iss. 6: 181-186.

4 Principles can be understood as preceding positive law, generalised and abstracted from statutory law that affect the interpretation and application of statutory rules by guiding and reviewing existing rules, as well as filling gaps in positive law.

5 Molinari *o.c.*: 42-45. *cf.*, A. Laufs. Arztrecht. Beck Verlagbuchhandlung, München 1988: 5 (Die Einheit des Arztrechts: Leben, Gesundheit und Autonomie). Notably the liberal notion on health care legal principles has (over)emphasized the principle of autonomy but is, however, not unchallenged. For instance, autonomy is hardly of relevance in the case of regulating prenatal diagnosis or pharmaceuticals. W. van der Burg. Gezondheidsrecht en bio-ethiek: op zoek naar een nieuwe verhouding (Health care law and bio-ethics: searching for a new relationship). *Nederlands tijdschrift voor rechtsfilosofie en rechtstheorie* (Dutch journal for legal philosophy and jurisprudence) 1996, Iss. 3: 201. Therefore, other basic values such as the right to life and its corollary concepts such as physical integrity and human dignity can still be of importance.

opinion that, although increasingly important to this discipline, the nature of the right to life is insufficiently specific to be considered as the third, or even the first principle of health care law. This having been said, the pre-eminence of the dual approach (the right to health care and respect for patient autonomy) underlies this study, but they should be seen from the perspective of other relevant human rights values. The affirmation of these fundamental rights is found in various legal documents, whether assertive or declaratory in nature.

The assumption of the conceptual unity of health care legal principles is closely related to the classical debate on social versus individual rights.[6]

---

[6] The conceptual approach of health care rights emanates from the medical and ethical discipline which identifies the following principles as (widely) accepted: the principle of autonomy, beneficence, non-maleficence, and justice as leading principles T.M. Beauchamp, J.F. Childress. Principles of Biomedical Ethics. New York. Oxford University Press 1989: 21. The principle of respect for *autonomy* refers to the right to make decisions about one's one life and body without coercion by others. Originally, such a notion was based on political liberal theories. In the political liberal approach, political individualism corresponds with personal autonomy in ethics as a rejection of paternalistic ethics. The principle of *non-maleficence*, includes the maxim: first ("or above all") do not harm others. This principle expresses a cardinal ethical principle in medicine. Whereas it seems logical not to harm all other persons, it is impossible to benefit all people. Therefore, the claim of doing no harm takes priority over the beneficence principle, which means that the obligation not to harm people is more stringent than the obligation to benefit people. From the previous assumption follows that doing good includes an imperfect or *prima facie* duty to do well to others but not under all circumstances, not if it is impossible to fulfil. I. Kant. Fundamental Principles of the Metaphysic of Ethics, transl. by T. Kingsmill Abbott. Longman London 1969: 16. The principle of *beneficence* expresses the value of doing well to others, showing sympathy to the ill. In medical ethics, the beneficence principle has been applied by distinguishing therapeutic from non-therapeutic experiments on patients. G.E. Pence (ed.). Classic Works of Medical Ethics. Core Philosophical Readings. McGrow Hill, Boston, 1998: 14. To help diabetic patients, an experiment on these patients is justified where therapeutic value can be shown, if the benefit is non-therapeutic another justification is required. Many philosophers have debated the principle of justice. Aristotle's formal notion of justice, which has been widely accepted, claims that equals should be treated equally and unequals unequally in the proportion of the relevant inequalities. Aristotle. The Nicomachean Ethics 1131a: 22-25. Justice therefore, requires a physician to treat each patient impartially, regardless of gender, insurance coverage, et cetera. These principles may be considered as central to medical-ethical practise. Since medical ethics and health care law have common underlying ideas, the (bio)ethical notions reflect basic health care legal principles.
Despite their similarity, a major difference between the discerned medical-ethical norms and the identified legal principles concern the enforceability of norms (coercive power). Medical-ethical principles can be enforced less precisely than legal rights. Consequently, the legal principles as basic notions of health care law has been preferred. "Since medical ethics do not offer universally applicable and enforceable protection, a trend of providing basic safeguards through law-making has emerged." K. Tomasevski. Health Rights in: Economic, Social and Cultural Rights. A Textbook. A. Eide, C. Krause, A. Rosas. Martinus Nijhoff Dordrecht 1995: 136. Still, preference for legal principles should not be read as legislation replacing medical ethics rather as two conceptions, which are mutually interrelated. K.E. Tranöy. Patient's Rights. Vital needs, human rights, health care law. *Medicine and Law*, 1996, Iss. 2: 184.

In this respect, several remarkable developments have occurred both in legal doctrine and legal practise, notably in judicial practise. These developments need further discussion to understand the seeming discrepancy between the basic values, notably the right to health care and patient autonomy.

2.1 Social versus individual rights

Primordial values such as the right to health care and patient autonomy reflect the dichotomy between *social* and *individual* rights. Traditionally, the right to health care, interpreted as access to health care, has been characterised as a social (programmatic or positive) right.[7,8] Social rights such as economic and cultural rights are not intended to protect the individual but are rather subjective rights in a given community. Their guarantee lies in the (minimum indispensable) standards and provisions which states are bound to take. On the other hand, patient autonomy includes individual (classical or negative) rights. Individual rights (and freedoms) are generally accepted as legally inalienable.

This classification has been accepted for many years. However, the modern international legal literature and recent rulings from (quasi)judicial authorities, have differentiated these opinions. The strict dualism has ever increasingly been considered as part and parcel of a continuum of rights and possible correlated obligations. These two categories of rights complement each other and are interdependent. Social rights must therefore aim at safeguarding individual rights and individual rights are to be considered in relation to the individual's participation in society.[9] Effectuating individual entitlements of basic rights require active intervention, while social rights must aim at safeguarding individual rights.[10] Hence the "water-tight" division between individual and social rights has rather faded in the current socio-economic environment. Concomitantly or inherent to such a diffusion of the nature of rights, the legal status of social rights – generally considered weak – is changing. Their interdepen-

---

7 H.J.J. Leenen, G. Pinet, A.V. Prims (eds). Trends in Health Legislation in Europe. Paris: Masson/World Health Organization 1986: 3.

8 H.J.J. Leenen, J.K.M. Gevers, G. Pinet. The rights of patients in Europe: a comparative study. Deventer Kluwer Law and Taxation Publishers 1993: 1.

9 Leenen, *o.c.* 1986: 3; conform Banaszak: (In der sozialen Rechtsstaat) "schützen die Rechte und Pflichten nicht nur die individuelle Sphäre der Freiheiten des Individuums, sondern erfüllen auch bestimmte soziale Funktionen, und ihre Beanspruchung sollte sozialorientiert sein, d.h. indem sie dem Schutz der Interessen des Individuums dienen, dienen sie gleichzeitig der Gemeinschaft." Banaszak B. Die Konzeption der Rechte des Individuums in Polen. *Osteuropa Recht* Dezember 2001, Iss. 6: 478.

10 H.J.J. Leenen, J.K.M. Gevers, G. Pinet. The Rights of Patients in Europe. A Comparative Study. Kluwer Law and Taxation Publishers, Deventer 1993: 1.

dent and complementary characters have increased, foremost due to international treaties and conventions.

Recent international developments related to social rights

The original concept of human rights as natural rights and inalienable entitlements has been inextricably bound up with the philosopher John Locke (1632-1704). Further elaborated by Jean-Jacques Rousseau and Immanuel Kant, the concept of natural rights has been discerned from civil rights of individuals.[11] The changed portrayal of mankind, undoubtedly caused by the political concept of a liberal state and the industrialisation all over Europe, has encouraged the notion of individual basic rights. For that moment, basic rights were focused on citizens' rights and political freedoms in order to protect the individual against abuse of power by the state.

In the course of time, human rights doctrine has endured substantial alterations. The classic notion of protection has evolved in what is called individual freedom rights and social rights. Whereas individual rights are aimed at the protection of the individual sphere of the individual liberty, the objective of social rights is to safeguard the participation of people in social goods.[12] Social rights fall under the category *Leistungsrechte,* they legally provide for an obligation or efforts by the government; while individual rights are inherent to the individual as a human being. Individual rights or so-called *Abwehrrechte* are said to be of a "negative" nature because they impose government and society not to interfere with the sphere of the individual. Most legal applications are of this nature, including patients' rights such as rights against being touched without one's consent and, touching in the form of a medical examination or treatment.[13] Social rights are labelled as positive because they entail or instruct government to ensure an equitable distribution of social goods and a just participation of the individuals in these goods.[14] The realisation of social rights requires active government intervention, which, in its turn, depends largely on the national socio-economical situation. The "political" or "programmatic" nature of social rights prevents them from being labelled as "legally enforceable rights".

---

11 J.D. Van der Vyver. The right to medical care. *Medicine and Law* 1989, Iss. 7: 579-83.

12 H.J.J. Leenen in: Promotion of the Rights of Patients in Europe. Proceedings of a WHO Consultation. Kluwer Law International, The Hague 1995: 50.

13 M.A. Somerville. Autonomy in health care, in: gezondheidsrecht in perspective (health law in perspective). J.H. Hubben, H.D.C. Roscam Abbing (eds). De Tijdstroom 1993: 73.

14 H.J.J. Leenen. Sociale grondrechten en gezondheid (Social rights and health care). Hilversum, DeBoer/Brand 1966: 169.

This interpretation is however changing. Notably the Committee on Economic, Social and Cultural Rights of the United Nations (subsequently, the (Esocul) Committee) has frequently pleaded for the significance and status of economic, social and cultural rights as *rights*. According to its authoritative interpretation, social rights do have immediate effect: "*any suggestion that the provisions indicated are inherently non self-executing would seem to be difficult to sustain*".[15] However, the Committee acknowledges the constraints due to the limited available resources, and party states have "to take steps [...] to a maximum of its available resources, with a view to achieve progressively the full realisation of the rights recognised in the Covenant by all appropriate means, including particularly the adoption of legislative measures".[16] The concept of progressive realisation is a recognition of the fact that full realisation of social rights will generally not be achieved in a short period of time. It is a necessary flexibility device, reflecting the realities and difficulties of the real world but that simultaneously imposes an obligation to move expeditiously and effectively as possible towards the full realisation of the rights in question.[17] Progressively refers however to the "maximum of a country available resources". While "it must be clear that the reference to resources was to the *real* resources of a country and not to *budgetary* appropriations".[18] The Committee states: "the phrase *to the maximum of its available resources* was intended by the drafters of the Covenant to refer to both the resources existing within a State and those available from the international community through international co-operation and assistance."[19]

It is clear that inadequate available resources require priority-setting in objectives and distribution of financial means. Also, the flexibility and freedom in domestic implementation of the obligations national governments have, create a certain margin of discretion to respective policy measures to *promote* social rights.[20] However, "in order for a State party to

---

15 General Comment no. 3 (Fifth session, 1990). The nature of States Parties obligations (art. 2, para. 1 of the International Covenant on Economic, Social and Cultural Rights), in: UN Doc. E/1991/23, para. 5.

16 Article 2 (1) of the Covenant.

17 General Comment no. 3, para 9.

18 P. Alston, G. Quinn. The Nature and Scope of States Parties' Obligations under the International Covenant on Economic, Social and Cultural Rights, *HRQ* 1987, Iss. 2. The John Hopkins University Press, p.185, quoted by F. Vlemminx. Het profiel van de sociale grondrechten (The profile of social constitutional rights). Tjeenk Willink Zwolle 1994: 134.

19 Alston *o.c.*: 46.

20 The Covenant imposes national governments three types of obligations: (i) an obligation to respect, (ii) to protect and (iii) to fulfil, incorporating an obligation to promote and to ensure. Limburg Principles Part II, principle 6. Derived from: A. Eide E/CN.4/sub2/1987/23. Notably the obligation to promote includes an obligation of conduct, contrary to the obligation to ensure that is defined as an obligation of result.

be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations."[21] Moreover, effective mechanisms to review the qualitative progress in "progressive realisation" are still difficult to realise. Possible devices suggest so-called indicators that measure the extent of realisation of promotional measures (*e.g.*, infant mortality and morbidity rates, access to primary health care, number illiterate persons).[22] Furthermore, universal minimum standards in various (non) legally binding declarations and agreements also provide for substantive parameters (minimum core obligation). Further specification, for instance by a general comment on the right to health, may highlight government's obligations.[23] Still, it has been concluded that reviewing the extent of measurable progress as performed by the national government in the long term is difficult to perform.[24]

Contrary to the obligation to *promote*, the obligation to *ensure* is less difficult to review. Different from the promotional obligation, the margin of discretion is quite less. This obligation imposes party states to take steps to ensure guaranteed rights. Among the measures that might be considered appropriate, legislation is highly desirable and in some cases may even be indispensable. In addition to legislation, there is the provision of judicial remedies with respect to rights which may, in accordance with the national legal system, be considered justiciable'.[25] Non-compliance with the party state obligation will be formulated as a violation of the Covenant "when it fails to remove promptly obstacles, which it is under a duty to remove to permit the *immediate* fulfilment of a right."[26]

Apart from the authoritative reading of the Committee concerning a more differentiated concept of obligations, case law of the European Court of Human Rights has also rejected the strict dichotomy of classic (negative) and social (positive) rights. Firstly mentioned in the *Marckx*-case, classic rights create positive obligations. The Court stated that: "*nevertheless, it does not merely compel the State to abstain from such interference: in addition to this primarily negative undertaking, there may be positive obligations inherent in an effective 'respect' for family life.* [...]" As envisaged by Article 8, respect for

---

21 Alston *o.c.*: 46. The minimum core obligations (core content) stipulate the obligations the State should effectuate immediately, irrespective of their available resources.

22 E/CN.4/Sub.2/1990/19.3 "The word indicator refers to statistical data which attempts to provide or 'indicate' (usually based on some form of numerical quantification) the prevailing circumstances at a given place at a given point in time."

23 Such a General Comment has been defined in General Comment no. 14 (*infra* note 37).

24 Vlemminx *o.c.*: 136.

25 Alston *o.c.*: 44.

26 The Limburg Principles. 8, principle 72.

family life implies in particular, in the Court's view, the existence of legal safeguards in domestic law that render possible as from the moment of birth the child's integration in his family. Since then, the Court has further accepted positive commitments based on other classic rights, notably Articles 6 and 11.[27] Still, such positive obligations based on the European Convention still have a rather embryonic and casuistic character.[28] On the other hand, in case a positive commitment has been accepted, the Court simultaneously put into perspective such obligations by allowing states to enjoy a broad "margin of appreciation" in the application of the obligation, particularly in case of obligations of conduct.[29]

2.2 The right to health care

The interdependence and interrelationship between social and individual rights is also a concern of health care. Illustrative is the interpretation of patient autonomy by Somerville. "The most important function of the right to autonomy is to allow one to protect one's life and health. This can require that one have a right of access to health care, because without this the right to autonomy is meaningless with respect to ensuring that one can achieve this aim" *(protecting one's life and health, AdE)*.[30] The interdependence between both rights has been confirmed by Leenen: "the right to benefit from social achievements (such as health care) has a corollary acceptance by the individual of responsibilities towards society; social rights are of no use if ensuring them involves the suppression of individual freedom of choice and the violation of privacy".[31] Social rights must therefore be aimed at safeguarding individual rights and individual rights must be considered in relation to the individual's partnership in society.[32] This means that besides the protection against harmful acts of others (refraining), "negative" rights can also necessitate "positive" obligations to society (*e.g.*, safeguarding financial and geographical access to basic

---

27 C.J. Forder Positieve verplichtingen in het kader van het Europees Verdrag tot Bescherming van de Rechten van de Mens en de Fundamentele Vrijheden (Positive commitments as part of the ECHR) *NJCM* Bulletin 1992, Iss. 6: 611. C.J. Forder. Safeguarding human environment, the Court has furthermore accepted similar commitments based on the right of private and family life, article 8 of the Convention (*López Ostra vs. Spain* and *Guerra vs Italy*, *infra* notes 112 and 114.

28 H.R.B.M. Kummeling, S.C. Bijsterveld (eds). Grondrechten en zelfregulering (Constitutional rights and self-regulation). Tjeenk Willink Deventer 1997: 46.

29 R. Lawson. Positieve verplichtingen onder het EVRM: opkomst en ondergang van de "Fair Balance"-test (positive commitments under the ECHR: Genesis and downfall of the "fair balance"-principle. *NJCM* Bulletin 1995, Iss. 5: 558-573, p. 566 and 570-571.

30 Somerville *o.c.*: 74.

31 Leenen *o.c.* 1986: 3.

32 Leenen *l.c.*: 3.

health care services) in order to realise individual rights such as autonomy. Such a perception fades the distinction between "negative" and "positive" obligation. In other words, the classic individual right of self-determination includes positive obligations to enjoy that right, and vice versa. The right to health care may, besides positive commitments, also imply negative obligations. As far as the positive commitments are concerned, it is questionable whether they are directly binding. The so-called self-executing or direct effect of social rights, better known as the concept of *erga omnes* obligations, is a controversial issue in international law. In the *Barcelona Traction* dictum, the International Court restricted its list of examples of obligations *erga omnes* in the field of human rights to three examples only, *viz.* the prohibition of genocide and the protection from slavery and racial discrimination.[33] By confining its dictum to the "basic rights of the human person", it seemed to convey that the clear message that the character *erga omnes* does not apply indiscriminately to all principles and rules protecting human rights.[34]

The Institute of International Law took a different approach, when it adopted a resolution on human rights and non-intervention at its session in Santiago de Compostella in 1989. In it, the Institute put forward the proposition that the very obligation of States to ensure the protection of human rights is an obligation *erga omnes*. Article 1 of the resolution reads as follows: "*Human rights are a direct expression of the dignity of the human person. The obligation of States to ensure their observance derives from the recognition of this dignity as proclaimed in the Charter of the United Nations and in the Universal Declaration of Human Rights. This international obligation, as expressed by the International Court of Justice, is erga omnes; it is incumbent upon every State in relation to the international community as a whole, and every State has the legal interest in the protection of human rights. The obligation further implies a duty of solidarity among all States to ensure as rapidly as possible the effective protection of human rights throughout the world.*" As mentioned earlier, Ragazzi questioned whether all human rights reflect obligations *erga omnes*.[35] Although agreeable as statements of desirable developments in the area of human

---

33 In the *Barcelona Traction* case, the International Court of Justice defined obligations *erga omnes* as "obligations of a State towards the international community as a whole". These obligations "are the concern of all States", accordingly "all States can be held to have a legal interest in their protection". Barcelona Traction, Light and Power Company, Limited (Belgium *v.* Spain), Judgement of 5 February 1970, 1970 ICJ. Rep. 3, at 32, para 33 quoted in: W.J.M. van Genugten, Mensenrechten in ontwikking: het "goede doel" voorbij. (Human rights in development) Inaugural lecture, Catholic University of Nijmegen, the Netherlands 1992: 19.

34 M. Ragazzi. The Concept of International Obligations *Erga Omnes*. Clarandon Press, Oxford, 1997: 140.

35 *Ragazzi o.c.: 140.*

rights, the International Court, by restricting its reference to basic human rights and listing a few specific examples, seems to have implicitly rejected this conclusion. While certain effects deriving from the concept of obligations *erga omnes* (such as its influence on the scope of the exception of domestic jurisdiction) may strengthen the protection of human rights generally, the fact remains that each obligation should be assessed on its own merits, with a view to ascertaining whether or not it is an obligation *erga omnes*.[36] Candidates protecting human rights other than those listed by the International Court in its dictum include positive obligations *erga omnes* (respect, prevent and ensure). In this respect health care and environmental obligations *erga omnes* have emerged. Since the concept *erga omnes* is closely related to the basic values of the international community, such basic values must be defined in international documents, explicitly or implicitly. Such constructive standards have been codified, *inter alia*, in various ILO Conventions and more recently the General Comment on Health.[37] Notably, the General Comment on Health specifies various States parties' obligations, which are of immediate effect. States parties have immediate obligations in relation to the right to health, such as the obligation to take steps (article 2, section 1) towards the full realisation of article 2, and to guarantee that the right will be exercised without discrimination of any kind (article 2, section 2 of the Covenant).[38] Conform the typology, those mentioned have been specified in terms of obligations to respect, to protect and to fulfil, incorporating an obligation to promote and to ensure. In particular, States parties are under the obligation to *respect* the right to health by, *inter alia*, refraining from denying or limiting equal access for all persons, [...], to preventive, curative and palliative health services. Furthermore, obligations to respect include a State's obligation to refrain from prohibiting or impeding traditional preventive care, healing practises and medicines, from marketing unsafe drugs and from applying coercive medical treatments, unless on an exceptional basis for the treatment of mental illness or the prevention and control of communicable diseases.[39] According to the Committee, obligations to *protect* include, *inter alia*, the duties of States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; to ensure that privatisation of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality

---

36 Ragazzi *o.c.*: 145.

37 General Comment no. 14 (Twenty-second session, May 2000). The right to the highest attainable standard of health (art. 12 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/2000/4.

38 General Comment no. 14, *o.c.*: para 30.

39 General Comment no. 14, *o.c.*: para 34.

of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties; and to ensure that medical practitioners and other health professionals meet appropriate standards of education, skill and ethical codes of conduct.[40] Whereas, the obligation to *fulfil* requires, States parties, *inter alia*, to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health. States must ensure provision of health care, including immunization programmes against the major infectious diseases, and ensure equal access for all to the underlying determinants of health, such as nutritiously safe food and potable drinking water, basic sanitation and adequate housing and living conditions.[41] Both the obligation to promote and to ensure differs in legal consequences, and thus in binding character to national governments.[42] The margin of discretion enables governments to enjoy a certain freedom in selecting and implementing necessary policy measures.[43] However, universal minimum standards related to the content of these measures put this freedom into perspective. As far as the obligation to ensure is concerned, depriving a significant number of individuals of, for instance, essential basic health care facilities, constitutes *prima facie* a violation of the right to health care and may have immediate effect.[44] The Committee confirms this point of view, referring to General Comment number 3, that States parties have "a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential

---

40 General Comment no. 14, *o.c.*: para 35.

41 General Comment no. 14, *o.c.*: para 36. This typology largely corresponds with the matrix considered by Toebes, who developed a matrix with various concrete obligations resulting from the right to health. B.C.A. Toebes. The Right to Health as a Human Right in International Law. Intersentia Hart Antwerpen 1999: 314-315.

42 A.P. den Exter, H.E.G.M. Hermans. International developments concerning the right to health care in the context of the ICESCR in: Health, Migration and Return. A handbook for a multidisciplinary approach. P.J. van Krieken (ed.) T.M.C. Asser Press The Hague 2001: 37.

43 The obligation to ensure basic primary care does not necessarily imply that the government itself is *actually* responsible for the provision of health care services. Non-governmental public institutions are frequently involved in providing such services and sometimes even more appropriate for this task. However, this should not relieve government from its obligation to guarantee a minimum of care in case of deficiencies of the market.

44 Van Genugten *o.c.*: 19. For instance, irregular migrants (including rejectees) in need of health protection and medical treatment. The situation is even more complicated in respect of diseases, which require permanent treatment such as haemodialysis or medication for AIDS. The aliens concerned, however, may consider a return to their countries of origin to be inhuman and incompatible with their right to life, if they cannot receive such treatment at home.

primary health care.[45] States parties cannot justify their non-compliance with the core obligations set out, which are non-derogable.[46]

Whereas new theoretical understanding concerning the Covenant's right to health confirm the direct effect, notably the obligations to respect and to ensure, the justiciability of such a right at national level, i.e. the susceptibility of judicial adjudication, remains problematic. A survey of case law in a variety of countries revealed that courts are generally reluctant to found their decisions on a right to health, apart from a specific health service based on the right to health or in case which this right is considered to protect individuals against certain threats.[47] Such rights were notably held justiciable when implemented in national law. The justiciability of the Covenant's right to health appeared disappointing and depends upon the willingness of courts to apply that right.[48]

2.3 Patient autonomy

Apart from the right to health care, the second principle underlying health care law is respect for (patient) autonomy. The affirmation of patient

---

45 General Comment no. 14, *o.c.*: para 43. Read in conjunction with, for instance, the Alma-Ata Declaration provides compelling guidance on the core obligations arising from article 12. Accordingly, in the Committee's view, these core obligations include at least the following obligations: (a) to ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; (b) to ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone; (c) to ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water; (d) to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs; (e) to ensure equitable distribution of all health facilities, goods and services, and (f) to adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups. According to the Committee, the following obligations are of comparable priority, *viz.* the obligation: (a) to ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (b) to provide immunization against the major infectious diseases occurring in the community; (c) to take measures to prevent, treat and control epidemic and endemic diseases; (d) to provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them, and (e) to provide appropriate training for health personnel, including education on health and human rights. General Comment no. 14, *o.c.*: para 44.

46 General Comment no. 14, *o.c.*: para 47.

47 Toebes *o.c.*: 229, 349.

48 In the Netherlands (monist system), only on two occasions the courts implicitly considered article 12 ICESCR to be justiciable, while evading the question of direct effect. Toebes *o.c.*: 230.

autonomy as pivotal value of health care law can be found in numerous legal documents, both national and international. Besides these two principles, it can be argued whether or not other seminal values underlie this field of law, including general human rights such as the right to life or its corollaries, the right to physical integrity and the right to dignity. The vast majority of considerations on human rights affirm the cardinal nature of the right to life, and its pre-eminent position to other fundamental rights of the individual.[49]

---

[49] Molinari *o.c.*: 42. The right to life is generally considered as an inalienable, inviolable human right. In Greek and Roman antiquity, however, not all human life was regarded as inviolable and worth of protection. Slaves and "barbarians" did not have a full right to life. Spartan law required that deformed infants were put to death. Human life's worth depended on its social utility. Plato, for instance, advocates infanticide by dumping born children in an inaccessible and unknown place. Plato Politeia V 9. The Stoic philosopher Seneca writes unapologetically: "unnatural progeny we destroy; we drown even children who at birth are weakly and abnormal". Seneca Ad Lucilius, de Ira quoted by J.W. Basore in: De Ira (transl.). J.E. Page (ed.) Heinemann London 1961, vol I: 409. In a well-known passage, Aristotle supports abortion if parents have more children than they could feed. Aristotle Politics VII Book 16 1335b19. The Stoics, too, who were indifferent to pain permitted self-destruction in circumstances of great pain or disease. For them it was considered as an essential part of human freedom that we continue here by our own consent, quoted by: G. Williams. The sanctity of life and the Criminal Law. Faber and Faber London, 1958:227. The social evaluation of life which leaves no room for the recognition of the inalienable right to life of human beings and the interpretation of life that it produces pleasure in Greek antiquity, indicate that the statement concerning the absolute inviolability and inalienability of human life was an illusion in this society. S.N. Okechukwu. The Right to Life and the Right to Live. Ethics of International Solidarity. Peter Lang, Frankfurt am Main 1990: 184.

In modern international law, the right to life, and safeguarding this supreme right is considered an essential condition for enjoying a range of other individual and social rights. The right to life as a modern concept goes far beyond the traditional view of protection against (arbitrary) killing. Such a restricted view is no longer valid as will be explained by the interpretation of international human rights documents. Drafting the International Covenant on Civil and Political Rights (1954), the Human Rights Committee already interpreted the right to life as imposing States adopting positive measures, *inter alia*, to reduce infant mortality and to increase life expectancy, especially measures to eliminate malnutrition and epidemics. General Comment no. 6. The right to life (Article 6) 30 July 1982 sixteenth session, no. 5. Similar interpretations were heard by the European Commission on Human Rights. Consequently, the right to life has two dimension, *viz.* abstaining from arbitrary killing and protection against life threatening situations or diseases. Intentionally deprivation of the right to life or failure to take such measures could mean that governments can be held accountable. That responsibility emanates from the fundamental nature of the right to life as a norm of *ius cogens* in international law B.G. Ramcharan. The Right to Life in International Law. International Studies in Human Rights. Dordrecht Martinus Nijhoff Publishers 1985: 10. Similarly, the International Court of Justice recognized the right to life as a right *erga omnes*, i.e. legal obligations of the States to the world community (*vis-à-vis* duties owed to states and foreign nationals, see the Barcelona Tractation case, *supra* note 33, which refers to the example of the protection from slavery, and racial discrimination which are by their nature obligations *erga omnes*. The prohibition of genocide, an illustration of the right to life, can also be considered as a right *erga omnes*.). Despite it is recognized in both customary law and conventions, and despite its *erga omnes* nature, the right to life may be subject to exceptions

Nonetheless, these values are not unique to the field of health care law. As mentioned, they constitute basic values of human rights law, including health care rights. Consequently, they show a certain overlap with specific health care values such as the right to health care and patient autonomy. Apart from overlap, both principles may also conflict with each other, in cases such as euthanasia. Within the framework of this research, despite its relevance, the right to life is not considered as a unique principle of health care law.

Autonomy: Historical background

The central notion that underlies the concept of autonomy is commonly indicated by the etymology of the term, *viz*, *autos* (self) and *nomos* (rule, governance or law). The term was first applied to the Greek city state. A city had *autonomia* when citizens made their own laws, as opposed to being under the control of some conquering power.[50] Such a perception of autonomy refers to independent actions or decisions without external

(non arbitrary and set by law). In the international community, only grave violations of the right to life (e.g. mass executions, apartheid) have been recognized as contrary to ius cogens.

In the health care setting, specific problems related to the right to life notably concern issues at the end of life (euthanasia and assisted suicide). Several legal scholars interpret the right to life as a "negative" right against the state and not against himself. D.J. Harris, M. O'Boyle, C. Warwick. Law of the European Convention on Human Rights. Buttersworths 1995: 38. Consequently, the right to life is a fundamental human right that equally implies an autonomous right to dispose of his life. L. Hamann quoted by G. Roedecke. Gibt es ein Recht auf den Tod? In: A. Eser (ed.) Suizid und Euthanasie als human- und sozialwissenschaftliches Problem. Stuttgart Enke Verlag 1976: 337.

Such an interpretation, however, overemphasizes the individual autonomy principle. Since international treaties and national Constitutions explicitly recognize the right to life rather than the right not to life, such a liberal interpretation of a fundamental right is not likely and should be constituted in positive law. Instead, the Parliamentary Assembly of the Council of Europe recently adopted a recommendation which upholded the prohibition against intentionally taking of life of terminally ill or dying persons, while "recognizing that a terminally ill or dying person's wish to die does not in itself constitutes any legal claim to die at the hand of another persons" (Parliamentary Assembly Recommendation 1418 (1999) on the Protection of the human rights and dignity of the terminally ill and the dying). In the "explanatory memorandum" the reporter Gatterer explains that "dying is a phase of life. The Council of Europe's Social, Health and Family Affairs Committee, reporter E. Gatterer. Doc. 8421, 21 May 1999 no. 53. Thus the right to die in dignity corresponds with the right to life in dignity" (The principle of unconditional protection of dignity is also reflected in the preamble of the Biomedicine Convention: "convinced of the need to respect the human being both as an individual and as a member of the human species and recognizing the importance of ensuring the dignity of the human being"). Member States thereby acknowledge a right to die in dignity. Furthermore, a terminally ill or dying person has the right to self-determination as of the course of the process of dying, he or she, however, has no right to be killed (Explanatory memorandum *o.c.* no. 54). The Convention's legal system therefore prohibits the killing of a human being even if the killing is wished for by the individual.

50 G. Dworkin. The theory and practice of autonomy. Cambridge University Press 1991: 12-13.

interference; when they are self determined. Liberty or freedoms is however not equivalent to autonomy[51] but may be a necessary condition for individuals to develop their own aims and interests. In order to clarify the difference, Dworkin refers to an example from John Locke.[52]

"*Consider a person who is put into a prison cell and told that all the doors are locked. The guards go through the motion of locking the doors but in fact one of the locks is defective and the prisoner could simply open the door and leave the cell. Because he is not aware of this he, quite reasonably, remains in his cell.*"

The prisoner is, in fact, free to leave the cell. His liberty has not, although he does not know this, been limited. His autonomy has been limited. His view of the alternatives open to him has been manipulated by the guards in such a fashion that he will not choose to leave. This example shows that self determination can be limited without limited liberty. Dworkin characterised autonomy as the capacity of a person critically to reflect upon, and then attempt to accept or change, his or her preferences, desires, values or ideals.[53] Thus autonomy is not simply a reflective capacity but also includes some ability to alter one's preferences and to make them effective in action.[54]

Generally, however, autonomy and self-determination can be considered as exchangeable notions. The underlying notion of individual self-determination, reflected by concepts such as respect for the human dignity and the integrity of the human body, functions as the cornerstone in international human rights law. The notion of autonomy plays a central role in the current legal doctrine. After the Nuremberg doctors' trails (1946-47), the genocide in the concentration camps and the inhuman and harmful experiments with prisoners made the world clear that human rights, including individual autonomy needed adequate legal protection. Corollary, international treaties and conventions have functioned as an important impetus to provide individual self-determination with a constitutional or specific national legal basis.[55] Although accepted as a

---

51 The Oxford Dictionary (1991) defines autonomy as "freedom of the will", equivalent to self-determination: the free determination of one's own actions (Webster's Dictionary, 1992).

52 Dworkin *o.c.*: 105.

53 Dworkin *o.c.*: 20.

54 Dworkin *o.c.*: 108.

55 As mentioned earlier, the right of self-determination has an ancient background in medical ethics. In the Hippocratic oath, the maxim of *primum est non nocere* has been accepted as not to harm the patient. Not harming the patient, besides physically, can also interpreted as mentally. Thus withholding information to the patient can be considered as a harmful act against the patient and an infringement of his right to self-determination. See also I. Paaso. Current challenges to the principles of medical law and their new interpretation. *Medicine and Law* 1995, Iss. 7-8: 622-3. After World War I, the concept of self-determination was

fundamental human right, autonomy is not unlimited. The basis for infringements to this right can be found in the right to life and the right to self-determination of other persons and the public interest. Restrictions to the right of self-determination can often be justified in case of threatening harm to others and in the event of a common threat to the community (*e.g.*, "public health"). However, such restrictions should answer to principles such as proportionality and subsidiarity. Generally, such types of limitations need to be determined by law.

Self-determination in the health care setting

Several developments within the health care sector such as increasing complexity, the fact that medical practise has become more hazardous and in many cases more impersonal and inhumane, often involving bureaucracy, and the progress made in medical and health science and technology have all placed new emphasis on the importance of recognising the individual's right to self-determination and often on the need to reformulate guarantees of other rights of patients.[56] Previously, judicial rulings concerning health care already recognised the interest of the right of self-determination as a human right. This was long before the endorsement of any multilateral agreement. In 1914, the distinguished American judge, Benjamin Cardozo, expressed the legal and moral right of a patient as follows:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault [...]"[57]

Developed from a moral to an accepted legal inalienable right, various domestic legal orders explicitly or implicitly protect such a principle.[58,59]

---

primarily aimed at collective self-determination of nations. Within the context of this research, the right to self-determination refers to self-determination of the individual.

56 WHO 1995 *o.c.*: 32.

57 *Schloendorff v. Society of New York Hospital* (1914) 105 N.E. 92 at 93; quoted by A. Grubb in: Choices and Decisions in Health Care by A. Grubb, J. Wiley Chichester 1993: 37.

58 *Cf. e.g.*, in Germany the citizen's right of self-determination is explicitly protected by the Constitution (Article 2(1) Grundgesetz), Hungary *mutatis mutandis*. The Swedish Health and Medical Care Act of 1983, states that good health – and medical care should be based on, *inter alia*, respect for patient's self-determination. The U.S. Constitution does not explicitly express the right to self-determination, instead the "privacy-right has been the guiding principle for assessing the right to self-determination.

59 Most recently, the European Commission Biomed2 programme supported a research on patient autonomy, privacy and informed consent, aimed to evaluate the realization of these notions in five European countries. This study affirmed the legal (mostly constitutional) basis of patient autonomy in these countries. More problematic, however, appeared the realization

Consequently, medical procedures generally require the patient's consent. Moreover, the right of self-determination created a new category of rights in the health care setting, the so-called patients' rights. Derived from the ancient autonomy principle as mentioned in the Greek etymology, in the contemporary legal doctrine patients' rights are generally considered as part and parcel of human rights.[60] Similar as other individual rights and freedoms, patients' rights are aimed at protecting the individual sphere and individual liberty. This new category of rights includes, *inter alia*, informed consent, confidentiality, access to (medical) records. In its turn, these rights generated several new rights such as disclosure, correction and removal of data recorded by different kind of information systems, and the right of a second opinion and not to be informed.[61] Such a trend of developing and modernising patients' rights has been observed all over Europe, notably in Central and Eastern Europe.[62]

3 FUNCTIONS OF HEALTH CARE LAW

In order to understand the basic principles of health care law, the previous section explored its *leitmotives* and recent developments concerning the substance of these values. This understanding is of relevance to the interpretation or application of positive law reflecting these principles, notably in case of omissions in legislation. Statutory law is part and parcel of the conceptual framework of health care law and can be classified in terms of modalities or functions of law. Traditionally, jurisprudence recognises the normative and instrumental functions of law (Chapter two). Hereafter, it will appear that legal theorists have specified these functions relevant to health care law. Defined as "law-jobs", these functions provide the legislature an analytical tool to initiate, direct, monitor and modify the legislative activity in health care. For a correct understanding of these functions, a general introduction briefly describes the historical events that underlie legal intervention in health care.

---

of autonomy in practice. H. Leino-Kilpi et al. Patient's autonomy, Privacy and Informed consent. IOS Press Amsterdam 2000: 136.

60 For instance: Leenen *o.c.*1993: 1; Annas *o.c.*: 3. Roscam Abbing *o.c.*: 1.

61 Leenen *o.c* 1993: 28-29, 60-61, 81-82.

62 In numerous CEE-countries newly drafted legislation introduced the concept of patients' rights, *cf. e.g.*, the patients' rights chapter in the Hungarian Health Care Act (Act No. CLIV, 1997), the Polish Act on Mental Health (Dz.U.1994 No. 111 Item 535), the Latvian Act on Medical Treatment, Part IV on the Right of Patients (1997), the Croatian Health Care Act (1997) and the Lithuanian Act on Patients' Rights and Patients' Injuries Compensation (No. I-1562, October 1996, as amended 1998).

3.1 Historical backgrounds and its legal setting

Historical backgrounds

In ancient society concern over individual health was a patrician preoccupation, a cult of the educated and leisured.[63] From that time, patricians' charity began to be concerned with the health of the population. This was exploited further by Christianity throughout the late ancient and early medieval world. Christian charity concerned itself with the health of the non-elite strata, which expanded the perception of society by the powerful.[64] Collective concerns about the health of populations shifted from providing a salubrious environment for patrician comfort to the provision of institutional medical care to the population.[65]

In medieval Europe, economic relations began to reconfigure the feudalistic structures into trading societies that encouraged the growth of large towns. It is during that period that the preoccupation with health raised in importance, notably the focus on dangerous and infectious diseases. Notably the unhealthy hygienic circumstances during the Middle Ages function as a landmark in what is called the early public health law history. Epidemic diseases such as leprosy, plague and syphilis were already the object of Christian charity but now became the subject of intervention by (national) authorities to protect the health of the society. Municipal authorities were concerned with preventive measures and regulations against contagious diseases and municipal environmental sanitation. It included some limited control of the disposal of human and other wastes, concern for water purity and the hygiene for housing. More elaborated (plague) regulations established so-called "health boards", originally in Venice but later also in the rest of Europe. These health boards were under the control of political authorities and functioned partly as information offices concerning contagious diseases. Later on, these boards also functioned as city immigration authorities that demanded health licences from visitors and their merchandise or goods.[66] During the Ages of Enlightenment and Industrialization, due to scientific developments, health legislation in Western Europe focused on sanitation and immunization (e.g., health education, demographic statistics and policies of isolation and

---

63 O. Temkin, C.L. Temkin (eds). Ancient Medicine. Baltimore, Johns Hopkins University Press 1967.

64 D. Porter. Health, Civilization and the State. A history of public health from ancient to modern times. Routledge London 1999: 11.

65 T.S. Miller. The Birth of the hospital in the Byzantine Empire. Baltimore Johns Hopkins University Press 1985.

66 Porter *o.c.*: 38.

treatment).[67] Moreover, enlightened conceptions arose on State institutionalised administrative health authorities to regulate the practise of the medical professions and the sale of pharmaceuticals.

Pre-eminently in the twentieth century, economic growth and urbanisation encouraged national governments to become increasingly involved in (public) health policy. Rationalisation concepts imposed national governments to intensify their role in the field of what has been called as "public health". In most part of the world, public health encompasses concerns for physical and mental health of the population, including the control over food and addictive substances such as tobacco, alcohol and narcotics, and finally, a broad range of environmental concerns such as the control of water, land and air pollution.[68] But since the rise of the classic welfare state, national authorities became gradually involved in health care. Notably after the Second World War, health care systems in Europe were based on the principle of solidarity that required legislative intervention. The predominant systems were the compulsory social insurance ("Bismarckian") model and the national health service ("Beveridge") model.[69] The leading regulatory role for national authorities in this field

---

[67] In eighteenth century Germany, the "medizinische Polizei" was established, functioning as the predecessor of the public health inspectorate. The tasks of this "medical police" encompassed the full range of public safety, including sanitation and hygiene and information. Major cities in Europe and the USA introduced such a medical police with extensive powers. A. de Swaan. Medical Police, Public Works and Urban Health in: In Care of the State. Health Care, Education and Welfare in Europe and the USA in the Modern Era. A. de Swaan (ed.) Polity Press Cambridge 1988: 126.

[68] F.P. Grad. Public Health Law: It's Form, Function, Future, and Ethical Parameters in: WHO 1998 *supra* note 2: 20.

[69] The first model is named after the German Chancellor von Bismarck who could be remembered as the founder of the workers' social insurance. In the 1880s, parliament voted the acts on health insurance, accident insurance and invalidity insurance. By law, a variety of public funds were established concerned with the administration and implementation of social insurance schemes. The legal conditions stipulated by law on medical care and sick pay, employer's liability for accidents, and invalidity at work, recognized the involvement of national authorities in social security. In the years following, the social security system extended moderately including new risks such as pensions, unemployment family charges. This example with far-reaching legislation was followed by more European countries in the next half-century.

In contrast, Britain introduced a system based on universalism in benefits and services, named after Sir William Beveridge. The Beveridge or National Health Service system was introduced after the great recession in the 1930's to provide all concerned with a minimum means of existence. The NHS system provides health care to all members of society, without regard to income or employment status. The state is the main payer and the central government sets the NHS budget. The state also delivers health care through its ownership and administration of the hospital sector. W. Beveridge. Social Insurance and allied services London, H.M.S.O. 1942.

The third type, the Marxist system or Semashko system was introduced during the Russian revolution in Central European countries. The Marxist model is not opposed to the Bismarck

covered, *inter alia*, the organisation, delivery and financing of health care services. Regulatory intervention became even more manifest when the latest financial crises in the seventies and eighties called for drastic "cost containment" measures in the largely publicly funded sector.[70] In order to safeguard human rights in health care and simultaneously initiate the necessary reforms, legislative intervention became inevitable and more complex.

Up to the first half of the twentieth century, regulatory measures were predominantly based on national (public health) law. But the increased mobility of persons and pandemic character of new health scourges necessitated, more and more, international cooperation and co-ordination with regard to health. Newly established organisations such as the World Health Organization and the International Labour Organization (ILO) became important international gremia dealing with global (occupational) health problems. Consequently, after World War Two, health protective measures have undergone considerable modifications and were extended by international and regional prevention and promotion programmes, for instance the Declaration of Alma Ata,[71] "Health for All by the Year 2000"[72] and the European Union action programmes.[73] These initiatives can be characterised by their protective, preventive and promotional nature of measures primarily related to public health. Such programmes called governments to formulate national policies and plans of actions. Secondly, to co-ordinate their actions at supra-national level.

As regards to medical ethics and human rights, the post-war Doctors' Trails at Nuremberg (1946-7) initiated a profound reorientation, particularly with concern to medical research. Established as a uniform legal basis for the prosecution of (medical) war criminals, its judgements concluded a ten-point code, known as the Nuremberg Code.[74] Above all, the Code

---

model. The socialist ideal continued to a large defree in the Bismarck system, but with the difference that they abandoned the insurance concept. The workers are entitled to benefits because they are workers, not because of the paid contributions.

70 E. Mossialos, J. Le Grand (eds). Health Care and Cost Containment in the European Union. Ashgate, Aldershot 1999: 1.

71 Adopted by the International Conference on Primary Health Care. Alma Ata, september 1978 World Health Organization.

72 World Health Organization, Geneva, 1985, which set a target date at the end of the second millennium for the attainment of several ambitious objectives such as a significant reduction of infant mortality, control of fatal diseases and increase of life expectancy for older persons.

73 *E.g.*, Europe against AIDS/Cancer action programmes OJ No. L 160, p. 52, 28 June 1988; OJ No. L 95, p.16, 16 April 1996.

74 The Nuremberg Code, containing standards to which physicians must conform when carrying out experiments on human subjects (1947). Inspired by the Code, besides the earlier mentioned declarations and convention, several statements and recommendations were made by (non-) governmental organisations (*e.g.*, the World Medical Assembly: guiding physicians in biomedical research involving human subjects, 1964, as amended).

functioned as a leading document of ethical principles in medicine. Since its establishment, the Code has been further elaborated in international declarations and conventions formulating States responsibilities concerning the dignity, integrity and self-determination of patients in health care.

Moreover, new technological developments in the health care sector have also raised numerous ethical and legal questions concerning life and death, diagnostic and treatment methods, *et cetera.* Their infringing character on recently adopted human rights imposed more and more legislative intervention.

The instrumental and normative perspective in health care

From the historical description it became clear that the scope and therefore the functions of health care law have changed, namely a shift from merely limited public health tasks towards the protection of human rights in health care and regulating the structure and financing of the health care system.

From a legal theoretical perspective, at least in the western democracies, two traditional functions of the law can be discerned, *viz*, the instrumental and guarantee or safeguarding function of law (chapter 2.6). Since health care law has been characterised as a subdiscipline of law, such a classification of functions is also applicable to this field of law. More specifically, the functions of health care law can been deduced from the leading notions of health care law: the right to health care and patient autonomy, and the subsequent normative commitments as defined in the various treaties and declarations. The determinant rights and obligations can be classified according to the elementary functions of health care law.

For instance, the right of access to necessary health care creates an obligation to society, respectively the state to enable citizens in need to have equal access to and receive adequate health care. This assumption implies the development of a "basic" health care system, accessible for the entire community. Basic health care services include public health (*e.g.*, vaccination and infectious diseases programmes, environmental hygiene), emergency care, primary care, categories of pharmaceuticals, *et cetera.* Moreover, safeguarding equal access includes a payment system that enables any person without adequate resources and unable to secure such resources, is to be granted to receive the necessary care. In this respect, health care law has an allocation function in order to guarantee a geographically and financially accessible system of "the state of the art" health care facilities. Access to health care also implies a right to receive care of proper quality. As a consequence, this give rise to regulative mechanisms concerning the quality of health manpower, health services, devices, *et cetera.* Such an instrumental perspective emphasises the functional, primarily allocative, directive aspect and facilitates elements of health care law.

On the other hand, from the individual human rights perspective, patient autonomy initiated a range of newly derived patients' rights, such as the right to receive information, consent, confidentiality, and various emanated rights. In order to guarantee the fundamental character of these human rights, constitutional and/or legislative provisions are indispensable. Through legislation claims and rights can be legitimised and ensured. In this respect, health care law reflects the normative or axiological dimension. Inherent to this assumption is the precondition of an objective motivation to legitimise possible infringements.

Conclusively, access to health care as well as patient autonomy symbolise the functional and normative dimension of health care law. Referring to the complementarity and interdependency of the health care legal principles, the functions of health care law are also interrelated. For instance, the implementation of these functions by means of legislation requires a balanced consideration of both the individual as the social dimension of health care law; the recognition of fundamental patients' rights by law is meaningless without enabling patients to enjoy the social aspects of these rights.[75] Hence, the functions of health care law are correlated.

Both the functions of health care law, as well as the correlation between these functions have been confirmed by several legal scholars. Roemer, for instance, structured the functions of health care law according to the subjects of intervention (discussed hereafter). It is questionable whether such an approach is generally accepted among legal theorists. It will appear from the following analysis that academic lawyers such as Montgomery and Furrow subscribe to such a classification of the functions of health care law. Others, such as Longley, applied Karl Llewellyn's general theory on "law-jobs" in order to justify governmental intervention in health care. By classifying the discerned functions, an analytical framework of health care law may provide a theoretically valuable instrument to substantiate health care legislation.

3.2 Roemer's functions of health care law

In the 1980s, many Western countries were experimenting with reforming their health care system and structure. A main cause was the first oil-crisis, which had considerable effects on the economies of most Western countries, also in the sphere of health care. In several countries, one direct consequence was that the available health care budget experienced considerable constraints, intensified by increased costs of high-quality

[75] *E.g.*, what is the meaning of the right to access to medical record, in case of illiterate persons (right to receive education)?

medical technologies and demographic developments such as the ageing population. Due to these circumstances most countries were forced to reshape their health care systems.

At the inter-governmental level, the World Health Organization (WHO) developed significant efforts to support such reform initiatives. One of those initiatives comes from a legal study of health care law and policy by Ruth Roemer. In 1980, she made a valuable contribution to the restructuring and rationalisng of health care law-making by discerning various function of health care law.[76] These functions were structured according to various subjects of intervention. Inherent to the nature of these subjects, and the increased complexity of health care, is intervention by the legislature. Traditionally focused on legitimising government intervention when protecting the population against epidemic diseases and creating guarantees against unlawful infringements of fundamental individual rights, health care law nowadays encompasses a broad scope of activities, regulating, facilitating and allocating different types of health care services. Roemer illuminated the role of health care law in terms of functions the law performs in protecting the health of individuals and community. These functions operate as a basis to develop legislation, to provide for a framework and to structure health programmes, and regulations under the law that make explicit the details of the programmes.[77] In the approximate sequence of their historical development, these functions are as follows, health care law:[78]

- prohibits conduct that is injurious to the health of individuals and the community (protection and prevention);
- authorises programmes and services that promote the health of individuals and the community (promotion of health, including promoting access to care);
- regulates the production of resources for health services (training personnel and health facilities, as well as influencing the planning of facilities: rational planning and allocation of resources);
- provides for social financing of health care (mobilisation of financial resources to provide for – needed – health care);
- exercises surveillance over the quality of health care (assure a minimum standard for the quality of care).

---

76 R. Roemer. Law and Health Policy in: R. Roemer and G. MacKray (eds). Legal Aspects of Health Policy. Issues and Trends, Greenwood Press Westport, 1980; R. Roemer. Health Legislation as a Tool for Public Health and Health Policy in: Health Legislation at the Dawn of the XXIst Century, *supra* note 2.

77 Roemer *o.c.*: 437.

78 Roemer *o.c.*: 439.

Although focused on the American setting, these functions of health care law reflect a universal concept since they encompass the underlying notions of health care law (the right to health care and patient autonomy). For instance, the interpretation as given by the Committee of Economic, Social and Cultural Rights concerning the right to health care (obligation to respect, protect, fulfil) largely corresponds to the discerned functions by Roemer.

Critics on the typology concern the vacuum of individual rights in health care. Roemer does not discern this normative function of the law as an autonomous category. Although mentioned as part of the quality of care-function, this does not include the entire range of patients' rights. A possible explanation could be the subordinated role of axiological values to the functional approach of health care law (1980s). In the contemporary doctrine, safeguarding patients' rights has been considered as one of the most important objectives of health care law. This has been confirmed by a range of multilateral and regional declaration, principles, treaties and conventions that have endorsed the rights of patients. Hence, a separate category to emphasise the relevance of this function is therefore justified.[79]

3.3 World Health Organization: Strengthening ministries of health

The described functions as discerned by Roemer, have been further elaborated and extended over the years. In 1988, a WHO study referred to the described reasoning of functions of health care law translated into functions of health care legislation.[80] Although described as possible functions of health care legislation, since legislation can be seen as the species of the genus, the concept of law, this classification reflects the role of the law in the health care sector, *viz*, to protect, prevent, promote, allocate, provide, and guarantee. The following functions have been taken into account:[81]

- to prohibit conduct, and ban or regulate the use of products injurious to health through, for example, control of environmental pollution and of the use of toxic chemicals;
- to authorise programmes and services that promote the health of individuals and the community, such as family-planning services or immunisation programmes;

---

[79] In more recent publications Roemer supports the notion of a separate function, *viz*, concerning ethical issues in health care. Roemer *o.c. supra* note 2: 92.

[80] World Health Organization. Strengthening Ministries of Health for Primary Health Care. Technical Report Series No. 766 WHO. Geneva 1988.

[81] WHO *o.c.*: 92.

- to regulate the production of resources and the production, deployment, and the management of the health manpower required for the delivery of health care to individuals and of the environmental health services, as by professional licensing laws or the establishment of health facilities;
- to provide the social financing of health care through, for example, social security or grand in aid programmes, and
- to exercise surveillance over the quality of health care by, for example hospital licensing or peer review.

Due to the increased interests in human rights in health care, the report included an important additional function, namely

- to ensure the rights of individuals, as by laying down requirements for informed consent to surgical or other procedures.

This report contains the authoritative views of an international committee of experts consulted by the WHO. Within their capacities, the committee gave the WHO its scientific advice concerning, *inter alia*, the legislative role of the Ministry of Health. As such, the report confirmed the earlier described functions of health care law by Roemer. Since these functions have been incorporated by the WHO's Health for All by the Year 2000-Strategy (protection, prevention, promotion, equal access, *et cetera*), it can be concluded that the WHO adheres this concept about the role of law in health care.

Within the spirit of the present time, the ambition towards the presumed functions of health care law cannot be denied. The notion of law (including law-making) as an omnipotent and omnipresent regulative mechanism may be rather obsolete, as notified in chapter two. Nonetheless, the essence of such a concept will be still useful, particularly its implications towards (re)defining and realising health legislation (policy). Apart from providing a legal basis, these functions do not necessarily imply an exclusive legislative elaboration, more or less suggested by Roemer. Instead, certain categories, such as quality of care or health manpower assessment, may be (further) regulated by self-regulative professional standards, guidelines or protocols. Within a legal infrastructure, and in view of the available capacities and domestic traditions, these self-imposed standards may function as even more effective mechanisms to achieve the chosen objectives.

3.4 Furrow: Four concerns of health care law

In the recent American literature, Furrow considers the role of health care law and/or quasi legal mechanisms according to four major concerns, *viz.* quality of care, costs of health care, equitable access, and fourth, respect for the person of the patient.[82]

Quality of care seems to be interpreted as the regulative function of the law inspired by the failure of market mechanisms in the health care providers and institutions cluster (licensing and accreditation).[83] Through (quasi) legal mechanisms, the leading notion is to improve both efficiency and quality of care since consumers cannot be certain of receiving health care of adequate quality, for the products of health care are too complex and information about them too costly to obtain. The malpractice system also addresses quality problems by retroactive compensation (in case of receiving care of inadequate quality) and attempting to deter those who would otherwise commit medical errors. Furthermore, varying quality assurance programmes by health care institutions further subscribe to the quality control aspect of health care law.

A second concern of health care law, concerns costs and attempts to maintain a financially affordable health care system. Despite substantial differences in the American health payment system, a common public policy object is cost containment that requires extensive legal intervention to regulate or restore competitive conditions. Nonetheless, within the European context, the legal means to direct and control health care expenditures may quite differ, for example with less emphasis on market competition. Thus, implemented using various public policy mechanisms and legal instruments, a second objective of health care law concerns cost-control.

Guaranteeing equitable access to a basic level of health care is considered as a third concerns of health care law. This has resulted in legal intervention to force health care providers to provide "free" health care, that is care financed by other patients, and in government programmes to pay for health care directly. As costs have increased, new technologies have further tested the meaning and commitment of equal access.[84]

Fourthly, health care law articulates a primary human right, *viz*, respect for the person of the patient. The law has taken on the role of protecting the autonomy of the patient. This concern is reflected in the doctrine of

---

[82] B.R. Furrow, S.H. Johnson, T.S. Jost, R.L. Schwartz. Health Law: Cases, Materials and Problems. West Publishing Co., St. Paul 1991: viii-ix.

[83] Furrow *o.c.*: viii.

[84] Furrow *o.c.*: ix.

informed consent, protection of confidentiality of medical information, *et cetera.*

3.5 Montgomery: Exposition of obligations

From a UK-perspective, Montgomery lists the following sectors in which law has a role, interpreted as responsibilities of the Department of Health: to provide and operate a National Health Services system (including the provision, finance and allocation of health care), to carry out public health, to regulate the health care practise (professional regulation), and to regulate the position of the patient (in terms of specific professional responsibilities).[85] Apart from the typical National Health Service system, Montgomery's categories of health care law largely correspond with the classification of Roemer and the WHO such as monitoring and improving the health status of the community (public health), the regulation of health manpower, services and pharmaceuticals (quality assurance, supervision and control), and safeguarding patients' rights (professional principles and duties). According to the similarities in classification and objectives, it can therefore be assumed that Montgomery subscribes to the functions of law in health care.

3.6 Longley: Llewellyn's theory of law-jobs applied to health care

One of the most comprehensive and rational considerations of the role of law has been advocated by Karl Llewellyn. He argued that in order for any group or institution, regardless of its size, to sustain stability and cohesiveness and thus function effectively, a series of socially necessary tasks have to be performed.[86] Crucially, authority must be established, goals set, conduct regulated, and disputes resolved. Although the theory is vague, open to interpretation, and arguably tautologous, it is a rough and useful instrument for functional analysis, and it is undoubtedly capable of generating some important insights. The law-jobs can be considered as a crude checklist of questions to ask when examining the structure and operation of a society.[87] These fundamental jobs do not indicate the adoption of any *specific* organisational or procedural arrangements, as these will be shaped by the context within which they are to be operating, but they do provide a kind of blueprint for collective activity.[88] It prompts the

---

85 Montgomery *o.c.*: 23, 53, 135, 227 *et seq.*

86 K. Llewellyn, "The Normative, the Legal and the Law-Jobs" (1940) Yale Law Journal 49, quoted by: D. Longley. Health Care Constitutions. Cavendish Publishing 1996: 12.

87 W. Twinning. Karl Llewellyn and the Realistic Movement. Weidenfeld and Nicholson, London 1973: 181.

88 Longley *o.c.*: 12.

question about the function(s) of statutes dealing with health care. Irrespective of the kind of health care system (national health service, health insurance system), Longley distilled four basic intertwined functions of the law or, "law-jobs".[89] With specific reference to the health care field, these qualities are:[90]

- the allocative function concerns the distribution of decision-making authorities. Questions such as who is competent to make choices and decisions, relate to the legitimacy and effectiveness of an organisation. It involves the structural and administrative framework within which the other tasks are carried out. This law-job brings into focus the exercise and control of delegated and discretionary powers and within the health service raises questions of the balance of authority and responsibility for the utilisation of resources between management, clinicians and the public;
- choosing goals and objectives; the setting of priorities and development of policy. Social invasive decisions concerning health care disparities are essentially political choices and need to be legitimised within a legal frame, due to the *rule of law*;
- simultaneously, the law expresses on policy objectives. This refers to the implementation and monitoring of activities to ensure that chosen objectives are achieved. In particular the monitoring aspect is increasingly significant; (side-) effects of policy-decisions can be revised by normative criteria, expressed by law, and,
- conflict regulation by means of dissolving disputes. Besides individual satisfaction, grievance resolution may provide additional information about structural deficiencies of the system, of importance to feedback of the system and an effective channel of accountability.

This brief summary of modalities of health care law outlines the role of law, respectively the legislature in health care law. Hereafter, it will appear that these functions have been formulated in international law, providing universal normative standards relevant to national authorities in the field of health.

---

[89] There are several distillations of Llewellyn's law-jobs theory. Twinning, for instance identified six jobs, *viz.* adjustment of the trouble case: preventive channelling of conduct and expectations; preventive re-channelling of conduct and expectations to adjust to change; arranging for the say and manner of its saying (allocation of authority and procedures for authoritative decision-making); provision or direction and incentive within the group, and the job of Justice Method. Twinning *o.c.*: 175.

[90] Longley *l.c.*: 12.

4 PRINCIPLES OF HEALTH CARE LAW IN INTERNATIONAL LAW

The seminal values underlying the field of health care law have been formulated and further developed in numerous documents. This paragraph identifies the main (legal) documents and attempts to explain the sources of authority of both the right to health care and patient autonomy in international law. Such a *tour d'horizon* completes the "core content" of these principles. Moreover, it identifies the normative commitments imposed to the national legislature. The analysis is focussed on the main multilateral declarations, treaties and conventions that include these rights. Apart from the previous considerations on the basic values, understanding the nature and consequences of these rights in international law is a second important step to formulate a conceptual framework of health care law.

4.1 The right to health care in international treaties

As to the multilateral declarations and agreements to the right to health care, the following have been taken into account:[91]
- the Universal Declaration of Human Rights (1948);
- the International Covenant on Economic, Social and Cultural Right (1966);
- the European Convention on Human Rights and Fundamental Freedoms (1950);
- the Convention on Human Rights and Biomedicine (1997);
- the European Social Charter (1961), and
- the Treaty of the European Community (EC Treaty 1997).

Universal Declaration of Human Rights; the International Covenant on Economic, Social and Cultural Rights

In the post war history, the adoption of the Universal Declaration of Human Rights (UDHR) on 10 december 1948, encompassed nearly the entire scope of what today are recognised as human rights and fundamental freedoms.[92] In the Declaration the general Article 22 has been formulated which can be considered as an "umbrella" article on social rights: *"Everyone, as a member of society, has the right to social security and is entitled to realisation,*

---

91 A.P. den Exter, H.E.G.M. Hermans. Constitutional Rights to Health Care: The consequences of placing limits on the right to health care in several western and eastern European countries. *EJHL* 1998, Iss. 3: 261-290.

92 Adopted and proclaimed by the General Assembly resolution 217 A (III) of 10 december 1948 and reaffirmed by more then 100 countries which participated the World Conference on Human Rights, held in Vienna in 1993. U.N. Doc. A/CONF. 157/23-4 (Part I) 13 October 1993, para 5.

through national effort and international co-operation, and in accordance with the organisation and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the development of his personality". Although the Declaration is without any concomitant legal obligations it has not lost its relevance since the "founding fathers" drafted the common standard of achievement. The principles of the Declaration have been implemented in several conventions and treaties, which together form the international framework for the right to health care. Due to the immediate effect of several treaties and conventions, the legal status of the Declaration has even increased.

Initiated by the Declaration, the United Nations Commission on Human Rights started to draft covenants on human rights, which would be legally binding on the States ratifying them. The General Assembly adopted a resolution, emphasising the interdependence of all categories of human rights, and called upon the Commission to adopt a single convention.[93] Western States succeeded in reversing that decision and in 1951 the General Assembly made a controversial and contested decision that two separate human rights covenants should be prepared, one on civil and political rights and another on economic, social and cultural rights.[94] In Article 25 of the Declaration it is stated that "[e]*veryone has the right to a standard of living adequate for the health*[95] *and well-being of himself and his family, including (...) medical care (...) and the right to security in the event of sickness* (...). A similar reference to health is made in the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966). Article 12 (1) provides for "*the right of everybody to the enjoyment of the highest attainable standard of physical and mental health*" and paragraph 2 conceptualises the measures that should be undertaken by member states in order to achieve

---

93 General Assembly resolution 421 (V) of 4 december 1950.

94 A. Eide, A. Rosas. Economic, Social and Cultural rights: A Universal Challenge in: A. Eide, C. Krause, A. Rosas. Economic, Social and Cultural Rights (eds) Martinus Nijhoff Publishers Dordrecht 1995: 22.

95 Health has been defined as: "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" in: World Health Organization. The Constitution 1948. Some members of the medical profession criticized such a rather philosophical or social description: in stead, they consider health in purely scientific terms and perceive medicine solely as a technological enterprise where time is wasted on dealing with the social causes of ill-health. In their eyes the doctor's role is not the carer, it is that of the "scientific problem-solver and curer". I. Kennedy. The unmasking of Medicine, 1981, especially chs. 1-3, quoted by J.A. Hayes. Health Care as a Natural Right *Medicine and Law* 1992, Iss. 5: 416. Such a strict definition of health is not generally accepted, more common is the health-concept from a social point of view. As a consequence, health care includes all that facilities in order to prevent ill-health, protect, safeguard and to improve a state of health, although not interpreted as an absolute right.

"the full realisation of this right".[96] As a result of divergent views it was formulated in a very general manner.[97] Although such formulations include a certain responsibility to the state with regards to the allocation, finance and provision of health care services, its claim is generally interpreted as a non-enforceable legal entitlement to health care. Therefore, the noble aspirations of universal access to health care must be interpreted within the context of the treaty, which means a basic level of health care, interpreted in accordance with the formulation, ratio and implementation of legal norms and economic capacities of a given society. In fact, the domestic economic capacities and the non-enforceability of these international treaty provisions temper the actual meaning of the right to health care and thus access to health care services.

As mentioned before, the legal status of the right to health care is changing. In a recent article on the legal consequences of the Universal Declaration, Meijers and Nollkaemper conclude to the self-executing effect *sensu stricto* of the Declaration for members of the European Union.[98] The situation is different for non-members. Based on two studies, *viz*, one of the International Law Association (1994) and another published in the Georgia Journal of International and Comparative Law (1996), only *certain* articles including "core rights" have reached the status of international customary law (the right to seek and enjoy asylum, right to education, prohibition against torture, *et cetera*).[99]

Most of the agreements reached between the Community and third party states (twenty-three between 1993 and 1997), refer (in) directly to fundamental human rights as included into the Helsinki Agreement (1975). Possibly the most explicit citation can be found in the Europe agreements based on Article 310 (ex article 238) of the EC Treaty, referring to the *"acquis communautaire"*, including fundamental principles such as a pluralistic democracy based on the *rule of law*, human rights as the conditions to a market economy.[100] According to both authors, the recognition of the binding effect of the Declaration has serious conse-

---

96 For a more extensive description of the genesis of the Declaration's and Conventions' health-provisions, see H.D.C. Roscam Abbing. International organisations in Europe and the right to health care. Kluwer, Deventer 1979.

97 Roscam Abbing *o.c.*: 18.

98 H. Meijers, A Nollkaemper. De universele verklaring van de Rechten van de Mens bevat thans bindend verdragsrecht (Presently, the Universal Declaration includes binding treaty law) *NJB* 1997, Iss. 25: 1113-1115.

99 "Report on the Status of the Universal Declaration of Human Rights in National and International Law, ILA, Rep. Of the 66th Conference 1994: 525-563; *Georgia Journal of International and Comparative Law* Iss. 1/2, 1995/6 (special issue).

100 *E.g.*, the Europe Agreements the Czech Republic (L 360/3, Dec. 19, 1994), Hungary (L 347/2 Dec. 13, 1993), Poland (L 348/2, Dec. 13, 1994).

quences for judicial review.[101] It makes the Declaration subject to universal application, review and interpretation by the European Community. The Declaration includes one of the agreements as mentioned in Article 300 EC (ex article 228) of the treaty, that is part of the law, as assured by the European Court of Justice (Article 220 EC, ex article 164). Thus the right to health care incorporated as international treaty law, and therefore binding on at least the European member states. Nonetheless, a differentiation referring to the typology of obligations (respect, protect, ensure and promote) has to be considered. Thus, despite the binding character of notably protecting and ensuring measures, positive promotional obligations enable governments a "margin of appreciation" in implementing the necessary measures.

The revaluation of social rights was affirmed by the reinforcement of the so-called "Limburg Principles" by the "Maastricht Guidelines on Violations of Economic, Social and Cultural Rights" (1997).[102] These guidelines elaborate the commitments of party states due to the ICESCR. The Committee of Economic, Social and Cultural Rights (as mentioned above, the Committee) confirmed these guidelines in terms of a "General Comment". This Committee observes compliance to the Covenant by party states and has now been in operation for ten years (1987-1997). During this decade, the Committee has developed a compelling interpretation of the states' commitments emanating from the Covenant. Besides its main task of studying party states reports and itself report on them, the Committee has formulated several General Comments that interpret treaty-provisions which are rather generally defined. This interpretation may support party states in understanding the meaning of the ICESCR during its implementation. Two General Comments are of particular importance, *viz*, on the nature of treaty obligations of party states and the highest attainable standard of health.[103] Whereas the main obligation in Article 2 (1) is to *progressively* achieve the full realisation of the recognised rights, the minimum essential levels of each of the rights a country should meet have restricted the inherent policy freedom.[104] The content of these so-called "core obligations" were based on the Alma-Ata declaration (1978) of the World Health Organization. This declaration emphasized the importance

---

101 Meijers and Nollkaemper *o.c.*: 1114.

102 UN Doc. E/CN.4/1987/17, Annex. Intended to function as a basis for elaborating a General Comment on the right to health care, the workshop resulted in several interesting criteria (*e.g.*, indicators such as reduction of stillbirths and infant mortality). The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights. Th.C. van Boven, C. Flinterman, I. Westendorp (eds) Studie- en informatiecentrum Mensenrechten Netherlands Institute of Human Rights Utrecht SIM special Iss. 20, 1998, *HRQ* 1998: 691-705.

103 *Supra* notes 15 and 37.

104 General Comment no. 2, *o.c.*: para 10.

of primary health care and non-discrimination in access to health care. A more extensive reading also includes preventive health care and the promotion of positive environmental and health care circumstances, to be realised by a number of "law-jobs", *i.e.* preventive activities, guaranteeing access to basic health care provisions through a social financing system, positive measures in favour of discriminated categories of persons, and protecting the rights of individual patients.

Besides the "progressive realisation" standard, a second parameter to review States progresses to the Covenant-obligations is the "violation approach", *i.e.*, determining which actions or omissions amount to violations of the Covenant's right to health'. Such violations can occur through the direct action of States or other entities insufficiently regulated by States *(acts of commission)*. But violations of the right to health can also occur through the omission or failure of States to take necessary measures arising from legal obligations (*acts of omission*).[105] Corollary to the violation approach is the possibility for individuals and groups to submit a complaint according to the optional Protocol related to the rights recognised by the Covenant.[106] This relatively new development enables further elucidation of the Covenant obligations to party states emanating from the right to health care. Subsequently, that could be of relevance to national law-making(policy).

European Convention on Human Rights and Fundamental Freedoms (ECHR)
The European Convention does not include provisions on economic and social rights. However, under expanding conceptualisation of the individual right to life, the right to health care can be considered under the rubric "right to life".[107] For instance, in *Tavares v. France* the applicant, whose wife had lost her life in a French hospital as a consequence of serious complications following the delivery of a child, argued that France was in violation of Article 2 of the Convention.[108] Although the Commission rejected that contention it has however repeatingly voiced its earlier standpoint according to which Article 2 *"enjoint à l'Etat non seulement de s'abstenir de donner la mort "intentionnellement" mais aussi de prendre les mesures nécessaires a la protection de la vie."* Further: *"[d]ans le cas d'espèce, il n'est pas contesté que des mesures réglementaires étaient imposées au centre hopitalier de Compiègne, ni*

---

105 General Comment no. 14, *o.c.*: para 48-49. The General Comment subsequently sets out article 12 violations in term of violations of the obligation to respect, protect and fulfil: para 50-52.

106 UN Doc. E/CN.4/1997/105.

107 V.A. Leary, Complaint Procedures and the Right to Health in: The Review, International Commission of Jurists. Economic, Social and Cultural Rights and the Role of Lawyers. Special Issue. december 1995, Iss. 55: 114.

108 *Tavares v. France.* Decision of the Commission. Decision of 12 september 1991.

qu'elles ont été respectées." The implication is clearly that certain regulatory measures aimed at protecting life and concerning the hospital system were inherent in Article 2.[109] However, the Commission, after satisfying itself that this basic requirement was fulfilled by the relevant French regime, declined to go into detail on the functioning of the system in the instance of this particular case. *Tavares* might serve as a reminder that, in allocating resources, it is the Convention's point of view that not only is it important to ensure a fair trial "within a reasonable time" but also that a certain minimum level of health care services be maintained.[110] Moreover, this *rapprochement* of social and socially related rights includes an enhancement of these rights within the framework of the Convention.

In another case *Karara v. Finland*, the right to health care was linked with the prohibition of torture or inhuman and degrading treatment (Article 3). The applicant complained that his deportation to Uganda would result in an irrevocable deterioration of his state of health and subject him to inhuman and degrading treatment. The HIV infected applicant claimed that deportation according to the Finish Deportation Act would interrupt medication and result in an acceleration of his illness. In view of applicant's relatively good medical condition and taking into account the available health facilities in Uganda, the Commission rejected this complaint.[111]

Other individual rights invoked to appeal a right to health care concern the right to private and family life (Article 8) and the right to freedom of expression (Article 10), notably in cases of health protection. This appeal is not that far-fetched given cases such as *López Ostra* case, in which the Court underpinned the violation of privacy due to environmental pollution that caused serious health problems.[112] The applicant complained about a waste treatment plant that emitted fumes, noise and strong smells, which made her family living conditions unbearable and caused serious health problems. She alleged that her right to respect for her home had been infringed due to environmental pollution. The Court analysed this in terms of a positive duty of the State; whether national authorities had taken the measures necessary for protecting the applicant's right to respect for her home and private and family life.[113] Since environmental problems continued after partial shut down of the plant, the Court considered that

---

109 M. Pellonpää. Economic, Social and Cultural Rights in: R.St. J. Macdonald, F. Matscher, H. Petzold (eds). The European System for the Protection of Human Rights. Dordrecht: Martinus Nijhoff Publishers 1993: 865.

110 Pellonpää *o.c.*: 865.

111 *Karara v. Finland.* Decision of the Commission on 29 May 1998. See also: M. de Boer-Buquicchio. Health and the Court in: P.J. van Krieken *o.c.*: 334 *e.s.*

112 *López Ostra v. Spain.* Judgement of the Eur. Court HR on 9 december 1994.

113 *López Ostra*, para 55.

the Spanish State did not succeed in taking adequate steps to secure the applicant's rights under Article 8(1).

Finally, in *Guerra* v. *Italy* there has accordingly been a violation of that provision 8.[114] Here, the applicants also claimed that they had been victims of a violation of Article 8(1). Although the object of Article 8 is essentially that of protecting the individual against arbitrary interference by the public authorities, it does not merely compel the States to abstain from such interference: in addition to this primarily negative undertaking, there may be positive obligations inherent in effective respect for private or family life.[115] Similar as to the *López Ostra* case, the Court only needed to ascertained whether national authorities had taken the necessary steps to ensure effective protection of applicants' right to respect for their private and family life as guaranteed by Article 8.[116] The Court reiterates that severe environmental pollution may affect individual's well-being and prevent them from enjoying their homes in such a way as to adversely affect their private and family life.[117] In this particular case, the applicants waited for essential information that would have enabled them to assess the risks they and their families might run, if they continued to live at a risk in the town exposed to danger of an accident at the factory. The Court holds, therefore, that the respondent State did not fulfil its obligation to secure the applicants' right to respect for their private and family life, in breach of Article 8 of the Convention. There has consequently been a violation of that provision.[118]

In summary, the Convention's right to life, the prohibition of inhuman and degrading treatment and the right to private and family life have occasionally been used to secure individual's right to health care, in this respect, safeguarding the enjoyment of applicants' health. Whereas the *López* and *Guerra* judgements protect against health related environmental offences, the *Tavaras* and *Karara* rulings claimed an obligation to ensure the quality of, respectively, access to health care facilities.

The Convention on Human Rights and Biomedicine

The Convention on Human Rights and Biomedicine of the Council of Europe is also relevant to the right to health care.[119] The Convention

---

114 *Guerra and Others v. Italy*, judgement of the Eur. Court HR on 19 February 1998 Strasbourg.

115 See the *Airey v. Ireland*, judgement of the Eur. Court HR on 9 October 1979, para 32.

116 *Cf.* the Court's reasoning in respect to article 2 in the *L.C.B. v. the United Kingdom*, judgement of the Eur. Court HR on 9 June 1998, para 36.

117 *Mutatis mutandis*, the *López Ostra* judgement, para 51.

118 *López Ostra*, para 60.

119 Officially, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. Council of Europe, ETS No. 164.

provides a common framework for the protection of human rights and human dignity in areas concerning the application of biology and medicine. It shares the same underlying approach with the Convention on Human Rights and Fundament Freedoms (ECHR), but also many ethical principles and legal concepts. This Convention elaborates several principles enshrined in the Human Rights Convention restricted to human medicine and biology.[120]

Article 3 of the Convention refers to equitable access to health care. According to that article "[p]arties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality." Such an interpretation of the health care right imposes an obligation on States to use their best endeavours to reach it. According to the draft Comments, the aim is to ensure equitable access to health care in accordance with a person's medical needs. "Health care" means the medical services, diagnostic, preventive, therapeutic and rehabilitative interventions designed to maintain or improve a person's state of health or alleviate a person's suffering.[121] Furthermore, equitable access to health care means first and foremost the absence of unjustified discrimination. Although not synonymous with absolute equality, equitable access implies effectively obtaining a degree of care.[122] The Parties to the Convention are required to take appropriate steps to achieve this aim as far as the available resources permit. It enables the health authorities to define the nature and scope of available resources, appropriateness of necessary measures, and appropriateness of care without crystallising individual claims. Although the Convention was approved in 1997, the exact long-term legal implications are still unclear.[123]

European Social Charter (ESC)

A rather weak interpretation of the right (of access to) health care has been confirmed by reading the European Social Charter. The Charter is a creature of the Council of Europe and considered as the "social counterpart" of the European Convention on Human Rights. According to Article

---

120 Explanatory Report, para 9.

121 *O.c.*: para 24.

122 *O.c.*: para 25.

123 For instance, it is not quite clear which treaty provisions may have direct effect. Most likely it is article 11, the non-discrimination provision, which will have direct effect. Each Party member, in accordance with its constitutional law, will have to determine this taking into account the nature and the concreteness of the specified norm. Furthermore, infringements on the rights or principles require the Parties to make a judicial procedure available to prevent or stop such an infringement (Article 23). It remains to be seen whether Parties can guarantee sufficient access to such judicial procedures.

11 (1) of the Charter, the right to protection of health imposes Contracting Parties appropriate measures designed, *inter alia*, "to remove as far as possible the causes of ill-health". In the opinion of the Committee of Independent Experts, a state can be taken to comply with this very wide and general undertaking if it provides evidence of the existence of an adequate medical and health system which has the following elements, *viz*, adequate and generally available public health arrangements that provide proper medical care for the whole community and ensure the prevention and diagnosis of disease; special measures to protect the health of mothers, children and elderly; general measures aimed at "the prevention of air and water pollution, protection from radioactive substances, noise abatement, food control, environmental hygiene [sic] and the control of alcoholism and drugs, all of which should be funded primarily by the state.[124] The crux of this provision concerns the phrase "as far as possible" that expresses the conditionally determined nature of a health care right. The level of "adequate" medical care is primarily determined by the domestic technical, financial and geographical capabilities, which obviously differ by country. Besides, given the enumeration of topics, adequate medical care is also restricted to community health-affairs such as prevention, protection and promotion of public health. According to this article, individual claims concerning the delivery of health care services are not justified.

By Article 12, the right to social security, Contracting Parties undertake measures "to establish or maintain a system of social security" (paragraph 1). This provision is not without meaning to health care since it refers to the treaties of the International Labour Organization (ILO) and the European Code of Social Security.[125] Both type of treaties encompass minimum norms of provided medical care services to the categories of persons entitled.[126] As far as the ILO Conventions are concerned, these provisions are binding to member States that have ratified these conventions. Simultaneously, several constraints may be justified since an absolute right would be unaffordable due to demographic changes. Possible constraints are: to exclude or limit the application of this right to certain categories of persons, the type of beneficiary care, and period of time. Such limitations have been enumerated by the different benefit packages of social health insurance legislation. Since both the ILO Conventions as the European Code encompass a substantial part of the population, to the

---

124 D. Gomien, D. Harris, L. Zwaak. Law and practice of the European Convention on Human Rights and the European Social Charter. Council of Europe 1996, Concludings: I 59.

125 Notably ILO C 102 Social Security (Minimum Standards) Convention, 1952; C130 Medical Care and Sickness Benefits Conventions 1969; European Code of Social Security (revised), Rome 1990, ETS No. 139. However, this revised Code did not came into force yet.

126 Article 10, respectively 13 of the ILO Conventions and Articles 8 -12 of the Code.

majority of the population, the right to health care has been made concrete by insurance and benefit package.[127]

Finally, In Article 13(1), the Charter proclaims separately the right to social and medical assistance, which require governments "to ensure that any person who is without adequate resources and who is unable to secure such resources [...], be granted [...], in case of sickness, the care necessitated by his condition". The meaning of "assistance" includes a definition that refers to the national competencies concerning the scope and extent of assistance.[128] The commitment does not require states to provide a comprehensive health service, as it covers only the treatment of illness, not health promotion, and extends only to those unable to purchase care privately.[129]

Treaty of the European Community (EC Treaty)

The European Union has no general competence to regulate in the field of health. The original Treaty of Rome did not foresee in a "European health system".[130] Health policy, notably the issue of access to health care services and facilities has been regulated by the domestic legal orders of the individual Member States. Community competences with respect to health were mainly based on general treaty provisions as far as they concerned the functioning of the common market.[131]

It was only in the Treaty of Maastricht (1993) that the European Union received the explicit legal competence "to take complementary measures in the field of public health" (Article 129 EC Treaty of Maastricht). Additionally, the Maastricht Treaty provided Community health protective actions by means of the consumer protection provision, Article 129a.[132] The

---

127 H.J.J. Leenen. Recht op zorg voor de gezondheid (The right to care for health, Preliminary advice) Utrecht 1997: 26.

128 Article 13 (4) refers to the European Convention on Social and Medical Assistance (1953) and protocol thereto ETS No. 14. According to Article 2 "assistance" means in relation to each Contracting Party "all assistance granted under the laws and regulations in force [...]". Such a description restricts any claim towards those facilities granted by national laws and regulations.

129 Montgomery *o.c.*: 53.

130 Treaty establishing the European Community (Amsterdam consolidated version). Official Journal C 340, 1997.

131 *Inter alia*, articles 94 and 308 EC (ex articles 100 and 235). Both provisions are aimed at the realisation of the common market. Further restriction of intra-communautaire trade however, can be found in other relevant treaty provisions aimed at [...] the protection of health and life of humans [...], for instance article 30 EC (ex article 36).

132 Section 1 reads: "In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their interests." Public health related actions under this article particularly concern product and food safety.

conferred public health tasks to the Community were however restricted by the principle of subsidiarity, *i.e.* only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States.[133] As a consequence, the Treaty constraints the jurisdiction of the Community concerning health to issues such health prevention considerably.

Despite the restricted Community competences, the Protocol of Maastricht meant a modest landmark in the predominant economic tradition of the Union. The treaty amendment created a legal framework for common action in the field of public health, emphasising the prevention of illness, notably major health scourges, and by promoting research as well as information and education.

The prevention of diseases raised several questions, *viz*, whether it is a subject that can be interpreted extensively, and therefore include measures affecting the organisation of national health care systems. In the legal literature, the broad interpretation of prevention has been denied.[134] Based on a restrictive reading, this article has resulted in relevant programmes concerning the fight on cancer, prevention of AIDS, other contagious diseases, and drugs. However, a main weakness of actions based on this article is the lack of enforceability. The legally non-binding character requires therefore more and more internal co-ordination and consistency to effectuate these programmes. Steyger, on the other hand does not consider the non-binding character for granted. According to her, it is arguable that "incentive measures", introduced by the Maastricht treaty, cannot consist of legislation, whether through directive or regulation.[135] With respect to the subsidiarity principle, she questions whether "incentive measures" are meant to be measures of a non-binding nature instead of legislation. This assumption should be precluded by subsection two of the health paragraph, including an instruction to for the Member States to co-ordinate their policies and programmes on health prevention. The Commission may, according to this subsection, take "any useful initiative" to promote such co-ordination. According to Steyger, the very words "any useful initiative" seems to fill in the vague concept of incentive measures mentioned in subsection four. Since subsection four provides the legal

---

133 And therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community, Article 5 EC (ex art. 3b).

134 E. Steyger. Europe and its Members: a Constitutional Approach. Dartmouth, Aldershot, 1995: 79. Apart from Article 129, Steyger states that the possible applicability of the former Art. 100A as a legal basis for measures aimed at the prevention on communicable diseases "cannot be considered as far-fetched". Therefore she refers to the titanium dioxide judgement of the Court of Justice, concerning the prevalence of article 100A in case of cumulation of legislative procedures. (C-300/89 European Court Reports 1991 page I-2867.

135 Steyger *o.c.*: 79.

bases on which measures in the area of health can be taken, these "useful initiatives" will be based on this subsection. However, nowhere is it said that these "useful initiatives" cannot consist of proposals for binding measures, adopted by qualified majority (subsection 4).[136] Actually, since these initiatives are meant to achieve the referred co-ordination, it will be quite likely that these initiatives will have a binding nature. This leads Steyger to the conclusion that adopting subsection two in relation to subsection four, the member states accepted that in the health area at least some of the incentive measures may be directives or regulation.[137]

The Amsterdam amendment (1997), however, does not confirm this conclusion. The lack of legal precision of Article 152(4)(a) still leaves scope for interpretation. Principally, according to Roscam Abbing, "measures" may include any kind of legal intervention, including directives.[138] The Treaty of Amsterdam replaced the Maastricht public health provision by article 152 EC. Apart from the renumbering, the main difference with article 129 is that Community action will no longer be limited to measures or activities, which are preventive in nature.[139] Since "such action shall cover the fight against the major health scourges, by promoting research ... as well as health information and education" (section 1), the Community may also act in order to improve public health. Further extended Community public health actions include measures, *inter alia*, setting standards of quality and safety of organs and substances of human origin, blood and blood derivatives and in the fields of veterinary and phytosanitary health (Article 152(4)(a)(b)).

Finally, in the fifth section it is mentioned that Community action in the field of public health "shall fully respect the responsibility of the Member States for the organisation and delivery of health services and medical care. It re-emphasises the reluctance of Member States to hand over their competences in organising and financing their national health

136 Steyger *l.c.*: 79.

137 Besides the role of these subsections, Steyger also describes the role of Articles 308 and 5 with regard to the health area. For reasons concerning the speculative character of their applicability, relevant case law of the Court is missing and its possible jurisdiction will not be discussed here. Therefore, see Steyger: 81-83.

138 H.D.C. Roscam Abbing. Public Health in the Treaty of Amsterdam (Treaty on the European Union). *EJHL* 1998, Iss. 2: 173.

139 A.P. van der Mei, L. Waddington. Public Health and the Treaty of Amsterdam. *EJHL* 1998, Iss. 2: 135.

care system. Consequently, individual claims to access to health care services cannot be based on Article 152.[140,141]

4.2 Patient autonomy in multilateral declarations and agreements

Apart from the right to health care, patient autonomy has been identified as a second basic principles of health care law. In view of the traditional duality between individual and social rights, patient autonomy reflects the individual dimension of classical human rights. In the context of rights of patients, patient autonomy functions as the underlying value of health care law. Their meaning and legal basis of such fundamental rights can be derived from various multilateral declarations and agreements. A survey of the main normative instruments that reflect these principles, offers a conceptual framework that has been applied to draft and/or reformulate specific rights of patients. As to the intergovernmental declarations and agreements, the following have been taken into account:

- the Universal Declaration of Human Rights (1948);
- the International Covenant on Civil and Political Rights (1966);
- the European Convention on Human Rights and Fundamental Freedoms (1950);
- the Convention on Human Rights and Biomedicine (1997);
- the Declaration on the Promotion of Patients' Rights in Europe (1994), and
- the Ljubljana Patients' Rights Charter (1996).

Of further relevance are several non-governmental declarations from the World Medical Association (WMA), the Council for International Organisations of Medical Sciences (CIOMS), which are in principle non-binding. As to the WMA, the Lisbon Declaration (1981) referring to patients' rights and the Declaration of Helsinki (1964, recently amended in 1989) referring to biomedical human research are worthy of mention as are the CIOMS International guidelines for ethical review of epidemiological studies

---

140 See in this respect also chapter eight that includes a more extensive analysis on recent developments initiated by the European Court of Justice.

141 During the latest inter-governemental conference (Nice 2000), the EU Charter of Fundamental Human Rights was adopted, which reaffirmes the right to health care as a communautaire principle, based on Article 152(1) of the EC Treaty and on Article 11 of the European Social Charter. According to the Council's explanations it should be interpreted as a right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. Whereas a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Council of the European Union. Charter of Fundamental Rights of the European Union. Explanation relating to the complete text of the Charter, Article 35. Luxembourg, december 2000. At this moment, however, the legal status of the Charter is still a subject of discussion.

(Geneva 1991) and the Ethical guidelines for biomedical research involving human subjects (Geneva 1993). These documents refer more indirectly to the rights to individual self-determination by means of "hard core" patients' rights (consent, information, *et cetera*). Although intended as non-binding recommendations, standards and or guidelines they further operationalise the seminal principles and may be of relevance to the judicial interpretation.

Universal Declaration of Human Rights (UDHR)
The Declaration has accepted the right to self-determination as a fundamental collective and individual human right (Article 1). The first sentence reads: "All human beings are born free and equal in dignity and rights." As to the individual setting, it includes the essence of existence, and functions as the precondition to the enjoyment of all the rights and freedoms of the individual. It has been reflected by, *inter alia*, the right to life (Article 3) and its corollary rights, i.e. refrain from torture or cruel, inhuman or degrading treatment or punishment (Article 5), recognition as a person before the law (Article 6), equal entitlement without discrimination before the law (Article 7), respect for privacy (Article 12). Individual freedom and human integrity imply respect for human life, absence of outside intervention without consent, equal access and treatment before judicial courts, *et cetera*. Therefore, Article 1 functions in the health care setting as the underlying basis of various individual human rights from which the prohibition of maltreatment and experimentation without free consent is probably the most significant to health care (informed consent). Jointly, these rights are relevant for the protection of the individual against violation of his physical and mental health. In the Declaration, however, these rights were primarily stated as a political declaration of principles without concomitant legal implications. Legally binding rights can, however, be found in the derived Covenant on Civil and Political Rights.

International Covenant on Civil and Political Rights (ICCPR)
The most important feature of the International Covenant on human rights is that it is a universal instrument, which contains binding legal obligations for the States parties (Article 2).[142] The rights within it represent the basic minimum set of civil and political rights recognised by the majority of the world community. It reflects norms of international customary law and is on this basis therefore binding on the States.

Illustrative of the importance of the right of self-determination is its place in both the Covenant on Civil and Political Rights as on Economic,

[142] See General Comment no. 3 on the nature of States parties obligations, *supra* note 15.

Social and Cultural Rights; according to Article 1 (1) "all people have the right of self-determination". Generally understood in the context of the international community, as a *collective* right. The UN Charter only refers to the "principle of equal rights and self-determination of peoples", without further specification. In the human rights approach, *individual* self-determination is also common.

Faith in fundamental human rights and freedoms as common standards for all peoples has been recently reaffirmed at the Vienna World Conference on Human Rights (1993).[143] Similar to the Declaration, both the right to life and the prohibition of maltreatment and experimentation without free consent have been adopted in the Covenant in Article 6 (1), reading "*Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.*" and subsequently Article 7: "*No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.*" The right to life is the only right in the ICCPR, which is expressly stated to be "inherent" in every human being. It has been described as the supreme right by the Human Rights Committee (HRC).[144] This Human Rights Committee is similar to Committee on Economic, Social and Cultural Rights in terms of composition and mandates. It has characterised its role as an "advisory and monitoring" body (considering the formulation of General Comments) and as an "inquiring and investigative" body (with respect to complaints from individuals. The Human Rights Committee supported a broad approach to Article 6: [...] "the Committee has noted that quite often the information given concerning Article 6 has been limited to only one or other aspect of this right. It is a right which should not be interpreted narrowly." The expression "inherent right to life" cannot properly be understood in a restrictive manner, and the protection to this right requires that States adopt positive measures. In this respect, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.[145]

However, during the extensive discussions of the preparatory committee, participating parties could hardly agree about the final text. This resulted in a merged compromise that does not give an indication either on when life begins, nor on when life ends.[146] In particular, in cases such as abortion and euthanasia, the question of possible exceptions was raised.

---

143 *Supra* note 92.

144 General Comment no. 6 "The right to life" (article 6), sixteenth session 1982, para 1.

145 General Comment no. 6, *o.c.*: para 5.

146 Roscam Abbing *o.c.*: 43.

Within the bounds of the ICCPR, Article 6 has a particular relationship with other Covenant articles, notably the articles 7 (prohibition of torture and cruel treatment or punishment) 9 (right to liberty), 10 (humane treatment of persons deprived of liberty), and 14 (equality before the courts). With respect to Article 7, the purpose is to protect the dignity and physical and mental integrity of the individual.[147] Both aspects refer to the prohibition of (inhuman) medical treatment or experimentation without (informed) consent. This article has been linked with Article 9 and 10 (1), *i.e.* "all persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person". More generally, Article 7 has been linked with in differing contexts with various provisions of the Covenant including articles 6, 8 (prohibition of slavery), 9, 14, and 23 (protection of the family). It has been often correlated to, for example, disappearances, torture and ill treatment, and the destruction of family life. Since the inception, the Human Rights Committee has taken a broad view of the scope of Article 7. In its opinion, Article 7, "clearly protects not only persons arrested or imprisoned, but also [...] patients in medical institutions".[148] As far as these experiments are concerned, special protection is necessary to persons not capable or giving valid consent. However, the Human Rights Committee has refrained from defining of the concepts covered by this article, nor does the Committee consider it necessary to draw up a list of prohibited acts or to establish sharp distinctions between the different kinds of punishment or treatment. These distinctions depend on the *nature, purpose and severity of the particular treatment*.[149]

The prohibition on medical and scientific experimentation has been commonly raised in regulations with respect to the removal and transplant of human organs or tissue. However, though the provision was drafted with the atrocities of the Nazi war crimes during World War Two in mind, it was clearly recognised that the provision as formulated went much wider. Modern practises such as psychosurgery, research on children, research concerning pharmaceutical products, the AIDS virus, foetal and embryo experimentation, and fluoridation might well raise issues for the Human Rights Committee to consider.[150]

---

147 General Comment no. 20, replacing General Comment 7 concerning "the prohibition of torture and cruel treatment or punishment" (Article 7), 10 April 1992, para 2.

148 General Comment no. 20, *o.c.* para 5.

149 General Comment no. 20, *o.c.* para.4.

150 D. McGoldrick. The Human Rights Committee. Its Role in the Development of the International Covenant on Civil and Political Rights. Clarendon Press, Oxford 1991: 366.

European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)

The text of the European Convention on Human Rights was largely inspired by the Universal Declaration and the International Covenant on Civil and Political Rights. In the European region, the Convention functions as the European equivalent of its international counterpart.

Encompassing comparable legally binding individual rights and freedoms, the Convention refers in a number of articles to the right of individual self-determination. Similar as mentioned in the ICCPR, the right to life (Article 2), and the prohibition of torture (Article 3) of the European Convention enshrine the pivotal principles, as mentioned in the Declaration and ICCPR. Notably Article 2 of the Convention has been considered as the prerequisite for all other human rights. Corresponding to Article 6 of the Covenant, Article 2 protects life itself. Some other authors such as Fawcett have recognized that the international provisions protect not life, but the right to life.[151] In accordance with Redelbach, it is a very formal and limited interpretation, which is contradictory to the theological assumptions of Article 6 of the Covenant: "the provision that everyone's right to life shall be protected by law was intended to emphasize the duty of States to protect life".[152] Article 2 imposes upon the national authorities an obligation to protect everyone's life, followed by a protection of intentional deprivation of life. It directly affords protection against actions and omissions by states, but not by individuals. However, an application may be addressed against an individual when the violation is due to the lack of protection on the part of the government, as complains can only be directed against acts or omissions for which the government bears responsibility.[153] This responsibility means, however, that States have to take positive measures to safeguard life.[154]

On the question of Article 3, it is indirectly related to the Convention's right of life. Referring to forms of torture used by the Nazis during the war, the right to be free from torture and inhuman or degrading treatment are amongst the most fundamental rights, as they are tied to an individual's personal integrity and human dignity.[155] Both the Commission and the European Court left no doubt about the fact that freedom from torture and other inhuman or degrading treatment or punishment includes both

---

151 J.E.S. Fawcett. The Application of the European Convention on Human Rights Oxford 1969: 30-31.

152 A. Redelbach. Protection of the right to life by law and by other means in: Ramcharan *o.c.*: 204, quoting the Official Records of the General Assembly, X Session, Anne, Part II Doc. A/2929, p. 30.

153 Gomien *o.c.*: 94.

154 *Osman v. The United Kingdom*, judgement Eur. Court HR of 17 May 1996, para 115-116.

155 Gomien *o.c.*: 105.

severe *physical* and *mental* suffering as well. The difference between the acts prohibited is considered as gradual. According to the Commission, starting from the concept of inhuman treatment: *"[t]he notion of inhuman treatment covers at least such treatment as deliberately causes severe suffering, mental or physical, which in the particular situation, is unjustifiable. The word "torture" is often used to describe inhuman treatment, which has the purpose, such as the obtaining of information or confession, or the infliction of punishment, and is generally an aggravated form of inhuman treatment. Treatment or punishment of an individual may be said to be degrading if it grossly humiliates him before others or drives him to act against his will or conscience."*[156]

However, there is no absolute standard for the kinds of treatment and punishment prohibited by Article 3. The question whether a treatment or punishment is inhuman or degrading must be reviewed by, *inter alia*, the circumstances of the case.

Convention on Human Rights and Biomedicine

The Biomedicine Convention is the first internationally binding legal text addressing bioethical issues and shares many legal and ethical principles and concepts with the above mentioned ECHR Convention. It is intended, *inter alia*, to protect human beings against possible misuse of new biological and medical techniques by safeguarding fundamental human rights and freedoms. Therefore, the sectarian Convention formulates new standards regarding the protection of the embryo and foetus. Already established rights have been reaffirmed and further specified, e.g. non-discrimination and the principle of informed consent. The combination of both individual and social rights that have been regulated in this Convention underlines the interrelationship and interaction between these type of rights in relation to health. This makes the Convention a health law treaty "pur sang".[157]

In the Preamble, the Biomedical Convention refers to other agreements such as the European Convention. "The two Conventions share not only the same underlying approach but also many ethical principles and legal concepts."[158] Moreover, "[p]arties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, [...] respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine" (Article 1). According

---

156 Report of 5 november 1969. Yearbook XII: The Greek Case (1969), p. 186, quoted by Gomien: *o.c.*: 226.

157 H.D.C. Roscam Abbing. The Convention on Human Rights and Biomedicine: An Appraisal on the Council of Europe Convention. *EJHL* 1998, Iss. 5: 379.

158 Draft Convention Bioethics Convention. Comments on the provisions of the Convention, no. 17.

to the Explanatory report, the concept of human dignity, constitutes the essential value to be upheld. It forms the basis of most of the values emphasized in the Convention.[159] The Convention furthermore affirms a well-established rule, which is that no one may in principle be forced to undergo an intervention without his or her consent (Article 5). Human beings must therefore be able freely to give or refuse their consent to any intervention involving their person. This rule makes clear patients' autonomy in their relationship with health care professionals and restrains the paternalist approaches which might ignore the wish of the patient.[160]

A weak point of the Convention is that the enforcement remains problematic. Although the Convention foresees an obligation on parties to provide adequate judicial protection to prevent or stop infringements to the Convention's rights (Article 23), the Convention does not create a supra-national judicial power such as the European Court on Human Rights. Instead, the Convention imposes parties to deliver a report explaining the successful implementation of the Convention's principles and rights in internal law (Article 30). Despite the absence of a specific international complaint procedure, the Human Rights Court can, on request, advise on the interpretation of the Convention in raised legal questions. To a certain extent, the Court's rulings can compensate the absence of international judicial review. Since the Convention was only recently approved, it remains to be seen what the exact, long-term (legal) consequences will be.

Declaration on the Promotion of Patients' Rights in Europe and the Ljubljana Patients' Rights Charter

In 1994, a European consultation on the rights of patients was held in Amsterdam. The purpose was to define principles and strategies for promoting the rights of patients, within the context of the health care reform process underway in most countries. The consultation endorsed the "*Principles of the rights of patients in Europe*", which laid down a framework for developing patients' rights. These principles include, *inter alia*, the essence of patient autonomy, in particular the protection of dignity and integrity of the person and the promotion of respect of the patient as a person. In article 1, paragraph 2, the right of (individual) self-determination is explicitly mentioned together with human dignity (paragraph 1); physical and mental integrity (paragraph 3); respect for his or her privacy (paragraph 4); the prohibition of discrimination, and the right to the highest attainable level of health (paragraph 6). These rights are not

159 Explanatory report Bioethics Conventions, para 9.

160 Explanatory report *o.c.*: 34.

invented, they are internationally recognised and formulated in many other declarations and conventions.

Finally, the Ljubljana Charter on Reforming Health Care articulates a set of principles which are an integral part of the current health care systems or which could improve health care in all the Member States of the World Health Organization in the European Region.[161] Such principles are human dignity; equity; solidarity and professional ethics (Article 5, paragraph 1). Thus, human dignity and integrity as the legal components of the autonomy principle. These principles have been emphasized by the need for health care systems which focused on people and allowed the *"citizens' voice and choice to influence the way in which health services are designed and operate"*.[162] Both the Charter and the Declaration, reflects the trend towards strengthening the rights of patients in health care. Such experiences can be associated with democracy: empowering people is a question of revitalising representative democracy so as to ensure the smooth functioning of basic social institutions, including health care establishments.[163]

5 CONCLUSIONS

Analysis of the normative framework of health care law identified two underlying principles, *viz*, the right to health care and patient autonomy. In the legal doctrine, however, this notion of health care law is not unchallenged. In the framework of this research, it is argued that other rights such as the right to life and corrolary concepts such as the right to physical integrity and the right to dignity, although of relevance, are not sufficiently specific to function as underlying seminal values of health care law.

Both primordial values have been recognised by international human rights law. International law conceptualises the obligations derived from both and related principles. What is more, modern understanding on international human rights re-interpreted human rights as indivisible, interdependent and interrelated. In terms of obligations, it means a shift away from the traditional dichotomy between social and individual rights. Such an interpretation of human rights has been accepted by authoritative institutions such as the United Nations' Committee on Economic, Social

---

161 Preamble of the Ljubljana Charter on Reforming Health Care, 19 June 1996.

162 World Health Organization. European health care reforms. The Ljubljana Charter on Reforming Health Care. Copenhagen, WHO Regional Office for Europe 1996: 5.

163 World Health Organization. Empowering citizens in the planning and management of health care. Draft for the consultation on the development of patients' rights in Europe. Gothenburg, Sweden, 18-19 August 1997. WHO Regional Office for Europe 1997: 4.

and Cultural Rights as well as the European Court of Human Rights. Its relevance to the right to health care and patient autonomy concerns a more thoughtful approach of treaty obligations in terms of obligations to respect, protect, to promote and to ensure.

In view of the specific role of law in health care, regulatory obligations have been classified as modalities or functions of health care law. Apart from the traditional guarantee function concerning patients' rights and its regulative function in public health matters and the structure of health care, it appeared that more and more the law's role in the finance, allocation, and quality of health care have increased in importance in order to influence social relations and institutions in such a manner that they confirm selected policy directions. As such, the traditional notion of law has been elaborated according to the specific qualities of the field of law.

Over the past decade limiting the incessant inflation in health care expenditure and funding methods to increase efficiency have been issues of paramount importance in decision-making of the legislature. Gradually, the traditional legal doctrine has undergone a reorientation towards an increased interest in the finance, affordability and quality of health care without loosening elementary principles such as equal access to health care. This tendency has been formulated most apparently by the World Health Organization study on functions of health care law. This authoritative international *gremium* explicitly acknowledged the original starting point as defined by Roemer. Legal theorists such as Furrow and Montgomery and Longley have, (in)directly and in part, recognised such an approach of systematising the role of law according to discerned functions of the law in health care. The corresponding functions, concern the traditional normative function of guaranteeing the rights of patients, surveillance over quality of care, to provide for the equal access to basic health care, and directing and monitoring the allocation of health care resources and therefore control over the main costs of health care.

Roemer's concept of health care law, elaborated by the WHO study, is strinkingly different from Furrow's views of health care law. Apart from the minor difference in number of functions, more relevant is the absence of the typical collective responsibility on public health (protection, prevention and promotion). A possible explanation centres on the interpretation of the health care conception and consequently the legal norms relevant to health care. Instead of a narrow notion related to cure as an engineering, problem-solving concept, or "the provision of health care to repair the defective human machine",[164] health care can also be interpreted as aimed

[164] J. Montgomery. Recognising a Right to Health in: Economic, Social and Cultural Rights: Progress and Achievement. R. Beddard and D Hill (eds.) London: MacMillan 1992: 186.

at care, *i.e.* control of the causes of the initial breakdown,[165] including prevention and the spread of infectious diseases. Such a broad conception refers to the social model of health as defined by the WHO Constitution. Poor environmental and socio-economical circumstances have a deteriorating effect to health. In view of this correlation, to tackle poverty and to restore a healthy environment as well as the eradication of infectious diseases is certainly a health concern. Instead of focusing on health as ensuring the absence of constraints on its existence, health care (law) includes also preventive and promotional measures to increase the health status of the community and individuals. Compared to Roemer's specific functions of health care law, the abstract theory of Llewellyn's general law-jobs is rather vague and open for interpretation. Nonetheless, Longley distilled several functions applied to health care, which partly corresponds with Roemer's classification.

In view of the classification of functions, law clearly has both constraining and facilitative qualities. It is instrumental in achieving public ends through the shaping of social processes. But it should also be emphasized that the law is more than an instrument in that, it is a means of promoting choice and ensuring accountability in public decision-making; principles which are the cornerstone of human rights and constitutional protections.[166]

The assumption of basic social qualities of law and their interpretation in international law is of particular relevance in case of legal reforms of the health care system, for instance the introduction of market elements in health care. As such, the discerned qualities function primarily as leading constitutional principles that provide the normative standards directing pragmatic choices in health care allocation, finance, structure, *et cetera.* Such an approach provides the legislature a useful instrument to overcome shortcomings in rationalising the law-making process. It contains both normative and functional suggestions to health care legislative strategies and activities that should be carried out both in the short and the long run. Health care legislation is therefore a "reflection" of health care law and underlying principles. It is considered as the corpus of standards that defines the legal framework of rights and law-jobs. Nonetheless, such a notion of law-making is still not complete. The relation with health policy is notable in its absence. The next and final step in drafting a legal-theoretical model that reflects the legislative process is to synthesise the previous experiences with health policy-making, notably in the Central and Eastern European context.

---

165 Montgomery 1992, *o.c.*: 186.

166 Longley *o.c.*: 11.

CHAPTER 4: SYNTHESIS OF A CIRCULAR MODEL OF HEALTH CARE LAW-MAKING: RELEVANCE TO CENTRAL-EASTERN EUROPE

1 INTRODUCTION

"*To revitalize their health services, governments in the former socialist states of Central and Eastern Europe are experimenting with a new wonder drug called market mechanism. This is rather like the doctor who gives penicillin to a patient who has a known allergy to it but will die without it. It is necessary to understand the associated dangers so that the appropriate measures may be taken to prevent the treatment from killing the patient.*"[1]

From a legal perspective, the allegory focuses on an analytical framework of law-making intended to increase understanding of the disease (a rather obsolete legal structure), the prescribed treatment (a "big bang" system change), the allergy (legislative imperfections) and the remedy (regulated and progressive reforms).

Due to the rather inconsistent legal reform strategy, legislative changes of the health care structure in Central and Eastern Europe have frequently been characterised as "crisis management". Too often, rapidly changing circumstances have resulted in less developed, temporary and *ad hoc* legislative measures. These experiences give rise to a reconsideration of the current unsatisfactory approach of law-making. In order to develop a rational, i.e. more structural and systematic, approach to health care law-making, a model founded on correlating legal-formal understanding with substantive parameters may prove to be a useful instrument (section 2). Consequently, it is questionable in what respect the application of such an analytical model may improve the contemporary practise of law-making in Central and Eastern Europe. The answer lies in the relation to health care law-making and policy-making since health care policy objectives shape, to a certain extent, the legislative agenda and *vice versa*. Fundamental legal principles, values such as equal access to health care and human rights, determine the policy objectives of the legislature. The balance between both perspectives reflects a substantiated compromise that corresponds to a minimum level of services and facilities available to the entire population. The ultimate model, therefore, combines the two interacting perspectives, as described in section 3.

---

[1] A. Preker, R.G.A. Feachem. Health and Health Care in: Labor Markets and Social Policy in Central and Eastern Europe. The Transition and Beyond. N. Barr (ed) Oxford University Press 1994: 288.

The rationale of the suggested model is one of incremental changes to the contemporary health care structure. Since the disappointing experiences of the early 1990s, which was in the main a duplication of an existent model, a careful gradual movement towards a more market related health care system has been subscribed by several actors in the Central and Eastern European health policy scene. The proposed circular concept of law-making translates this notion into law-making by maintaining elements of the *ancien régime* combined with additional legal changes. These reforms can be structured according to a framework of universal legal norms irrespective of the uniqueness of each country's present status of the health care system. From a legal-analytical perspective, the progressive approach of constantly monitored effects may reveal possible ramifications and pitfalls in reforming the legislative structure. As such, the circular notion of law-making buttresses the legislative reform process by timely intervention and corresponding underpinning objectives and principles. Here, it is assumed that it may provide a scientific basis for developing health care legislation.

2 A CONCEPTUAL MODEL OF HEALTH CARE LAW-MAKING

While in a state of flux with rapid and profound changes, the discerned functions of health care law provide a useful tool for creating a conceptual framework of legislation. It is a theoretical concept that reflects both the normative and instrumental qualities of law and may assist the legislature in (re) defining health care legislation. More concretely, it could provide a stipulated course and direction in line with an intended strategy. Health care legislation as part and parcel of health care law functions as an inherent means to realise the main objectives of intended legal reforms. WHO propagated such a systematic approach of law-making several years ago.[2] Despite its (theoretical) attractiveness, deficits in the implementation and evaluation of legislative mechanisms and insufficiently considered measures complicate a successful realisation of the law-making reform strategy in most Eastern European countries. Integration of the universal qualities of health care law into a previously explored model of law-making could improve this activity. Therefore, chapter two interpreted law-making activity according to a methodological concept, reflected by a (simplified) model and divided by discerned stages of law-making (figure 4.1). The first element was identified as "objectives of law-making" and refers to the law-jobs or functions of law. The objective approach requires the intervention of the legislature, whereas the magnitude, complexity and urgency of

[2] WHO 1988, chapter 3, *supra* note 80.

problems that occur necessitate the prioritisation of legislative issues, based on an initial problem-analysis. An extensive descriptive analysis of the specified subject(s) will ultimately result in initiating a range of legislative measures that need to be implemented and monitored for their effects. To review the extent of realisation by its underpinning objectives, and to analyse possible (side-)effects of the intervention mechanism, evaluation is an effective instrument that could ultimately result in adjustment or modification of the instrument. Consequently, during a motivated consideration of the chosen objectives, priorities, means and content of the legal document, evaluation criteria may contribute towards a more systematic and substantiated approach to law-making activity. Subsequently, it may increase rational decision-making. This type of decision-making should, however, be focused on health care law-making.

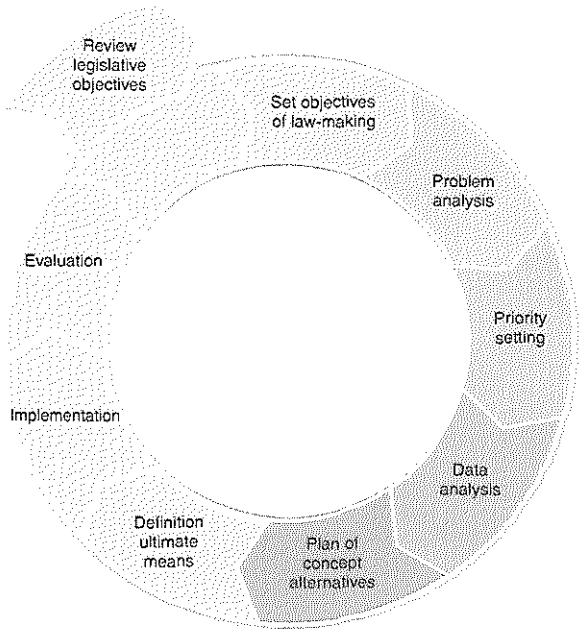


Figure 4.1: Concept of a model of law-making

Elaboration of a law-making model
In the health care setting, the legal functions were successively grouped according to the following clusters: public health; organisation of health resources; financing and tariffs; quality control, and patients' rights. The discerned clusters symbolise the basic legal principles as formulated by the World Health Organization. These law-jobs were specified as:

- to prohibit conduct, and ban or regulate the use of products injurious to health;
- to authorise programmes and services that promote the health of individuals and the community;
- to regulate the production of resources and the production, deployment, and the management of the health manpower required for the delivery of health care to individuals and of the environmental health services;
- to provide the social financing of health care;
- to exercise surveillance over the quality of health care, and
- to ensure the rights of individuals.

In a similar manner as the stages of law-making, the functions can be graphically reflected (figure 4.2).

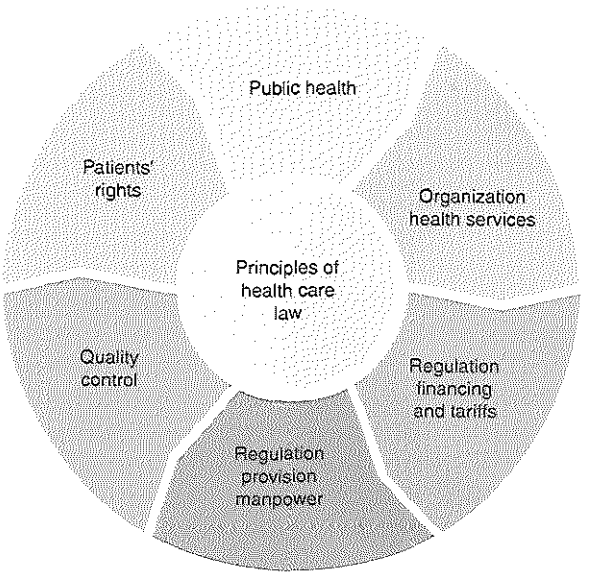


Figure 4.2: Clusters of health care law

Figure 4.2 discerns the normative commitments of the legislature in the field of health law based on its underlying basic notions. Both figures can be easily combined. Matching both figures, the diagram transposes the analytical stages of decision-making model to the field of health care law. As a result of the circular approach, law-making activity can be viewed according to the successively discerned elements (figure 4.3). Such a theoretical model of health care law-making needs further explanation.

The conceptual framework of health care law-making is defined as a coherent model of concepts, definitions, assumptions and other analytical instruments intended to develop and assess a normative framework of legislation by its underpinning notions. It is assumed to provide a scientifically substantiated basis for health care legislation. Since it is an intellectual construction, it does not have to represent the actual situation. Such a model is always a simplification, though not a blueprint of reality. Accordingly, any description must include certain elements of reality while excluding others. Its qualities mainly concern formulating and verifying theoretical concepts of health care law-making, which might have consequences for the actual legislative activity. Obviously, the chronology of the suggested sequence of law-jobs does not include a hard and fast rule but offers an analytical instrument to redefine health care legislation in a more systematically manner. It "colours" the theoretical perspective of health care reforms, it enables the correlation of the multitude of changes in the interactive law-making process.

Differences in implementation and stages of development of the reform process do not *a prima facie* alter the methodology, neither do they influence the timetable of intended reforms. In general, the primacy of public health has been considered as a fundamental condition for a community to enjoy its health.[3] It requires measures that protect, prevent and promote the health of society. As a consequence, such an interpretation requires the legislature to define and facilitate the conditions for a system that guarantees a certain level of physical and mental health (including healthy environment, decent sanitation, hygiene, vaccination programmes, medical care, health education and promotion). Apart from basic public health facilities, other health care resources that concern individual aspects of health care necessitate the planning and allocation of such provisions according to the needs and available resources (organisation aspects). Whereas to guarantee and maintain a financially affordable health care system, regulation of the financing, including tariffs, is a legislative affair *par excellence.* These three elements, public health, regulating the organisational aspects of health care resources and the sources of finance initiate the need for additional regulative mechanisms related to quality control or supervision and patients' rights.[4] Graphically,

---

3 R.J. Donaldson, L.J. Donaldson. Essential Public Health Medicine, Dordrecht 1993: IX.

4 Notably in case of infringements of patients' right to a (financially) accessible health care system legislation is indispensable. Whether or not there is a formal relationship between the elements and relevant legislation, they interact with each other. Legislation must, therefore, be drafted which takes into consideration the interconnection between these various elements. Moreover, without assessment there is a serious risk that the law might give rise to side or contra-effects. H.J.J. Leenen. Health Law and Health Legislation: Possibilities and Limits. *Supra* note 2, chapter 3.

these law-jobs correspond with the inner circle of clusters of intervention according to the suggested sequence (figure 4.3).

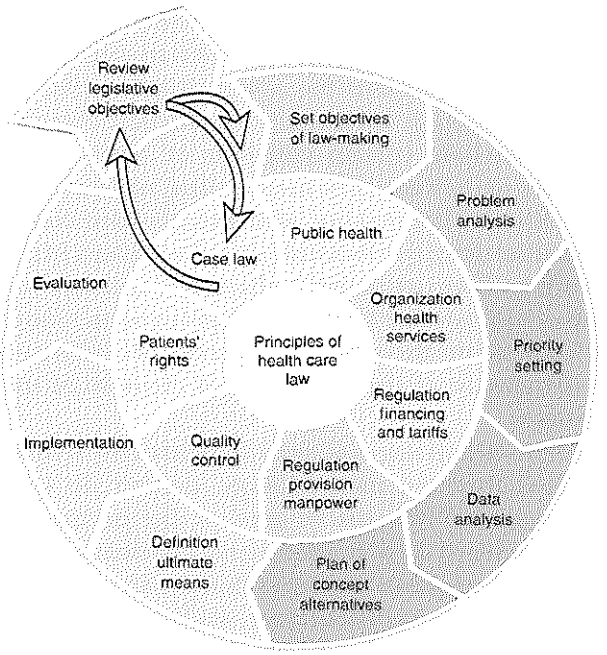


Figure 4.3: A model of health care law-making

It will be clear that the complexity of (re)defining health care legislation needs a long-term strategy that cannot be realised in a singular process. Reforming health care legislation requires a continuous approach carried out progressively by selected cluster(s). The review element in the legislative process already suggested this, more or less. In this respect, besides review based on legislative evaluation, judicial review also reveals possible shortcomings in legislation. Judicial evaluation of (the rationale of) legislation exposes incidental and/or structural legal deficiencies. Consequently, such defects may initiate a reconsideration of the original legal norm, whereas the systematic sequential approach of reforming health care legislation strengthens the notion of a circular and gradual process.

Finally, the nucleus of the circle reflects the fundamental principles of health care law in the process of (re)defining law-making. The right to health care and patient autonomy function as central benchmarks that represent the underpinning principles of this frame of law-making. Changes in interpreting these principles may affect the role of law and the legislature in health care, and therefore influence the content of health

care legislation. Hence, such an integrated circular model correlates normative principles, the functions of the law, and the legislative process. Moreover, the systematic approach by means of stages of law-making and discerned law-jobs in health care may contribute towards a review of legislative decision-making. It may reduce the level of "trial and error" by rationalising the process of law-making in health care.

Correlation between the law-making activity and policy-making
The premise of the (start of the) legislative process as a rather autonomous and mechanical activity without external influence needs to be adjusted. For instance, the initiated transition from a rather centralized tax-funded health care system, towards a (kind) of health insurance scheme is the result of a political decision-making process and is subsequently based on primarily socio-economic motives. Thus, changing the health care legislative framework cannot be placed within a vacuum but must be commensurate with legal, political and social principles, transformed in a strategic plan of further defined and elaborated health policy objectives. In other words, health care legislation and health policy are interrelated: health care legislation both expresses (autonomous) axiological norms (e.g., guarantees the rights of individuals, equal access, non-discrimination) but also reflects policy objectives (e.g., cost-efficiency, efficient allocation of health resources).[5] Health care legislation balances between fundamental normative principles and legitimising instrumental policy objectives. Integrated into the previous model, health policy objectives cover the same categories as the discerned law-jobs of health care legislation. The circular approach reflects the continuing interaction between law-making and policy-making, whereas policy objectives initiate legislative intervention, otherwise, diverging judicial interventions may require legislative correction and/or adjustment of existing policy objectives/programmes. Indeed, law-making has a legitimising function here besides its traditional guarantee function. The presumed hierarchy between guarantee and instrumental qualities manifests itself particularly in health care, *viz*, the dilemma between reflecting primarily economic effectiveness and efficiency *versus* expressing universal access to health care (equality).

This dilemma can be resolved by differentiating the equality principle. Pure equality is an illusion, people differ in social qualities, health status and knowledge. Such inequalities affect the extent of individual access to health care. Here we see the primary societal task of society, the government optimising legal equality among its citizens. Yet, it is questionable whether it is feasible to achieve this ambition. In a well-known statement,

---

5 Roemer, *o.c.*: 437-8; H.J.J. Leenen, G. Pinet and A.V. Prims (eds) Trends in health legislation in Europe. Paris 1986, Introduction: VII.

Aristotle recognised the relativity of the equality-concept: "treat equal what is equal and treat unequal to the extent of inequality". Interpreted as such, it "only" expresses a claim of proportionality.[6] The consequences of the interest to be served should not be too problematic to other interests. What matters is the motivation to differentiate. In health care, this motivation can be found in the impossibility of guaranteeing full access to universal health care. Here, the collapse of previous Eastern European health care ideals is exemplary. Curtailment of a previously unrestricted right to access is inevitable, even necessary, to guarantee a sustainable health care system accessible to the entire population. To legitimise such limitations the legislature, the pre-eminent social body, has to guarantee a certain level of *basic* health care (decent minimum proposal).[7] This Rawlsian approach can be justified since certain categories do not have the ability to choose in a rational manner and opt for a certain level of facilities, while those citizens above a certain basic level of facilities may be expected to, for instance, take out additional health insurance against supplementary, luxury facilities and co-payments. Thus, a certain degree of legal equality should be aimed at, while above this level, differences could be acceptable.[8] Although initiated for economic reasons, from a legal point of view such a perspective can also be justified by criteria open to objectivity.

To find equilibrium between traditional legal and instrumental policy objectives is one of the most difficult aspects in the current health care legislative debate. Particularly in countries transforming their health care system, changes of the legal structure will instigate a debate on the underpinning concepts of the role of the legislature and therefore government in health care. On the one hand, newly developed legislative strategies intend to introduce (market based) efficiency measures. On the other, they have to express basic societal values. The centre of the model reflects these principles which may correct a too instrumental approach of law-making initiated by instrumental objectives. *Vice versa*, legal principles are bound by instrumental values that attempt to develop and maintain sustainable access to health care. Both perspectives are intertwined and interact (figure 4.4).

However, the rational suggested approach of the legal decision-making process does not have to correspond to the actual process. As mentioned earlier, the real legal or policy decision-making process has rather been

---

6 Aristotle, L. Ethica Nicomachea, translated by H.G. Apostle. D. Reidel Publishing Company, Dordrecht 1975. 1131a25-32; The Politics. S. Everson ed. Cambridge University Press, Cambridge 1988. 1282b15-1284a2.

7 Nonetheless, such a decent minimum has proved difficult to explicate and implement. *Cf. e.g.*, H.E.G.M. Hermans and A.P. den Exter. Priorities and Priority-Setting in Health care in the Netherlands *CMJ* 1998. Iss. 3: 346-355.

8 J. Rawls. A Theory of Justice. Cambridge, Mass. Harvard University Press 1971.

characterised as "muddling through", instead of the more mechanical rational approach. Whether or not reflecting the actual process, and given its limitations, the rational concept of transforming policy targets into legislative objectives and the suggested sequence of continuously passing stages may help to clarify problems, structure the diffuse process of making choices or selecting objectives. In this respect, it may function as an instrument in attempting to increase the transparency and accountability of the decision-making process, without having the illusion of altering, in the long run, how policy-makers or law-makers reach decisions.[9]

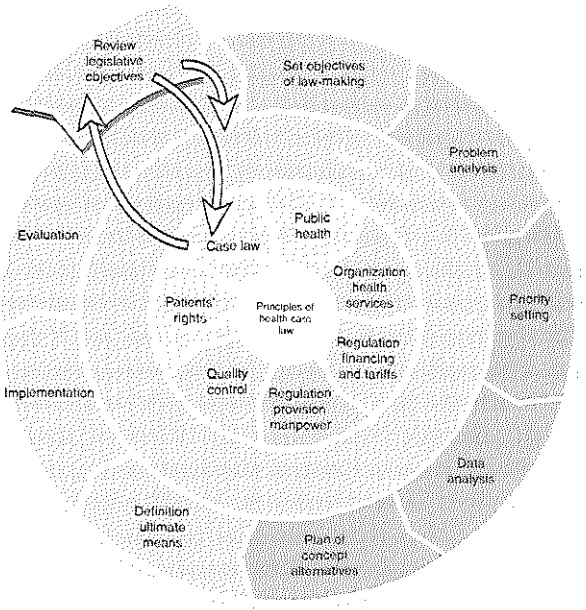


Figure 4.4: Synthesis of health care law-making and policy-making

3 RELEVANCE TO CENTRAL AND EASTERN EUROPEAN HEALTH CARE REFORMS

The relevance to the legislature concerns the consequences of the synthesis between the dynamic approach of the legislative activity and health policy. While the model provides over a conceptual normative framework to increase transparency in legal decision-making, the interrelation between law-making activity and policy-making enables the implementation of health

[9] A-M Foltz. The policy process in: Health policy and systems development. An agenda for research, J Janovsky ed. WHO Geneva 1996: 211.

policy reforms in a more systematic and structured manner. Moreover, evaluation and feedback to the underlying benchmarks may initiate further adjustments of both the policy strategy and legislative instruments. This assumption of a dynamic process of on-going legislative changes corresponds with the notion of a progressively changing legislative infrastructure in Central and Eastern Europe. A brief recapitulation of previous reform experiences may explain this correlation.

In the early 1990s the pace of change can be roughly characterized by the image of a "fresh breeze blowing from the West" defending radical market-oriented changes. The following quotation expounds that philosophy: "*The countries of Eastern Europe would do well to import Community legal and regulatory frameworks. The advantages of a ready-made framework are clear: it has been tried and tested in a modern market economy; it is compatible with Community legislation and regulation; it ensures a degree of consistency among the East European countries; and it can be adopted with a minimum of delay; averting the enormous amount of administrative and parliamentary time required to prepare and process new laws and enabling legislation.*"[10] This conception of law was based on disillusionment with the functioning of previous structures and institutions, distrusts towards authorities and an unrestrained trust in "Western" concepts as parliamentary democracy and market economy. Nonetheless it was sharply criticized by Stark stating: "*a new social order cannot be created by dictation*". This notion applies not only for economic and political institutions, but also for the law'.[11] Following Stark's statement, instead of economic growth abruptly "transplanting" Western market models it had catastrophic effects in most Central and Eastern European countries such as rapidly increased unemployment, hardly controllable inflation rates, and a collapse of the gross national product. "Even a selective compilation of different Western laws offers no guarantee that this artificial-created legal product will be compatible with the legal and day-to-day practices which held sway in the states that until recently were still socialist." [...]. The current legal expansion in the direction of Eastern Europe displays two weaknesses, which has characterized the "law and development" movement: inadequate theoretical underpinnings and insufficient research on the conditions of transfer and reception of law. Theory must be capable of adopting a critical attitude *vis-à-vis* the intrinsic

---

[10] "The path of reform in Central and Eastern Europe", *European Economy* 1991, Iss. 2 (special issue), EC Directorate-General II, p. ix, quoted by Armin Hoeland. The Evolution of Law in Central and Eastern Europe: Are we Witnessing a Renaissance of Law and Development? in: European Legal Cultures. V. Gessner, A. Hoeland and C. Varga (eds). Dartmouth, University Press, Cambridge 1996: 483.

[11] S. Stark. Path Dependence and Privatization Strategies in East Central Europe. *East European Politics and Societies* 1992, Iss. 6: 19 and Hoeland *o.c.*: 483.

weaknesses and limits of the modernisation formula of a market economy and a state governed by the *rule of law*.[12]

Previous experiences in health care system reforms

From a legal point of view, health care system reforms have frequently been insufficiently underpinned.[13] Exemplary are the observed difficulties during the (abrupt) introduction of a compulsory premium-related health insurance system, large-scale decentralisation and privatisation in several Central and Eastern European countries.[14] These legal reforms failed to ensure a more efficient and effective ordering of resources, undermined access to and the quality of health services and public health measures available to the public. This development may have a direct negative effect on the health status of the general population, which will increase the need for health care. Demographic developments and the introduction of new medical technologies will strengthen those needs. Thus, besides a country's economic strength,[15] deficiencies in legal reforms also affect the health situation of the population. This trend would be further exacerbated by an increase in the real prices for pharmaceuticals and other consumables sensitive to exchange rate fluctuation and/or subject to price liberalisation.[16] Such experiences have occurred in the Czech Republic

---

12 Hoeland *o.c.*: 484.

13 A.P. den Exter, H.E.G.M. Hermans (eds). The Right to Health Care in several European Countries. Kluwer Law International, The Hague 1999: 170-2; A.P. den Exter, H.E.G.M. Hermans, E.H. Hulst. Health Care Legislation in Central and Eastern Europe. A Problem-Oriented Method of Legal Analysis of Health Care Systems in Central and Eastern Europe. The Albanian Example. *Rev. CEE Law* 1997, Iss. 2: 117-132.

14 *C.f., e.g.*, T. Sinuraya. Decentralisation of the Health Care System and Territorial Medical insurance Coverage in Russia: Friend or Foe? *EJHL* 2000, Iss. 7: 15-27; A.P. den Exter. Health care legislative reforms in Armenia: preparations for a purchaser-provider split. *Medicine and Law* 2000, Iss. 4: 655-661; A.P. den Exter. Legal Reforms of the Polish health care system in view of accessing the European Union *EJHL* 2001, Iss. 1: 5-25.

15 Whereas upward trends in unemployment and consumer prices have a direct negative effect on the health service expenditures in Eastern European countries since health service expenditures per head primarily depend on the economic strength of a country. Majnoni d'Intignano, B. Health Care Financing in Europe. Health Care Reforms in Europe (proceedings of the first meeting of the working party on health care reforms in Europe), Madrid, 1992. World Health Organization, Regional Office for Europe, Copenhagen, Doc. ICP/PHC 210(C)BD, quoted by Zarkovic G, Mielck A, John J Beckmann. Reforms of the Health Care Systems in Former Socialist Countries: Problems, Option, Scenarios. Medis Institut für Medizinische Informatik und Systemforschung 1994: 31.

16 E. Goldstein, A.S. Preker, O. Adeyi, G. Chellaraj (eds). Trends in Health Status, Services, and Finance. The Transition in Central and Eastern Europe. World Bank Washington, Technical Paper No. 341, 1996: 3.

(1992),[17] and to a limited extent, also in Hungary (1993).[18] The disappointing outcomes of massive deregulation and funding experiences resulted in a reconsideration or postponement of sudden and substantial legislative changes. At the present moment, Central and Eastern European countries seem more guarded about duplicating (elements of) existing models fearing they could transfers western problems in these countries.[19] A more progressively introduced system change would seem to be more advisable. Such a concept may include several stages of reform according to the following scenario.

Initial reforms

An extensive analysis of the content of the reform stages is far beyond the scope of this chapter. Here, several elements will be briefly discussed, since they affect all aspects of health care. Most important is the concept of the gradual introduction of legal changes.

The concept of a gradual change to the system implies innovative legal changes that correspond with the underlying notion of a step-by-step modified health care system. Instead of losing the good parts of the system along with the bad, changes to the legal structure should be aimed at maintaining the successes of a universally accessible health care system while using western understanding to create a system more responsive to individuals' needs and, simultaneously, initiating economic incentives that encourage cost efficiency. This concept implies a critical reflection on both former experiences and future legal changes. Instead of enforcing massive breakthroughs, a series of correlated incremental changes of the legislative framework seem to be more appropriate coping with the unavoidable adjustments.[20] In view of the overall trend towards a more market-related health care system, legislative reforms may start with (relatively) minor

---

17 During this time the state budget available for health care was transformed into a compulsory premium-based health insurance plan. Deficits in collecting premiums and control mechanisms, as well the high premium percentage, the high unemployment jeopardized the solvency reserves of various health insurance funds. Hence, deficits of the health insurance funds have necessitated national government to step in to prevent bankruptcy. K. Kissimova-Skarbek. Health care reforms in the CCEE/NIS. European Health Policy Conference: Opportunities for the Future. Conference Proceedings 5-9 december 1994 Iss. V World Health Organization, Regional Office for Europe, Copenhagen, 1995: 232; E. Tragakes. Issues of Spending, Health Insurance and Efficiency *o.c.*: 69.

18 Experiences with the replacement of global hospital budgets in Hungary into performance-based diagnostic related-groups threatened to cause bankruptcy, which was avoided by strict budget-capping mechanisms.

19 M. Cesen, V. Mocnik Drnovsek. The process of health legislation reform in the Republic of Slovenia. *EJHL* 2000, Iss. 1: 73-84.

20 A.P. den Exter. Conceptualising a Model of Health Care Law-Making: Relevance to Central and Eastern Europe by Exploring Hungarian Reforms. *AJH* 1999, Iss. 1-2: 67.

adaptations in strengthening the public health sphere including organisational, allocative changes in health care services (*e.g.*, redistribution of collective and individual health tasks, establishing health promotional and disease preventive activities at county and local level). In this respect, given the future enlargement of the European Union, participation in the health action programmes or other (incentive) measures based on Article 152 EC Treaty can be transposed into national health [care] law.[21] Other relevant documents concern, *inter alia*, EU Council recommendations related to public health.[22] These documents directly refer to national measures including legislation in the field of disease prevention, information, maintenance of and, if necessary, the development of high quality of care. Here, (future) members are encouraged to improve the health status and public health conditions that are below fixed minimum standards. Such regulative reforms may function as a precondition for a gradual shift towards a public/private funded insurance system since many Central and Eastern European governments have given preference to this type of financing method above the chronic deficiencies in the contemporary health care funding system.[23] Combined with allowing private physicians to act as independent contractors to health financing agencies with newly introduced reimbursement mechanisms, more and more the government will withdraw from the organisation, provision and finance of health care. Additional financial resources, as well as cost effectiveness of their utilization, could be raised by combining various methods of funding. After all, the introduction of new financing methods does not *a priori* conflict with the previous national health care system.

Restructuring the health care organisation is one of the main aspects in the overall reforms. Interesting experiences have occurred in countries characterised by a "classical" NHS model. Governments are making or have intended to make the health care system more competitive by retaining public funding.[24] The purpose of these reforms is to make resource allocation in health care more efficient, more innovative and more responsive to the consumers' preferences. The separation between the purchaser and provider of health care was an essential element in the

---

[21] J. Dommers, Agenda 2000 and the Role of Public Health in Applying for EU Membership. *EJHL* 1997, Iss. 4: 315-319.

[22] *E.g.*, recommendation of the Council 92/442/EEC, Off. J. of the EC No. L 245 26.8.1992.

[23] E. Goldstein, e.a.: *o.c.*: 24, also: M Beckman, Zarkovic G. Transition to Health Insurance in Former Socialist Countries in: The Process and Management of Change. Transition to a Health Insurance System in the Countries of Central and Eastern Europe. Proceedings of the second meeting of the working party on health care reforms in Europe. Essen, Germany, 19-21 October 1993: 8

[24] G. Fattore. Cost Containment and Health Care Reforms in the British NHS in: Mossialos and Le Grand, *supra* note 70, chapter 3: 733 *et seq.*

reform strategy. As far as the split of primary care services is concerned, many Central and Eastern European countries are already familiar with this concept. Primary care providers function as gatekeepers to second-line services such as specialist care and hospital care. Strengthening their position can improve efficient care.

A further step is to make primary care providers financially responsible for (part of) the cost of follow-up care provided by others to their patients.[25] In this respect, several European forms of "budget holding primary care centres" already have experience with financial responsibility for purchasing some second-line care (*e.g.*, Russia, Leningrad; Sweden, Bohus).

The purchaser-provider split can rather easily be realised by introducing a kind of contract model. In such a scheme (groups of) general practitioners, dentists, pharmacists, *et cetera* work independently and are contracted by a third-party purchaser (*e.g.*, health authority or insurer) who acts as a prudent buyer of care on behalf of its members, whose terms are negotiated by representatives of the profession. Part of the contracting of providers concerns the negotiations on the quality, volume and price of care. It is assumed that selective contracting by third-party purchasers will initiate competition among providers. At a latter stage, contracts with other providers (specialist care and institutional care) could then be a natural complement to these contracts and in fact could then be supportive to the conditions agreed upon in the contracts between purchaser and the primary care physicians.[26] Where agreement is not forthcoming, the government can use its legal power to impose a contract. Conversely, the contract gives rise to private law rights, and providers can bring actions for breach of contract if payment is wrongly withheld.[27]

The trend of a system of public financing (*e.g.*, general taxes, earmarked taxes, compulsory insurance premium) combined with a system of contracts between providers and third-party purchasers of care reflects a shift away from a vertically integrated system towards a separation of the purchaser and the providers of care, who have to conclude contracts with each other.[28] The initiated measures (also characterised as "managed competition") are intended to enhance efficiency and innovation while preserving equity in an altered framework of publicly operated health care systems.[29]

---

25 W.P.M.M. van de Ven. Market-Oriented Health Care Reforms: Trends, and Future Options. *Soc. Sc. Med.* 1996, Iss. 5: 656-657.

26 Van de Ven *o.c.*: 658.

27 J. Montgomery. Health Care Law. Oxford University Press 1997: 106-107.

28 Van de Ven *o.c.*: 656.

29 The prototype model of managed competition was developed by Enthoven as an alternative to the fragmented, inefficient inequitable U.S. health care system, in which unmanaged competition had resulted in an expensive and uncontrollable medical arms race. A.C. Enthoven. Consumer Choice Health Plan, *New England J Medicine* 1978, Iss. 298: 650, 709.

Through introducing competition between providers (and/or third party purchasers), consumer choice, open bidding, negotiated contracts or physician performance incentives, participants are forced to compete with each other. The increased competition that arises among providers, institutions or insurers forces them to be more efficient and to improve the quality of care provided by taking greater account of patient needs.[30] Despite the presumed attractiveness of managed competition concept, a major legal dilemma concerns the scope of health services to which patients are legally entitled. Such entitlements may conflict with the objectives of the managed competition reforms to encourage cost effective substitution of care and to increase consumer choice.[31] Encountering an appropriate definition of health care (and thus the benefit package) combined with sufficient room for managed care and attractive for alternative methods health care delivery creates another dilemma.[32]

To deal with such dilemmas will be one of the main issues that may occur in the suggested strategy. In the short term, legislative incentives that initiate the provider-purchaser split should anticipate the described problems. Concomitantly, developing a more competitive health care system necessitates the reconsideration of quality control measures (services, manpower) in order to increase the deficient quality of health services, low standards, poor equipment of health facilities, and dissatisfaction of health personnel. Furthermore, quality incentives will necessitate the (re)formulatation of patients' rights (free choice of provider, insurer).

For the moment, it can be concluded that current Western reforms strategies with, for instance, separate (financial) resources for separate services packages offer interesting opportunities to Central and Eastern European health care reforms.[33] However, introducing comparable incentives require a basis in the legal systems as they now stand. This means that the contemporary legal structures are not automatically incompatible with suggested new initiatives. But the legal conditions among which the transformation of the current regulative structure should occur, require a critical analysis of the underpinning health care legal concepts.

---

30 E. Tragakes. Health care reforms in the CCEE/NIS: issues of spending, health insurance and efficiency in: European Health Policy Conference: Opportunities for the future. Copenhagen, 5-9 december 1994, Volume V: 71.

31 F.H. Schut, H.E.G.M. Hermans. Managed Competition Reforms in the Netherlands and Its Lessons for Canada. *Dalhousie Law J.* 1997, Iss. 2: 441.

32 Schut and Hermans *l.c.*: 441.

33 See, for instance, H. Hermans, J. Nooren. Contracting and the Purchaser-Provider Split in Western Europe: A Legal-Organizational Analysis. *Medicine and Law* 1998, Iss. 2: 167-188; C.M. Flood. International Health Care Reform. Routledge, London 2000: 174-199.

Towards a pluriform health insurance system

At a latter stage, the hybrid finance scheme will more and more substitute elements of the NHS system in a mandatory health insurance model. This includes generating additional financing mechanisms to provide extra funding, since the often unbalanced compulsory insurance scheme cannot guarantee (near) universal health care by itself. In Central-Eastern European countries, voluntary insurance, just as other cost-sharing modalities, has been considered a promising mean of providing additional revenues for non-essential care excluded from statutory insurance.[34,35] In any case, a restricted private scheme conditionally offers the better-off the possibility of opting out of the statutory insurance scheme and to insure themselves additionally and/or exclusively with a private insurer. "Where voluntary insurance is available in Central and Eastern Europe [...], it currently provides only a small proportion of the total health care financing. It is, however, a source of financing that may grow significantly as institutional and regulatory frameworks are developed and the transition to new funding mechanisms progresses."[36]

In order to remove major impediments to competition among (private) insurers, an effective anti-cartel policy should be supported based on the analogy with article 81 and 82 (ex arts. 85 and 86) of the EC Treaty. Measures to introduce competition among social insurers are highly controversial, in so far as an entirety can be characterised as a system of social security. It is generally accepted that Community law has no direct influence on the organisation of a health insurance. Although member states are free to establish their own system, *inter alia*, the introduction of competitive measures is bound by certain barriers and meeting particular criteria as far as the content of the system is concerned.[37] The future enlargement of the European Union with several Central and Eastern European countries will have considerable consequences for health care system reforms. All four markets relate to the health field: goods (*e.g.*, pharmaceuticals), services (*e.g.* private health insurance), labour (*e.g.*, migrating health personnel), and capital (*e.g.*, investing in cross-border

---

34 Such arrangements (although in an embryonic stage) can already be found in several CEE countries: *e.g.*, the Czech Republic, Slovakia and Slovenia.

35 Cost-sharing is a form of splitting the costs of health care services in order to make users economically responsible for their behaviour. However, in the Central and Eastern European setting its primary aim is to raise the revenues.

36 R.B. Saltman, J. Figueras (eds). European Health Care Reform: Analysis of Current Strategies. WHO regional Office for Europe, Copenhagen 1997: 133.

37 H.E.G.M. Hermans, I Tiems. Convergence in the Dutch Health Insurance: Possibilities and Obstacles in a European Perspective. *EJLE* 1997, Iss. 4: 371-388.

facilities) and the effects of EC standards and regulation need, therefore, to be considered carefully in adjusting system reforms.[38]

Furthermore, the introduction of competition would also require new legislation on the methods of remuneration to providers. Instead of receiving fixed salaries, a fee for service payment system to physicians, as well as other personnel of health services is a possible option.[39] The remuneration of hospitals can be funded by budgets based on a number of calculated variables and norms, *viz*, number of beds, diagnosis related groups (DRGs), lump sum per diem, *et cetera*. Nonetheless, such innovative cost containment and cost-efficiency measures are strongly related to the number of hospital beds and physicians. Compared with the numbers in established market economies, the amounts in Eastern Europe are excessive. World Bank report figures show that the ratios of physicians and hospital beds exceed the figures in established market economies.[40] In order to lower costs, reduction in the surplus of physicians and hospital beds is an extremely difficult but necessary condition. On the other hand, the call for raising the extremely low and unsustainable remuneration levels of doctors to acceptable levels will increase, although it is not realistic to expect that doctors' remuneration to be raised to acceptable levels in the absence of very substantial cuts in the number of doctors. The belief that doctors' salaries can be increased while maintaining or slightly reducing their numbers is a fantasy which goes hand in hand with another fantasy that health insurance systems can increase the total funds for the health care under the current socio-economic and political climate.[41] Changing only the system of health care financing without changing the structure of health care services, and without reconstructing the entire socio-political framework of the health care system, would probably only make worse the existing crisis of the health care system in former socialist countries.[42]

When the number of self-employed health professionals increases, improving the countervailing power of individual physicians with respect to the contracting funds will also need further regulatory attention. Here, the government could stimulate certain legislated self-regulatory activities of professional organisations (tariffs, quality of care and efficiency-incentives, *et cetera*).

---

38 See also chapter 8.

39 During the last few years, several Central and Eastern European countries have already changed the methods of remuneration of providers (*e.g.*, Czech Republic, Hungary, and Slovenia), at least for the physicians in private sector.

40 World Development Report 1993. Investing in Health. Washinton DC. WorldBank 1993; UNDP, Human development report 1993. New York. Oxford University Press 1993.

41 Tragakes *o.c.*: 68.

42 Zarcovic *o.c.*: 18.

Reforming the health care financing mechanism, combined with organisational changes and decentralisation tendencies are without doubt important tools in reforming the health care system. However, the increased necessity to contain costs and improve efficiency will further pressurize the rights of patients. With all respect to the existing codes of deontology and professional ethics, they cannot substitute patient rights legislation, however valuable these codes may be for training health professionals. The existing legal codes showed serious lacunas in regulating patients' rights. Besides the rudimentary confidentiality of medical data, other provisions concerning newly developed rights hardly existed. Such deficiencies in legal background are illustrative for the rather paternalistic approach towards patients in most Eastern European countries.[43] Protecting patients' rights therefore impel the legislature more then ever before to develop or modify the contemporary codes in a more sophisticated framework of (new) patients' rights including the inviolability of the human body, informed consent, disclosure, correction, and removal of data recorded by different types of information systems.

Since the early 1990s, patients' rights have become a main issue in medical practise and government health policy (*e.g.*, choice of provider). Harmonisation of health care legislation with international and European standards has made, and is still making, visible progress. Elementary rights as informed consent, disclosure of medical files, *et cetera,* gain in importance or were already codified. A weak point, however, is the rather *ad hoc* approach in which patients' rights are translated to legislation. Here, (inter)national instruments may offer a useful contribution in achieving a coherent legal infrastructure that guarantees that patients are treated with respect, dignity and humanity and affirming the principles in the patient-physician relation.[44]

---

[43] Several Eastern European scholars have subscribed this statement, for instance in Hungary: A. Dósa. New legislation on civil commitment in Hungary. *Medicine and Law* 1995, Iss. 3: 582; B. Blasszauer. The Old Medical Ethics meets the new. *Hastings Center Report*, June 1986: 25-27. In Poland, prior to 1991, except for the Collection of Ethical and Deontological Principles of the Polish Medical Society, legislation did not take a position on the need to inform the patient of the condition of his/her health. Consequently, the extent of information passed on to the patient depended on the doctor's own judgement. The patient had no access to medical records and the right of confidentiality had somewhat been obscured under the influence of the existing medical practice. M.E. Sokalska. Editorial, *EJHL* 1994, Iss. 1: 324. Rather staggering results of an inquiry among Polish patients confirmed the still subordinate position of patients' towards health professionals (Najwyzsza izba kontroli, Departament Zdrowia i Kultury Fizycznej, Informacja o Wynikach Kontroli Przestrzegania praw Pacjenta. Warszawa, Styczen, 1997. No. ewid. 73/96P/96/095).

[44] *Cf., e.g.*, the Amsterdam Consultation on Patients' Rights (1994) and the Ljubljana Charter on Reforming Health Care in Europe (1996).

Further elaboration of a risk-related insurance model

By (re) defining a framework of patients' rights the gradual withdrawal of the government in health care will emerge the dilemma of guaranteeing these rights. Notably, as far as the finance is concerned, a more risk-related insurance system will inevitably impel limiting access to health care. Modalities of such more risk-related elements concern the different cost-sharing mechanisms such as co-payments and external sources that will be or have already been introduced (co-payments, co-insurance, and external sources (loans or grants).[45] Consequently, comprehensive and free access to health care cannot be entirely guaranteed in the long-term.

A comparable shift from a declining share of public to private funding has been noticed in EU countries. Patients in many countries have experienced substantial cost-sharing increases as a result of higher charges. Indeed, this seems to be an important component in the shift of the public-private mix in these countries.[46] For the moment however, the introduction of such measures in Central and Eastern European countries is a matter of heated controversy, since certain patients' categories (*e.g.*, lower income groups and the chronically ill) have often worse health and/or need more drugs than the better off. This raises the issue of equity and questions its legitimacy as such. Besides, limiting access by introducing types of cost-sharing measures can also conflict with international accepted standards as the ILO Conventions and the European Code.[47] For the moment, it is uncertain how the judiciary in Central and Eastern European countries will cope with this issue. Acceptance of the binding effect of ILO Conventions may pose a serious threat to proposed or already accepted types of cost-sharing measures.

---

45 I.e., a provision of health insurance or third-party payment that requires the individual who is covered to pay part of the cost of medical care received. This is distinct from the payment of a health insurance premium contribution or tax, which is paid whether medical care is recovered or not (OECD). Cost-sharing is a form of splitting the costs of health care services in order to make users economically responsible for their behaviour. However, in the CEE setting its primary aim is to raise the revenues. I. Sheiman in: Den Exter and Hermans 1999 *o.c.*: 110-111.

46 M. Huber. Health Care Financing in European Union Member States. An Initial Perspective Based on Recent OECD Work on Overall Social Trends in Health Care and its Financing in the Single European Market. R. Leidl (ed) IOS Press Amsterdam 1998: 63.

47 At least in the Netherlands. The Central Board of Appeal concluded that national regulation that imposed an own contribution in case of maternity assistance was a violation of Article 10 of the ILO Convention 102 (CRvB May 29, 1996, RSV 1997/9). Its relevance concerns its compliance with the interpretation of the ICESCR by the Committee. The self-executing effect of treaty provisions may endanger certain types of co-payments. Up to now, it is unclear how the judiciary in Central and Eastern European countries will answer this question.

Despite the potential controversies, recently modified Constitutions already anticipate health care curtailments by law.[48] In the very near future, the legislature has to elaborate considerable restrictive measures in order to guarantee a sustainable health care system. Accepting a framework of patients' rights may therefore have considerable consequences for changing the finance mechanisms and the scope of entitlements. For instance, in order to maintain universal access to *basic* health care to all citizens, the legislature has to define the scope of a basic benefit package of health care entitlements in line with the available resources. In this respect, experiences such as in the Netherlands resulted in the exclusion of different types of technologies (treatment, pharmaceuticals, procedures, *et cetera*) from the basic benefit package, according to a series of "sieves" or filters.[49] Determination of such criteria pre-eminently requires a transparent public debate about the possible and desirable choices and their social effects. Emanated from such a debate, the legislature could formulate clear criteria to determine the basic package of benefits of care.

The example of limiting access to health care and previously mentioned considerations, emphasize that the need for an integral approach of reforming the health care legislative framework is evident. In this respect, the suggested concept of law-making that is based on such an approach of progressively implemented health care reforms may probably function as such a method. Here, law-making is considered as a less directive and more consultative activity, with the involvement and co-operation of all relevant actors: health professionals, purchasers and patients as a pre-requisite to acceptance of legal norms.

---

[48] *E.g.*, article 51 of the Constitution of the Republic of Slovenia (1991) reads: "[e]ach person shall have the right to health care *as determined by statute*. Rights to government financed health care shall be regulated by statute." The Czech Charter of Fundamental Rights, as part of the Czech Constitutional order (1992) proclaims in article 31: "[e]verybody has the right to protect *under conditions set by the law* his/her health. Citizens are entitled under public health insurance to free medical care and to medical aid. While Article 41 (1) of the Charter restricts the claim to free medical care by "*only within the scope of the laws* implementing these provisions".

[49] A.J. Dunning. Report of the Government Committee on Choices in Health Care. Ministry of Welfare, Health and Cultural Affairs, Rijswijk, the Netherlands, 1992. Comparable experiences have been reported in, *inter alia*, New Zealand, National Advisory Committee on Core Health and Disability Support Services. Core Services 1993/94, Wellington (1992); Oregon (USA) Health Services Commission. Privatization of Health Services. A report to the Governor and Legislature. Oregon Health Services Commission, Portland, Oregon (1992); and Sweden. Health Care and Medical Priorities Commission. Priorities in Health Care (1995); No Easy Choices, Ministry of Health and Social Affairs, Stockholm (1993).

4 CONCLUSIONS

The objectives of suggested legislative reforms in transition countries have been determined in accordance with national priorities in the light of the socio-economic context. Despite the diversity of that setting, the framework of universal legal qualities of health care law may function as a normative mechanism, which provide minimum obligations to the legislature and concomitantly operationalise (the strategy of) legislative actions progressively.

One of the model's main elements in the decision-making process includes monitoring and evaluating the legislative consequences which may result in further modification of current legislation. This process emphasises the interdependence between the discerned clusters of health care law-making and thus impel a well-considered and consistent strategy of law-making. Certainly, the method cannot remove all the imperfections of the transition processes. The unpredictability, the complexity of the process and multitude of participants and their agenda's may put into perspective the potential value of such a method, but it can nonetheless contribute to a better understanding of legislative activity.

As far as the direction of intended health care reforms in most Central and Eastern European countries is concerned, the described method starts with relatively minor legal changes of the legislative structure. A partial restructuring of the existing national health care system, while retaining its benefits has certain advantages above the uncertainties of a complete shift towards a comprehensive compulsory insurance system. The modifications may start with the improvement of the quality and organisation of an often heavily regulated and insufficiently equipped public health sector (environmental and communicable disease control functions, health promotion and education, *et cetera*). As far as the financing of health care resources is concerned, the assumed concept does not reject the current tax-based system in advance. It rather supports the notion of improving current financing mechanism combined with progressively introduced market incentives such as a contract model with an additional premium-based finance system and restricted to certain services. In this respect, reforming the financing legislation could utilise useful competitive elements, measures to improve cost containment and quality of care as experienced in traditional NHS countries. Subsequently, at a latter stage, the final shift towards a comprehensive health insurance system can be considered including cost-sharing strategies.

Needless to say, as the transition process continues changed circumstances require a perpetual modification of obsolete norms and impel newly developed legislation. As a consequence of the growing complicated relations in the health care arena, legislation will be more complex.

Continued shrinking economies and/or increasing health care expenditures will lead to consider more profound reforms of benefits instead of relatively uncontroversial, nonessential services (*e.g.*, cosmetic surgery). Further limitations of the basic coverage scheme will be unavoidable but will, nevertheless lead to strong inequities while undermining the principle of solidarity. To cope with this dilemma the underpinning legal principles function as minimum obligations to be respected. They express fundamental values and, as such, operationalise the legislative (reform) strategy. In more concrete terms, this implies access to a certain level of health care services and facilities to be guaranteed for the entire population, while above that level, efficiency and effectiveness motives may initiate further legal reforms. In this respect, Aristotle's proportionality claim can justify a further differentiation in access to health care. The relevance of the theoretical model is that both the guarantee and the instrumental qualities of the law are included. An analytical construction that is based on a circular concept of law-making and which attempts to rationalise decisive considerations in the legislative process.

Part Two

The relevance of the law-making model in Central-Eastern Europe: A three country analysis

GENERAL INTRODUCTION

The adoption of the "Health for All by the Year 2000" (HFA) agenda by the World Health Organization initiated world wide the launch of government strategies targeted at fulfilling this ambition.[50] In the European region, such strategies have centred on the pre-requisites for good health, including health protection, disease prevention, health promotion, equal access, quality of care, and other (in) directly related conditions. As regards the legal conditions supporting this strategy, it is questionable in what respect national governments have succeeded in realising the targets of the HFA strategy. Too often, regulative mechanisms have been considered as instrumental means to justify policy objectives. Apart from this "mechanical", or instrumental approach, legislation has primarily a normative, notably guaranteeing function (e.g., safeguarding access to health care). The diversity in qualities characterises the dynamic approach of law-making, *viz*, anticipating future changes initiated by societal developments. As such, legal norms express fundamental values, which provide a frame of benchmarks that substantiate the opted health policy strategy. Particularly in the case of radical system changes, and therefore transforming the legal structure, both the instrumental and normative perspective of law-making are of importance. Overemphasising the instrumental standards harms the normative dimension of health care legislation. A more balanced legislative strategy, which simultaneously attempts to increase the consistency and transparency in the legislative decision-making, may contribute towards nullify the legal deficits. To develop such a strategy, in part one, a theoretical method of law-making has been developed.

Part two, in turn, attempts to verify whether such a dynamic method is applicable to the legislative practise. Therefore, this part of research begins with a description of the main features of the legislative framework in three selected countries in Central and Eastern Europe. The examined legal norms will be classified according to the discerned clusters of health care law since they correspond with the law-jobs in health care (Roemer, 1980). From the legal documents available, it should be possible to examine the state of law-making practise on health care and whether it corresponds to the typology of clusters of health care law (comprehensiveness). The transformation of the health care legal system requires leading constitutional principles that provide normative standards to justify, direct and review this reform process. The developed conceptual approach could help to identify possible deficiencies in the current legal framework and, subsequently, enable an analysis of legal problems and shortcomings from

---

[50] Global Strategy for Health for All by the Year 2000 launched by the 32th World Health Assembly in 1979, based on the Alma-Ata report and Declaration.

the underpinning analytical framework and suggest proposals for legal decision-making in a more rational manner (effectiveness).

In addition, the comparison of the main stages of the *actual* legal decision-making process with the *analytical* method of law-making may contribute towards verifying the validity of the hypothesis, *viz*, a rational model of health care law-making to review the process and content of legislative reforms. Therefore, the subsequent chapters examine the possible pattern in the method of law-making in the selected countries. After all, such a pattern (e.g., targets, problem analysis, identifying and selecting mechanisms for improvement, implementing changes, evaluation results, modification strategy and practise), enables structuring and falsify the decision-making process. For instance, what are the underlying objectives *c.q.* principles; were they placed in a priority order; if so, were they publicly accepted? Furthermore, have current regulatory measures, alternatives been sufficiently analysed? Defining and implementing the legal measures, are the enforcement procedures adequate to effectuate the legal norm; are the results systematically being reviewed; did this result in updating legislation, previous targets and/or strategy objectives? The legal decision-making process will be reviewed whether it corresponds with the concept of the analytical model. In case of a positive correlation, it could be the basis of a more systematic approach of legislative problem-solving. For instance, the discerned patterns in the decision-making process enable the anticipation of possible conflicts and provide a structured and rational concept of law-making.

The examined legal systems include those of Hungary, the Czech Republic and Poland. These countries have a leading role in Central-Eastern Europe in initiating health care reforms, notably the introduction of a "western"-orientated health care system. The manifested legal problems are therefore more urgent than, but also exemplary of, the difficulties in less developed countries in this area, such as Bulgaria and Romania. Moreover, these countries will be the first to access the European Union. Since the ratification of the Europe agreements (1993-1995), these candidate Member States have embarked on national legislation approximate to Community law in an early stage. EU accession imposes, *inter alia*, the incorporation of the "health acquis" and the harmonisation of the "internal market" law. To cope with the magnitude and complexity of Community law, the analytical model could provide a valuable instrument in structuring and analysing law-approximation as relevant to the health care reform process. The incorporation of Community law is the subject of an extensive review in part three. Part two, however, focuses primarily on domestic legal reforms.

CHAPTER 5: HEALTH LEGISLATION IN HUNGARY

1 INTRODUCTION

This chapter starts by examining the main features of the legal framework of the Hungarian health care system since the reforms began in the early 1990s. Analysis of the current stage of legislation (section 2) enables the positioning and ordering of the legal reform strategy; whether there are parallels with the discerned clusters of health care law is dealt in section 3. Besides the clusters of health care law, the law-making model as developed in part one reflects the stages of law-making activity. Therefore, the final section (section 4) will examine the relationship between the analytical method of law-making and the actual legislative process. The theoretically discerned stages of law-making will be used to reveal and analyse possible developments in law-making and, subsequently, to formulate normative statements about the underlying strategy as well as its contents. Such statements may confirm the relevance of the theoretical model in the law-making process and function as a first indication of the model's validity.

The analysis is restricted to four selected clusters of health care law which have faced substantial changes, *i.e.*, public health, the organisation and planning of health care resources, health financing and patients' rights. Since the main legal changes have been introduced by parliamentary acts, the analysis excludes a large number of derived regulations.

2 SOURCES OF HEALTH LAW

2.1 Historical background

A major landmark in the Hungarian post-war history was the first freely elected parliament, which acceded to office in 1990. As such, Hungary did not differ from other Central and Eastern European countries which faced similar political reforms. Institutional reforms can be characterised by the introduction of the *rule of law*, democracy and respecting human rights. Hungary, however, is one of the countries in the forefront of institutional reforms. What discerns Hungary with other countries in this region is its legacy, the era of "goulash-communism".[1] This phrase reflects a kind of "enlightened" communism, *i.e.* experimenting with a socialist market mechanism unique in this hemisphere. New economic reforms introduced

[1] Which was certainly preferable to gulag communism.

in the late 1960s and accelerated during the 1980s, led to remarkable progress in establishing a basic legal and institutional framework for a market economy. Later, in 1987, it was stated that radical political reforms were needed. The ruling communist party therefore initiated the first steps towards democratisation of the government system. Key elements of the political reforms include the independence of parliamentary deputies and gradually decreasing the role of the Presidential Council which characterised the shift from "government by decree" towards a parliamentary system.[2]

These developments occurred prior to the transformation of the political system in 1989-1990 and meant a substantial modification of the written Constitution of 1949 which was still in force at that time. The last revisions are often referred as the "new" Hungarian Constitution since the initiated reforms resulted in amending nearly eighty percent of the former Soviet based model.[3] It meant a virtual and radical shift with a past in which the Communist Party had absolute and undivided power. Following the establishment of the first democratically elected government in 1990, the reform process of separation and balance of power was further accelerated.

This does not mean that the transition process was not problematic. On the contrary, particularly the proactive role of the newly established Constitutional Court caused serious conflicts with both the legislative and administrative powers.[4] Furthermore, lacking experience in drafting legislation, absence of a coherent strategy for legislation, and paralysed decision-making resulted in severe deficiencies in its outcomes. Nonetheless, it appeared that the basic legislative, judicial and administrative institutions have been established. As a consequence, the institutional reforms seem to be largely completed. At the moment, the main legal challenges concern the *democratisation* and *modernisation* of legal mechanisms.

---

2 L. Vass. Changes in Hungary's Governmental System in: The Emergence of East Central European Parliaments: The First Steps. Á. Ágh (ed.) Hungarian Centre of Democracy Studies Foundation, Budapest 1994: 186-187.

3 Promulgated by Law No. XXXI, 1989. As stated in the pre-ambule, this document is intended as a "transitional" Constitution.

4 J. Pataki. The Constitutional Court's search for Identity, Report on Eastern Europe June 21: 7, quoted by: C.W. Gray, R.J. Hanson, M. Heller. Hungarian Legal Reform for the Private Sector. *George Washington J. International Law & Economics* 1992. Confirmed by A. Sajó. How the Rule of Law Killed Hungarian Welfare Reform. *EECR*, special report, Winter 1996: 31-41. In "Wirtschaftliche und soziale Rechte in Ungarn", László Sólyom, president of the Hungarian Constitutional Court, defends the changed attitude expressed in the Court's rulings by referring to the *rule of law*-argument as interpreted by the German and Italian Constitutional Courts, respectively the Bundesverfassungsgericht and Corte Constituzionale. J.A. Frowein, T. Marauhn (eds). Grundfragen der Verfassungsgerichtsbarkeit in Mittel- und Osteuropa. Berlin, Springer, Band 130, 1998: 223-224.

Historical reforms in the field of health care can be divided in three areas, *viz*, the period prior to the "socialist" period, the period when the Communist Party ruled the country (1948-1989) and the post-communist period.[5]

Prior to the Second World War, Hungary had a social health insurance system largely similar to that in Germany and Austria. It was based on "Bismarckian" principles of compulsory insurance covering certain occupational related social risks (invalidity, sickness and accidents).[6] After the war, this situation changed drastically. In 1948, the Soviet-oriented government introduced a "socialist" health care system, abolishing existing insurance funds and companies, private practises and dissolving and nationalising health care institutions.[7] During this epoque, the Ministry of Health became the dominant actor for the overall co-ordination of health policy, including the planning of health care facilities and services. The "classical" socialist planning mechanism covered a period of five years, planning the means of health care and introducing various reforms. The idea that these plans regulated the health care sector thoroughly is a misconception and, in reality, aspects such as investments and manpower did not go according to the "health care plan".[8] Finally, according to the new Act on Health Care (Act II of 1972), health care coverage became a citizens' right, provided free of charge, albeit there were some exceptions.[9]

After the Communist Party lost the elections in 1989, the need for radical health care reforms became increasingly apparent. A period of transition initiated major changes of the health care system. Reforms concern, *inter alia*, the transferral of the ownership and responsibility of health care facilities to local authorities by the Act on Local Governments (1990). Simultaneously, the Social Insurance Fund Administration, responsible for the collection of premiums for health care and old age pensions, started to operate as a quasi-autonomous government agency. In 1992, the Health Insurance Act separated the Social Insurance Fund into two separate funds, apart from the national budget. As such, the financial

---

5 L. Gulácsi. Hungarian health care in transition. Studies on the improvement of the effectiveness of health care in Hungary by implementing quality assurance. University of Amsterdam (Dissertation) 2001: 35.

6 In 1870, the General Fund of sick and disabled workers was established, and Act XIV of 1891 introduced a compulsory insurance for industrial workers, followed by agricultural workers. The poor were covered by a National Fund of Patient Care that was established in 1898 and which reimbursed the health care costs for the poor. Gradually, newly established funds extended the *ratione personae* (personal scope) and the *ratione materiae* (social risks).

7 The "socialist health care model was also known as "Semashko-model", that abandoned the insurance principle, *supra* note 69, chapter 3.

8 Gulácsi *o.c.*: 36.

9 Such as the prescription of pharmaceuticals, for which patients had to pay an own contribution. Gulácsi *o.c.*: 34.

sources of health care and old age pensions were changed from taxes to compulsory premiums, financed by employers and employees. Other major reforms during this era concern the modernisation of public health, the introduction of general practitioners and newly defined patients' rights legislation. From a legal perspective, the reforms can be based on the constitutional right to health care.

2.2 A constitutional right to health care

After the first free elections, Hungary has faced major political and legal reforms. A general point of criticism concerned the plethora of laws introduced by the Hungarian parliament. The new Hungarian parliament had been working as a "law factory".[10] In general, this might be the case, however, where health care legislation is concerned, the situation is less clear. Health care legal reforms were not a priority on the political agenda, notably in the early 1990s. This situation has, however, changed rapidly during the last few years for various reasons. Worsening morbidity and mortality rates, alarming quality of services, overcapacity of (human) resources, financing problems and hardly controllable expenditures imposed radical system reforms, and on its legal basis.[11] It became clear that ideas of pluralist democracy and "marketisation" would also affect the health care sector. Inspired by primarily "Western" concepts, in 1995 the government presented an ambitious health care reform program.[12] Leitmotiv was a constitutionally-based universal right to health care. Article 70 D, adopted from its communist predecessor, states:

> *"Those living within the territory of the Republic of Hungary are entitled to the highest possible level of physical and mental health"* (section 1)

and,

> *"The Republic shall effectuate this right by labour-safety measures, organising health care institutions and medical care, encouraging the possibility of regular physical training and by protecting the developed and natural environment"* (section 2).

---

10 Á. Ágh. Bumpy Road to Europeanization: Policy Effectiveness and Agenda Concentration in the Hungarian Legislation (1990-1993), *supra* note 2, p. 74. For instance, between May 1990 and January 1993 it passed 134 new laws, 128 amendments and altogether voted for 487 decisions.

11 European Observatory on Health Care Systems. WHO Regional office for Europe. Health Care Systems in Transition: Hungary, 1999: 6-8; 27-28; 69-70.

12 Ministry of Welfare. Programme of Health Services Modernisation. Ministry of Welfare. Republic of Hungary, Budapest. October 1995.

Though the Constitution still defines access to health care as a citizen's right, recent legislation formulated such a right in terms of entitlements based on (compulsory) individual insurance contributions. For this reason, the legislature was forced to establish a Parliamentary Committee for the elaboration of a new written Constitution, which would replace the current Basic Law in force.[13] Based on the Committee's draft, a revised version of the health care right reads:

> *"Citizens shall be entitled to health care. Its scope and manner of provision shall be determined by statute".*[14]

In casu, the Health Insurance Act (1997). From such a definition, access to health care services is considered as a social insurance entitlement based on an income related premium instead as a citizens' right. Moreover, the parliament is authorised to limit the nature and scope of services financed by social insurance "*by statute*". Finally, the draft opens the possibility of private (health) insurance schemes.[15] The draft provision corresponds to the changed legal situation concerning the health care right. Notably the possibility of private insurance anticipates future options to differentiate sources of funding.

However, for the moment, Article 70 D remains in force. Though the first section proclaims only a declaratory non-legal enforceable statement to the highest possible level of health, which actually does not exist, section 2 is more important. It reflects a traditionally strong social right to health care almost interpreted as an individual right. It still envisages the socialist conception of free and universal access to health care services and facilities. Although laudable in intent, the strong formulation has created expectations that Hungary is unable to fulfil. The substantial own payments of patients (both formal and informal) already refute the myth of free health care. Up to this time, no legal cases were found in which the judiciary has decided on the discrepancy between the "socialist" notion on access to health care and the reality of co-payments. It remains to be seen how this will develop in the near future,[16] especially when the "transitional"

---

13 This *ad hoc* Committee was established in 1995 by the Parliament, resolution No. 63, 1995. The objective of the Committee was to formulate a draft Constitution, intended to replace the "new" Constitution of 1989. This Committee prepared the document "Conception of the new Hungarian Constitution" containing the principle contents of a new Basic Act.

14 Article 46, section 2.

15 Article 43 section 3.

16 Although Sólyom makes reference of two (unquoted) Constitutional Court cases dealing with limiting *social* insurance entitlements by means of own payments by the insured. In these cases, the Hungarian Constitutional Court adopted similar German and Italian constitutional criteria to review the constitutionality of limiting social insurance based legal entitlements. *O.c.* Frowein and Marauhn, 1998: 223.

Constitution of 1989 remains effective. It can be expected that in the foreseeable future the Hungarian Constitutional Court will focus its attention on social constitutional rights, such as the health care right.[17] In view of the Court's activist position passing unpopular judgements, clashes with the legislature related to the observed discrepancy are not unlikely.[18]

Apart from the Constitution, the broad interpretation of a health care right has been embedded in the legal structure of the Hungarian health care system, a system which is still under construction. In four selected fields of health care legislation, *viz*, public health, the organisation and planning of health care services, the finance of health care services, and patients' rights, substantial changes have occurred. These changes directly influence the meaning of the right to health care. Exploring these clusters enables the elaboration of the contents of a health care right.

2.3 Public health

As in most former communist countries, a Constitutional right to the highest possible care have been incorporated in the legal order by emphasising the role of public health, in particular prevention and protection. Hungary is not unique in this respect.

Mainly due to the WHO's *Health For All in the Year 2000* agenda, all over Europe a shift in strategies can be observed centred on the pre-requisites for good health, including health protection, disease prevention, health promotion, equal access, and quality of care.[19] This development reflects a widening of the public health concept, reading: *"Public health is what we, as a society, do collectively to assure the conditions for people to be healthy. This requires that continuing and emerging threats to the health of the public be successfully countered. These threats include immediate crises, such as the AIDS epidemic; enduring problems, such as the injuries and chronic illness; and growing challenges, such as the ageing of our population and the toxic by-products of a modern economy transmitted through air, water, or food. These and many other problems raise in common the need to protect a nation's health through effective,*

---

17 Apart from interpreting the constitutionality of legal norms, including international agreements, the Court is also authorised to annul parliamentary acts and other regulations that it find unconstitutional. Furthermore, the Court may also review draft laws before they are put to a vote by Parliament (abstract review). The jurisdiction of the Court has been further extended by the possibility of negative review of legal norms (in case of failure to act) and (individual) complaints against a legal norm applied, besides some other competencies.

18 A first indication can be the Constitutional Court's doctrinal acceptance of objective legal government obligations in case of health care and health environment. The next stage could be the acceptance of enforceable legal entitlements based on detailed defined social rights. Constitutional Court ruling 48/1998 (XI. 23) AB, *Magyar Közlöny* (Official Gazette).

19 *Supra* note 1 General introduction part two.

organised, and sustained efforts led by the public sector".[20] This definition imposes on the national authorities specific obligations to improve the health of the population and are primarily codified by public health legislation. Traditionally, health protective and preventive measures and its regulation concern communicable disease prevention and protection of the natural and industrial environment. Nowadays, it also encompasses the fields of mental health, elderly care, occupational health genetic care and its consequences. Besides widening the scope and subject of public health, the nature of intervention has also changed. Today, public health also includes health promotion by means of health education and improving people's health condition. Secondly, providing basic curative and rehabilitative services and facilities as an integral part of community health. Evolving approaches to public health, however, emphasise respect for individual rights; trust between public health personnel and the community, conditions of non-discrimination, and adequate access to health care and education.[21] The question is in what respect an attempt has been made to realise this by legislation. In concrete terms, the evolved concept of public health in Hungary has resulted in emphasising the accessibility and improvement of quality of care health services and facilities. In view of the alarming figures of the epidemiological and demographic situation of the Hungarian population, the need for an adequately functioning and universal accessible framework of community health care resources became evident in the early reform stage. It is assumed that improvement of these services would contribute towards improving community health status and life expectancy.[22] Consequently, one of the first acts on health care concerned public health, establishing the National Public Health and Medical Officer Service (ÁNTSZ).

The Act on National Public Health and Medical Officer Service (ÁNTSZ) Act XI, 1991 establishes the National Public Health Service (ÁNTSZ) and determines its structure and functioning.[23] The ÁNTSZ is a state agency that has been given many new responsibilities in the field of prevention and health promotion. Recently its competencies have been extended to licensing health care providers, professional supervision, setting standards

---

20 Institute of Medicine. The Future of Public Health. Washington DC: National Academy Press. 1988: 19.

21 L.O. Gostin, Z. Lazzarini. Human Rights and Public Health in the AIDS Pandemic, New York, Oxford. Oxford University Press, 1997: 43.

22 Although it is generally accepted that the health status is mainly correlated to factors not directly related to health care services such as life-style (tobacco, alcohol, *et cetera*), environment protection, living standards. Improving the health care infrastructure has a relatively minor impact.

23 ÁNTSZ, Állami Népegészségügyi és Tisztiorvosi Szolgálat.

and accreditation of health care facilities. This agency replaces the former State Supervision of Public Hygiene and Infectious Diseases. The new law stipulates that the management and surveillance of performing public health tasks is a government responsibility, represented by the Chief Medical Officer heading the Service who is appointed by the Minister of Health.

The objective of this act is to provide and guarantee a certain level of uniform and accessible public health services and facilities to all citizens. As such, this act incorporates the underlying notions of prevention of declining health status of citizens, protection and promotion of the human health and to improve the health status expectancy of the community. To realise this objective, the act formulates the following tasks and obligations of the ÁNTSZ, *viz*,

- to formulate public health programmes and supervise their implementation;
- to monitor and evaluate the population's health status and all factors which influence the health status;
- to define health status standards and to monitor their enforcement;
- to perform measures on communicable diseases;
- to organise and carry out vaccination programmes;
- to define recommendations for health nutrition and monitor implementation;
- to provide health education and information (AIDS, drugs, tobacco, *et cetera*), and
- to supervise the quality and supply of pharmaceutical, devices, health care services.

The enumerative summary of obligations and competencies of the ÁNTSZ reflect both the protective, preventive and promotional tasks of the government, which are much broader in its scope of responsibilities. Implemented both on a national and regional and local level, this act incorporates the traditional and new public health functions. Other public health (related) acts, which attempt to operationalise both the preventive and promotional dimension of public health, are successively:

The Act on Labour Safety

Act XCIII, 1993 on Labour Safety defines the conditions of safety at work in accordance with Article 70 D of the Hungarian Constitutional. As such, the act's objective is to protect health and work performance ability during work in organised form, as well as humanising working conditions and thus preventing accidents at work and other occupational diseases (preamble Labour Safety Act). According to this act, several government and ministerial decrees were established, *inter alia*, Decree no. 89/1995 on the Employment Health Services, defining the scope of the employment health

service's competencies, and Decree no. 27/1995 regulating the specialised qualifications of the employment health service.

The Act on Consumer Protection
Besides the labour safety conditions, consumer protection is another aspect of public health. The Consumer Protection Act CLV, 1997 aims to protect consumers' interests, with special emphasis on the safety on goods and services. Therefore, it establishes general legal norms on the safety of market goods and services during its manufacturing, provision or distribution. It further imposes the manufacturer, distributor to provide consumer information about the basic characteristics of the products (instructions for use, hazards associated with its use, quality, price, *et cetera*). In case of a legal dispute regarding the quality or safety of goods and services, product liability, and performance of contract, the case may be taken to the arbitration board.[24]

The Act on Pharmaceuticals
Finally, a major element of public health legislation includes the regulation of pharmaceuticals. The Act on Pharmaceuticals XXV, 1998 regulates the manufacture, distribution and utilisation of pharmaceuticals. It has incorporated a number of European directives into Hungarian law defining the conditions for introducing pharmaceuticals on to the market, conditions for conducting research on human bodies and clinical investigations, and for preparing new drugs. Newly established institutions such as the National Institute of Pharmacy and the National Institute of Hospitals and Medical Technology administer the registration and licensing system.[25] The purpose of the Act on Pharmaceuticals is to ensure that the medicaments, which are officially registered, are available for preventive and therapeutic purposes and answer the defined quality norm.

2.4 The organisation and planning of health care services

The excessive capacity of the Hungarian health care provision system, particularly in the acute hospital care, combined with the failure of adequate measures to fight the increase of chronic diseases, were important reasons to reconsider the overall health care delivery system, notably primary care.[26] Decentralisation and privatisation have appeared as the

---

24 Chapter VI Enforcement of Consumer Rights.

25 Decree No. 14/1990 (IV.17) Ministry of Social Affairs and Health.

26 E. Orosz. Hungarian Health Care System in Transition: economic exigencies – faltering health policy – distrustful public. Workshop National Academy of Sciences/National Research Council Commission on Behavioural and Social Sciences and Education, Task Force on Economies in Transition, Washington DC, september 19-20, 1996: 29.

two main tendencies in the reforms. Important regulative competences have been transferred from central to local government. The withdrawal of the state in regulating health care went hand in hand with the (quasi) privatisation of certain health care services and the establishment of new (often well-equipped) medical institutions. At the same time, a network of family physicians (*háziorvos*) replaced the existing system of general practitioners (GPs) whether or not working in a private practise. Apart from the semantic change, it also included a reorientation on the role of the family doctor, *i.e.* his responsibilities as "gatekeeper", emphasising preventive care and health promotion. Since the legal reforms were mainly focused on restructuring GP and hospital care, the emphasis is on decentralisation and privatisation of these services. According to the new Act on Local Governments, local governments became the key actors in the health sector whereas additional legal norms such as the Acts on the State Budget and Private Practise supported the organisational changes. However, these initiated changes directly affect the planning function as stipulated by the Health Care Act and implicitly the Health Insurance Act. Discussing these legal norms reveals the main legal changes in this field.

The Act on Local Government

Act LXV 1990 on Local Government transfers the ownership, management and responsibility of health care facilities to local governments.[27] The act should assist in decentralising the previous system and increasing its responsiveness to local needs and demands. According to this act, local government bodies are obliged to provide basic health care services (core services) as defined by the Health Insurance Act and derived decrees.[28] They can fulfil their new tasks in different ways, they can:

- use their own institutions;
- purchase the services from other local government institutions;
- provide the services jointly with other owners of institutions, and
- contract any person or institution, which provides health services.

The effectiveness of decentralising competencies to local governments is closely related to the possibility of funding health care expenditures at a local level. Since local governments have little capacity to levy local taxes, they rely on central government transfers – apart from payments of the Health Insurance Fund – for the majority of their funds. However, local governments are free to allocate central funds as distinguished from the Health Insurance Fund operating funds. This led to several problems in health care, threatening equal access to these services. For instance, the

---

[27] In combination with Act CXXI of 1996.

[28] In conjunction with Act XX. 1991 on the Tasks and Sphere of Authority of Local Self-Governments and their Organs.

central budget does not impose any requirements on funds transferred to the local government.[29] As a result, local governments are not uniform in their funding of the health care facilities. Funding often depends on personal contacts between the managers of the facilities and local politicians. The inequalities created primarily concern preventive programmes financed by those funds.

Apart from the decentralisation of hospital facilities and polyclinics to local governments, a second development concerns the privatisation of primary health care, notably general practitioners. The original legal basis can be found in the Act on the State Budget in conjunction with the Act on Private Practise.

The Act on the State Budget

The State Budget Act, XXXVIII of 1992 and Act 156/1995 elaborates the legal conditions for the transfer of property and transformation of (health care) institutions.[30] From a legal perspective, the "transferral" of hospitals and other specialised institutions cannot be characterised as privatisation since the formal regulative and financial competencies remain with the original owner, *i.e.* local government. After all, the assets of (the department of) an institution are not being transferred to a private institution *c.q.* individual. Only *managerial* competences have been transferred to a contracted association or non-profit organisation ("functional" privatisation). Since no transformation of ownership has taken place this means that local governments remains responsible and accountable for guaranteeing access to health care.

Local governments are, however, not financially responsible in case of the bankruptcy of a transferred institution, due to an exception in the Municipal Bankruptcy Act. This situation changed when the exception was abolished (January 1999). Whether this measure will accelerate the full privatisation process of health care institutions is difficult to say. What is clear is that local governments' budget cannot afford the continuation of the inherited delivery system. Closing (wards of) hospitals or privatisation are two possible solutions.

The Act on Private Practise

The situation for general practitioners is quite different. Already in 1989, Act 113/1989 (XI.15.) MT legalised private practise for family physicians. In addition, Ministerial Decree 6/1992 of the Minister of Health defined the responsibilities of family physicians, established the National Institute

---

[29] National Economic Research Associates (NERA). Financing Health Care. The Health Care System in Hungary. Vol. 25, October 1998: 47-48.

[30] Respectively § 89-91 and § 6.

for Family Practise and introduced the right of consumers to choose their own physician. The introduction of a family physician-system is aimed at strengthening primary care. At the moment, the majority of family physicians are working in a private (group) practise as private entrepreneurs contracting with both the National Health Insurance Fund as well as local governments to provide the necessary care. The physician is obliged to accept patients living in his/her geographic area and who would like to join his/her practise. The second possible option for family physicians is to start as an independent entrepreneur, but without contracting local government. As such, the practitioner provides care based on his license, but he should provide the necessary care for those citizens who choose his practise.

The introduction of the family physician has been supported by several measures such as a free choice of physician and the shift towards capitation-based payment (see Financing of Health Care Services). Such methods were intended to constitute incentives to an improvement in the quality of the services provided and to strengthen the role of the general practitioners. However, important problems were not solved. A general problem is that the quality assurance of provided services is still insufficient. Another is the lack of preventive activities. Family physicians continue to offer mainly prescription and referral services, and little more due to ignorance of (new) medical responsibilities of the family physician.[31] Though the general practitioners also have an important task in the field of public health, *viz*, screening, consultation, parts of public health and epidemiological activities, and participation in health education and promotion. The regulatory instruments to define these tasks remain absent.

Legal consequences of decentralisation and privatisation

The introduction of new ownership structures, institutions and modification of existing organisational structures necessitated the legislature to reconsider the foundations of the legal framework, *i.e.* the Health Care Act II of 1972. This was originally considered as the most important legal instrument to regulate and plan practically all aspects of health care. Criticism centred on the unspecified role of the various health care actors, obsolete norms concerning the (changed) tasks and responsibilities of the government in health care, and the concept of patients' rights which was completely missing.

Early 1998, the government presented a draft Health Care Act to parliament attempting to give in to criticism by, *inter alia*, defining the main principles and functions of the health care system. Relevant to the

[31] Orosz 1996 *o.c.*: 22.

organisation of health care services is a more detailed formulation of the role and competencies of (newly established) institutions and necessary tools to effectuate its targets.

As far as the planning function of health care services is concerned, former Central Planning instruments, notably the budget, volume and prices have been largely replaced by a contract model between health insurance authorities and health providers, regulated in the Provision of Compulsory Health Insurance Act, 1997. Consequently, the Health Care Act does not deal with this aspect of planning. These changes imposed major modifications of the current legislation, notably the Health Care Act and the Health Insurance Act. In more detail, the changes have been implemented in the following acts:

The Act on Health Care

The Health Care Act, CLIV 1997 came into force July 1998 and in conjunction with the Health Insurance Act, the Health Care Act can be considered as the most important legal document in the current reform process. Its main objective is to set up an appropriate legislative framework for the provision of medical services in Hungary and to define the functions of all major participants in the health care sector, *viz*, the parliament, national, regional and local governments, health care providers, purchasers as well as formulating the rights of patients. This act regulates all important aspects of the health care provision, except financing which is regulated in a separate act. The main objectives of the new Health Care Act have been formulated as:

- a revision of legal and organisational structures in the health care system;
- to formulate rights and duties of both patients and health professionals;
- to redefine the role of the government in health care;
- to formulate conditions to improve the quality and efficiency of health care provision, and
- to introduce monitoring and enforcement mechanisms.

Divided into eighteen chapters this act regulates major issues in health care, clustered as (i) equality of opportunities in access and solidarity, (ii) quality of care and quality assurance of health care providers, and (iii) patients' rights (to be covered in the next section). To guarantee equal opportunities in access and solidarity, the act operationalises a wide range of public health tasks, which were based on the WHO "*Health For All by the Year 2000*" programme. Chapter IV defines a range of basic health care services and facilities accessible for the entire population, financed by public means. Furthermore, it defines the general tasks and responsibilities of those institutions concerned. In general, most of these issues were already mentioned in the 1972 Act, but with much less detail neither the responsi-

bility of all the actors. Besides modernising, the amendments also completed the missing elements of the previous act.

According to chapter VII, the national government has a responsibility to improve the health status of the population, to guarantee and control the organisation of health care services, and the functioning of the health care system. To realise this obligation, Article 142 section 2 specifies the tasks which are to be covered by the central budget, *viz*, emergency care; blood supply; particular high technology care procedures; compulsory public health care tasks, and other traditional public health tasks based on this act. As such, the amended Health Care Act, including derived regulations should contribute towards creating equal opportunities for the entire society to access to health care.[32]

Besides the organisational provisions to guarantee equal access, the act introduced various provisions dealing with the quality of care and quality assurance of health care providers. Changing ownership structures, the shift in financing resources, and new diagnostic and therapeutic technologies imposed on the legislature to improve quality of care and strengthen quality assurance measures. Apart from a licensing and accreditation system, training and education, other instruments to ameliorate the quality of care covered the development of professional standards, protocols and guidelines, and the regular evaluation of examination and licensing norms. In this respect, the act attempts to create the legal and professional conditions to match current practise with internationally accepted professional standards by codifying statutory principles, methods and rules for health education, personal and technical conditions for providing health services, rules of quality assurance in health care institutions, and to review these on a regular basis (chapter V). Subsequently, it is the task of the relevant professions to elaborate of these guidelines and protocols.

Furthermore, this act regulates the main organisational aspects of reproductive care, medical experimental research, transplantation of organs and tissues, the provision of blood (products), and catastrophe health care. Previously, these subjects were not, or not in such detail, regulated by law.

Act on the Provision of Compulsory Health Insurance

It appeared that decentralisation and the privatisation of health care services demanded major organisational and amendments to the Health Care Act. At the same time, the existing planning mechanism appeared outdated. The introduction of a Health Insurance Fund only made this more obvious. The traditional concept on planning the volume and prices

[32] *E.g.*, Decree no. 26/1998 (VI.17) NM of the Minister of Welfare, and the establishment of the National Service of Blood Supply, Welfare Gazette 1998/12.

of the health care the state provided was based primarily on the inherited Soviet Central Planning model.

The new Health Care Act has excluded the planning function. Instead, the Compulsory Health Insurance Provision Act 1997 implicitly transposed this task to the Health Insurance Fund, notably through the concept of contracting health care. Acting as a purchasing agency, the National Health Insurance Fund contracts with both individual and institutional health providers who are reimbursed according to determined prices. Since there is freedom of contract, the purchaser buys that volume of health care necessary to fulfil its obligations towards insurees. Freedom of contracting enables the purchaser to cancel or terminate a contract if the provider does not meet earlier stipulated conditions. The underlying notion of freedom of contracting providers is to create an incentive (competition) between providers to provide cost effective and cost efficient care. Based on the contract model, the purchaser identifies and selects providers (whether public or private), negotiates and supervises contracts for services specified by law.

However, since the reforms, no well-defined concept of the content of contracting and price calculation paid by the National Health Insurance Fund has been developed, whereas private enterprises' activities are extremely heterogeneous. When private providers strengthen their market position, which is quite likely since the national and local governments resources are insufficient to answer the physicians' and consumers' demands, they will be increasingly able to dictate market prices for high technology services such as haemodialysis.[33]

Albeit facing substantial difficulties in achieving the theoretical advantages, the concept of a contract can be considered as the key element in the shift away from the Central Planning model. Since the contracted care includes a universal package of services, covering both individual and certain preventive and promotional types of health care (public health), the Health Insurance Fund practically took over the planning of health care provision.

2.5 Health care financing

The initiated reforms on the organisation and delivery of health care go hand in hand with liberalising the health care finance system. Newly privatised health care providers and physicians have gained more autonomy and led to new actors being introduced to the decision-making process, *i.e.*, associations and chambers of physicians. A state budget financing

[33] E. Orosz, G. Ellena, M. Jakab. World Bank Report Hungarian Health Care System in Transition: The Unfinished Agenda. July 1997: 20.

system, generally considered as the main reason for the chronic underfunding of health care, did not fit in the changed circumstances based on market elements. To overcome the lack of sufficient financial resources, Hungary started to experiment with new financing methods in health care. The shift from a tax-based to an insurance-based system was one of the most important steps, originally introduced in 1992. New legislation imposed a new financing system financed by individual premiums instead of the central budget. By introducing a (compulsory) insurance system, the complexity of the financing system increased dramatically since full "marketisation" in financing was, as in most other countries, not acceptable. New financing and reimbursement mechanisms were introduced by law, just as were freedom of choice for patients and legal mechanisms to prevent risk selection.

Despite the relevance of the insurance model, central budget funding did not disappear entirely. It is still an important financial resource of health care.[34] Nonetheless, major legal reforms heralded the introduction of a compulsory and supplementary health insurance system, regulated by the following acts:

Act on Compulsory Health Insurance

Prior to the introduction of the Compulsory Health Insurance Act 1992, insurance reforms already introduced a kind of health "insurance".[35,36] The

---

[34] The central budget funding covers, *inter alia*, compulsory immunisation, prenatal care, emergency ambulance services, catastrophic medicine, high technology care, blood supply and clinical medical research. Act CLIV, 1997 and LXXXIII, 1997.

[35] In 1992, the National Insurance Act split the Social Insurance Fund into an independent Pension and Health Insurance Fund (Act LXXXIV, 1991 on Self-Governance of Social Insurance, and Act X, 1992 on the Social Insurance Fund's Budget. Both funds are managed independently from the state budget. The Health Insurance Fund Administration (*Országos Egészségbiztosítási Pénztár*, OEP) acts as an autonomous purchaser of health services, and originally supervised by the Health Insurance Self-Government. This quasi governmental body was granted extensive rights concerning budgetary decisions. Due to the lack of adequate supervision, the supervisory role was transferred to the Prime Minister's office (1998), respectively the Ministry of Finance (1999). Since January 2001, however, the National Health Insurance Fund has been supervised by the Ministry of Health.

[36] Apart from the introduction of the Health Insurance Act 1992, simultaneously, a new reimbursement method for medical doctors was introduced. The system of fixed salaries was replaced by output financing in 1993. Primary health care practices already started with the new system in 1992, which included a basis salary to be supplemented according to the number of patients who have chosen a particular doctor. This method of per capita-reimbursement was extended to other parts of the system in the course of 1993-1996. Outpatient specialist care was changed from fixed salaries to an adapted version of the German points system. These changes were intended to introduce a competitive element and improve the previous non-existent incentive structure. The method of reimbursing active hospital beds is based on three systems: a combination of the DRG system adapted to the Hungarian conditions (this system stratifies health care services into categories, characterised by predetermined scores, i.e. weighing factors); the German "performance oriented" system

Act on Compulsory Health Insurance provided the legal basis for the organisation and financing of the health insurance scheme. In fact, the Compulsory Health insurance Act encompasses a number of laws, of which Act LXXXIII, 1997 on the Provisions of Compulsory Health Insurance is the most important.[37] In January 1998, these acts came into force.[38] These acts further completed the previous separation between the Health Insurance Fund and Pension Fund (1992).

The new Health Insurance Act 1997 formulates several important conditions and procedures for health insurance entitlements.[39] The main responsibilities of the National Health Insurance Fund (*OEP*) are derived from Article 154 of the Health Care Act 1997: "with reference to medical services provided by the health care institutions and in accordance with the contents of a separate act (Act LXXXIII, 1997), health insurance agencies shall provide for (i) the reservation of the required capacity in reasonable time, and (i) the financing of [...] services provided by health care institutions." This means that a) the *OEP* contracts with health care providers to guarantee the insured adequate care within a reasonable time,[40] and b) the insured are entitled to a universal package of services, including preventive care; primary, secondary and tertiary care, and childcare "provided in kind" and free of charge.[41] According to the act, co-payments are required for: some dental services, pharmaceuticals and medical devices, treatment in sanatoria, and some "hotel" aspects of hospital services.[42]

Despite major improvements, the introduction of health insurance legislation left several problems unsolved. Both the Provisions of Compulsory Health Insurance Act as well as the Health Care Act fail to define the benefit package covered by the National Health Insurance Fund. Due to the lack of an explicit catalogue of defined services, all services are practically included although some types of health care services are not covered by the HIF. Using a negative list, the act specifically excludes the

---

for active beds, and a formula based on bed-days for chronic beds; and individual payments for "unusual activities" such as cardiac surgery. L. Gulácsi and A. Kovacs. Health Care System and the Health Status of the Population. Hungary 1995: 13.

37 *I.e.*, Act LXXX 1997 on the Entitlement for the Provision of Social Insurance and Private Pension, and the Funding of these Services, Act LXXXI 1997 on Social Insurance Pensions, Act LXXXII 1997 on Private Pension and Private Pension Funds, Act LXXXIII 1997 on the Provisions of Compulsory Health Insurance and Act LXXXIV, 1997 amending Act III, 1993 on Social Administration and Social Provisions.

38 With the exception of Act LXXXII which came into force in september 1998.

39 *E.g.*, the personal and material scope, benefits in kind, co-payments, contractual relations, (judicial) enforceability and liability procedures, *et cetera*.

40 Article 9 Act LXXXIII, 1997.

41 Art. 10 *et seq* Act LXXXIII, 1997.

42 Respectively, Decree No. 84/1997 (XII.17) NM, No. 21/1995 (II.8), No. 30/1995 (IX.12) NM, and No. 17/1997 (VI.30) of the Minister of Welfare.

services financed by the central budget as mentioned in article 142 section 2 of the Health Care Act (*e.g.*, catastrophic health care).[43] In the near future, limiting the scope of services covered by the National Health Insurance Fund will be inevitable given the structural distorted funding of the Fund.[44] Such a debate introduces a new impetus into the public/private insurance discussion. After all, restricting the number or scope of entitlements creates a potential market for both *non*-profit as *for*-profit insurance companies (voluntary health insurance) to reinsure the generated deficit by means of additional or supplementary insurance. Up to now, the politicians have avoided such a discussion. But it must be clear that priority setting by means of limiting individual entitlements will, to a large extent, determine the future discussion.[45] Anticipating such a debate, the existing Voluntary Mutual Health Fund could play an important role as re-insurer of non-insured risks.

Act on Voluntary Mutual Insurance Funds

The introduction of voluntary mutual insurance funds are an integral part of reforming Hungary's social security system. Act XCVI 1993 on Voluntary Mutual Insurance entitled, *inter alia*, private (*non*-profit) health care funds to operate on the Hungarian market offering health insurance. The mutual health insurance funds function as a fund (mutualité) for special groups,

---

43 Article 18 (5) and (6).

44 Since 1991, the deficits of the HIF have increased annually. Until now, both the Ministry of Health and the HIF have been unable to contain expenditures. This illustrates the difficulties to containe costs. Since the *OEP* is not responsible for defining the annual health insurance budget, it has no incentive to reverse the tendency of yearly repetition of increasing deficits. Since its establishment, the autonomy which was originally intended, has, *de facto*, created relationship of dependency with the Ministry of Finance since it has committed itself to replenishing the deficits. A possible solution could be the introduction of financial risk of the *OEP* in budgeting as an incentive towards introducing its responsibility in defining the budget. A second option would be limiting the scope of the compulsory benefit package to bridge the financing gap since such a measure would strengthen the role of private insurance. NERA *o.c.*: 172.

45 During the economic crisis of 1995, earlier attempts to limit the benefit package failed. Act XLVIII, 1995 on the Amendments of various Acts for the Purpose of Economic Stabilisation curtailed in-kind and cash benefits. The main exclusions concerned dental care and sanatoria treatments, and the introduction of co-payments for some services. The adverse effects, for instance the negative effect on access to dental care, forced the government to re-introduce dental care into the basic benefit package. Act XIV 1996 on the 1996 Budget of the Social Insurance Funds and Government Decree No. 61/1996 (IV.26) Korm. In 1997, the Health Care Act 1997 addressed the issue of priority-setting in a more rational manner by introducing waiting lists. The selection of patients is based on objective medical criteria. Such waiting lists have been developed for organ and tissue transplantation and for other services that cannot be provided within two months. Decree No. 22/1998 (XII.27) EüM of the Minister of Health on Health services provided on the basis of waiting lists: Health Care Systems in Transition *o.c.*: 29.

for instance, railway personnel, the public transport sector, and the police forces. The objective of this act is to strengthen the social security system by enabling health funds to purchase additional services for its members and their relatives. The members do not participate the compulsory public health contribution but receive the same kind of services as do the mandatory insured. The package of services is covered by the insured voluntary contributions. The insurance companies (based on individual characteristics) determine those fixed contributions. The package of services health funds provided and financed may include, occupational health programmes, basic health care services, and supplementary specialised care.[46]

The voluntary mutual insurance funds should be distinguished from private *for*-profit insurance. Private *for*-profit insurance primarily concerns non-health insurance (life, car insurance, *et cetera*). In Hungary, this type of health insurance is still underdeveloped. The main reason is that the compulsory health insurance scheme encompasses almost the entire health care market. For the moment, private health insurance is mainly focussed on specific types of luxury care.

2.6 Patients' rights

The initiated democratisation of society also affected the legal norms concerning the physician-patient relationship. It appeared that the dominant paternalistic attitude of the medical professionals and violations of the rights of patients did not correspond with the notion of human rights in health care. Consequently, the basic notion of patients' rights became a major issue in the legislative reform process. In the legal discourse, this principle had been reflected by several pivotal rights, such as the right to information, consent, and access to medical files. An important impetes for these rights was the establishment of a newly established Constitutional Court in 1989. Immediately after the change of political system, this Court had to deal with a number of cases with regard to the privacy right and freedom of information.[47] Its decisions served as precedents for subsequent cases and defined the basic principles of new legal norms. In 1992, the legislature started firstly to regulate access to information. Access to information appeared a major controversial issue, notably in relation to secret police files. Since fundamental constitutional rights are involved, the legislature had to protect the privacy of individuals. As such, privacy legislation is of direct importance to the health care sector. Guaranteeing patient's access to information and simultaneously the protection of

---

46 Article 51 section 1 Act on Voluntary Mutual Insurance Funds.

47 2/1990 (II.18) ABH; 11/1990 (V.1.) ABH; 20/1990 (X.4) ABH; 15/1991 (IV.13.) ABH.

sensitive (medical) data can be directly traced back to the Data Protection Act. From the following analysis (data protection legislation, the Civil Rights Ombudsman and the Health Care Act), it would appear that the Hungarian legislature has been quite successful in drafting patients' rights legislation.

Act on Protection of Personal Data and Disclosure of Data of Public Interest
The constitutional basis of the Data Protection Act (Act No. LXIII, 1992) can be found in Article 59, respectively Article 61 of the Hungarian Constitution, which states: "In the Republic of Hungary, everyone shall have the right to ... the protection of private secrets and personal data." In this setting data protection has found its place among the provisions securing the right to privacy. Freedom of information has been separately regulated from data protection, *viz*, Article 61 reading: "[i]n the Republic of Hungary, everyone shall has the right [...] to know and disseminate data of public interest." Furthermore, the amended Civil Code states: "[t]he data processed by computers must not violate individual rights." Based on these provisions and the increasing number of citizens' complaints related to data processing, a first draft act on data protection was proposed in 1987. After a long parliamentary discussion and interventions by the Constitutional Court that persuaded the legislature to speed up its legislative activity, the Act on the Protection of Personal Data and Disclosure of Data of Public Interest was promulgated in november 1992. This act established a Data Protection Commissioner and Data Protection Register. Under Act LIX of 1993 on Parliamentary Commissioners, the Data Protection Commissioner should have been elected by October 1, 1993. Only by mid-1995 was the institution of commissioners finally established by Parliament after much internal parliamentary wrangling. Two striking points in the drafting stage were the proactive role of the Constitutional Court in the legislative process and the delay in effectuating the legal norm due to political disputes surrounding the nomination of major actors.

According to the Preamble of the Data Protection Act, it establishes standards regulating the protection of personal data and the implementation of the right to access to data of public interest. To realise these rights, the Data Protection Commissioner shall supervise the implementation of this act and other legal rules on data processing, examine complaints lodged with him and ensures the maintenance of the Data Protection Register (Article 24). Under the act, the exchange of sensitive data is only lawful when registered in the Data Protection register. This Register is one important instrument run by the Commissioner. He monitors the conditions for the protection of personal data and for the accessibility of data of public interest, suggests proposals for the adoption or modification of legislation on data processing and disclosure of data of public interest, and expresses his opinion on such draft legislation (Article 25 section 1). Due

to imprecise formulations, this element of the procedure is a cause of concern. It is unclear which organisation or individual is responsible for sending draft legislation to the Commissioner's Office, at what stage of the codification process, and with what sort of deadline. In his annual report the Data Protection Commissioner criticised these procedural deficiencies since, in many cases, drafts waiting for interdepartmental harmonisation are sent with impossible short deadlines.[48] As the Commissioner put it: *"Failure to take account of the opinion of the Data Protection Ombudsman, which serves to prevent future constitutional problems as well as preventing the violation of the rights of citizens, affects not only the Office, but – since the Commissioner attempts to protect the rights of citizens in the name of the Parliament – it also fails to ensure the respect due to the Parliament itself."*[49]

Act on Processing and Protection of Medical Data and Related Personal Data

Since the Data Protection Act did not provide patients the necessary legal instruments to guarantee their rights, a new act on processing and protecting medical data was drafted. The Act on Processing and Protection of Medical Data and Related Personal Data entitles patients to gain access to their medical records.[50] According to this law, health care institution may not refuse a patient's request to receive information about his medical record. Due to a complaint lodged by the Data Protection Commissioner in May 1997, the Parliament solved an important omission in the act, *viz*, access to medical records by relatives of a deceases person who had never given notice of such a request. This example illustrates the moderating role of the Commissioner's recommendations in modifying legislation.

Both the Commissioner and the non-governmental Hungarian Civil Liberties Union (HCLU) raised the criticism is that this law does allow the police to process medical data (outside health care services) for the purposes of medical crime prevention. The Commissioner stated that the police should be entitled to process such personal data only on an individual basis and where criminal activity is suspected. In the course of its parliamentary debate, the Commissioner's interpretation of the proposed instructions have been accepted and made into law.

However, with respect to data processed for epidemiological purposes, the recommendation of the Parliamentary Commissioner was less success-

---

48 First Report of the Parliamentary Commissioner for Data Protection and Freedom of Information Hungary, 1995. Summary. Selected cases and recommendations 1995-1996. Budapest, Office of the Parliamentary Commissioner for Data Protection and Freedom of Information. I. Székely (ed.) 1996:22. The criticism concerned several more important draft acts and decrees submitted to the Commissioner in 1995.

49 *O.c.*: 23.

50 Act No. XLII 1997.

ful. Initiated by the HCLU, the Commissioner recommended revision of the mandatory reporting requirements on HIV/AIDS patients in Hungary. The criticised provision stated that if the result of an HIV test is positive, the person undergoing the test should be obliged to disclose her/his personal identity. The main argument against the requirement for mandatory reporting was that the draft did not provide a clear definition of public health and epidemiological interest. Consequently, collected data may be used for a variety of purposes.[51] International recommendations, such as those of the World Health Organization, invariably support anonymous testing because of the strong correlation between anonymity and confidentiality. Both are necessary for motivating the members of the risk groups to subject themselves to the test, and to become sufficiently well-informed, during pre-test and post-test counselling, on the risk factors latent in their way of life, on the precautions which might help to save them and others from the infection. Confidentiality is *a sine qua non* for people with HIV to submit themselves to regular medical examination and to make the necessary precautions in order to save others from the dangers they represent.[52] During a meeting of the National AIDS Committee a large majority of its members voted for anonymous screening. Nonetheless, Parliament adopted the proposal of its Committee of Welfare and Public Health putting an end on to anonymous testing for HIV/AIDS. The Committee justified the proposed amendment by the need for putting HIV positive individuals under medical control. According to the HCLU, the effect of the law as amended will run contrary to its objective. Instead of contacting physician, members of risk groups will avoid the testing sites.

Act on the Parliamentary Commissioner of Human and Civil Rights

The Parliamentary Commissioner for Human and Civil Rights was elected at the same time as the Data Protection Commissioner (1995).[53] Since then, several *ex officio* investigations have been carried out criticising the (lack of) treatment of vulnerable groups in health care.[54]

---

51 Motion of the HCLU to the Data Protection Ombudsman on the collection of data in the sphere of public health and epidemiology in: Data Protection and Freedom of Information. Workshop on Data Protection and Freedom and information. J. Fridli, G.A. Tóth, V. Ujvári (eds). Budapest, May 22-25, 1997: 189-192.

52 *O.c.*: 192.

53 Act No LIX 1993.

54 Based on article 16 section 1 and 2 of the 1993 Act on the Parliamentary Commissioner for Human and Civil Rights, the commissioner is entitled to start an investigation to effectuate and protect the constitutional rights of citizens. These investigations concerned the situation of in patient psychiatric patients (OBH 2255/1996); persons who committed suicide (OBH 5006/1997), and handicapped patients in nursing-care homes (OBH 600-4/1996 and OBH 600-19/1996).

Following the Commissioner's reports, the National Institute for Psychology and Neurology published the so-called Rosenthal Report prepared by foreign physicians.[55] The report stated that the Hungarian government had not fulfilled its obligations laid down in international agreements to enact regulations to improve the circumstances of mental patients. According to the report, mental patients are kept in inhuman circumstances, professional control is non-existent and rehabilitation and budgetary funds for judicial review of decisions are lacking. The legislator gives in to most of the complaints in the new Health Care Act (to be dealt with hereafter). The recommendations in the chapter X, on the medical treatment and care for psychiatric patients, which sets procedural rules for both voluntary and involuntary admission and treatment.

Act on Health Care

Apart from the organisational provisions, the new Health Care Act, Chapter two explicate the concept of patient autonomy, by regulating the basic rights of patients.[56] To a large extent, this chapter has been based on the WHO Declaration of Amsterdam, stipulating, *inter alia*, the right to receive health care, self-determination, information, consent, representation and free choice of provider. In view of the large number of (detailed) provisions (Articles 5-25) and the primary place in the act (chapter II, X), it may be concluded that endorsing the rights of the individuals was the main pillar of this law. During the parliamentary debate, solidarity and equality – two other major principles of the Health Care Act – were not discussed in such detail as the rights of patients. Strong opposition against regulating the rights of patients by such a Parliamentary Act came from the Medical Chamber, representing medical doctors. The main argument was that over-emphasising the legal rights of patients would endanger the patient-physician relationship. Furthermore, they feared an increase in administrative activities at the expense of the available time per patient.[57] Despite the objections of the Medical Chamber, the original patients' chapter has been accepted in general terms by the parliament.

To effectuate patients' rights, except for psychiatric patients (chapter X), the act does not specify the possibilities of judicial review and its procedures to enforce their basic rights or entitlements. This can be considered as a serious shortcoming of the act. An explicit referral to, for example, Civil Code procedures could have prevented possible uncertain-

---

55 Mental Disability Rights International. Human Rights and Mental Health: Hungary. Washington College of Law, American University, Center for Human Rights and Humanitarian Law 1996.

56 Act No. CLIV 1997, chapter two.

57 B. Doktorits. General Secretary Hungarian Medical Association (MOK), August 1997.

ties.[58] Nonetheless, an intermediate out-of-court procedure was introduced by Article 34, *viz*, a mediation council intended to resolve legal disputes between patient and health care provider. Unfortunately, a deficit of adequately trained councils caused this out-of-court procedure to be postponed until January 2000.[59]

Grosso modo, legal reforms cover the entire field of health care and have been introduced incrementally, although its effects were substantial. The new legal order means a clear break with the past. It reflects a transformation of a system towards a more "market-based" health care system initiated by various motives, including the normative. In the near future, the process of change will continue emphasizing a further rationalisation of health care by continuing decentralisation of funding and privatisation of health care provision while, simultaneously, maintaining fundamental principles such as solidarity and universal health insurance coverage. Obviously, such a dilemma has raised major (legal) problems that need further discussion.

3 PATTERNS IN LEGISLATIVE REFORMS

The description of the main features of health legislation enables a positioning and ordering of the legislative reform strategy. It enables parallels to be drawn with the functional approach of the legal-theoretical model (chapter 4). To verify this thesis, the outcomes of legislation will be compared with the theoretically discerned law-jobs. Similarities between the actual law-making process and the theoretical approach could be a first indication of the relevance of the analytical method; whether or not the law-making model is a feasible instrument to review law-making practise. When that is the case, the notion of the health care law-jobs could define the direction and content of legal decision-making in a more rational manner. In other words, review of law-making practise according to a legal-theoretical model to rationalise an irrational activity. The comparison starts with a chronological description of the Hungarian legislation examined to position these acts according to the analytical clusters of health care law (public health, organisation and planning, financing and patients' rights).

In Hungary, legislative reforms in the field of health care started with reconsidering public health law. The interest of the legislature in this field

---

[58] Nonetheless, it remains to be seen in what respect the Civil Code procedure will be adequate to enforce individual rights in health care. For the moment, the Ministry is confident that the general ability to go to court is a sufficient guarantee. In case of complaints about a lack of enforcement procedures, then, further action by the Ministry will be considered. H. Páva, Deputy Director of the Legal Department, Ministry of Health, August 1998.

[59] Article 245 section 4.

can be illustrated by new draft laws initiated in the initial stage of reforms. These proposals vary from the introduction of a decentralised network of public health officers (ÁNTSZ) with important changes in tasks and responsibilities, to the harmonisation of consumer and occupational health legislation, imposing health protection, prevention and promotion measures. Analysis of the content of these drafts also revealed a changing notion on public health towards disease prevention and health promotion. Various reasons underpin the legislative attempts to operationalise the new concept of public health. The alarming figures about the epidemiological and demographic situation, the Health For All 2000 agenda, and the alignment to EC public health policy have largely influenced the content of public health legislation. By incorporating international quality standards concerning the production, distribution and utilisation of pharmaceuticals on the Hungarian market, the 1998 Act on Pharmaceuticals confirmed the thesis that Hungarian public health legislation has been largely affected by international developments. In the very near future, notably the role of the European Union will increase in importance since EC public health programmes are now open to participation by applicant countries (e.g., cancer, AIDS, and health promotion). As a consequence, regulative priorities will include an anti-tobacco and alcohol campaign by levying a kind of health tax to discourage smoking and drinking; restructuring public health services such as laboratories, and matching medical standards on education with EC regulation.[60] Such (intended) legal measures correspond with the new public health approach of strengthening health promotion and disease prevention.

Following the revision of public health services, major changes in the organisation and planning of health care services emerged. Particularly, the introduction of family physicians and "partial" privatisation of specific health care services reflect a decentralisation and privatisation tendency of primary care services. The Local Governments Act 1990 legitimised, *inter alia*, the transfer of ownership of health care facilities to local communities. As a consequence, substantial parts of the former health care system have been privatised, such as the pharmaceutical sector, the production of medical equipment, supplies, ancillary services, and ambulatory health services (private offices, hospitals, pharmacies, and diagnostic centres).[61] Where other facilities such as hospitals and clinics are concerned, "privatisation" is less clear. Here, the concept of "functional" privatisation has created uncertainties with respect to competences and liability. Consequently, many of these health care providers consider themselves as

---

60 As concerns the anti-tobacco policy, in 1999 a new law came into force, *viz.* Act XLII, 1999 on the Protection of Non-smokers.

61 Gulácsi and Kovacs *o.c.*: 22-23.

entrepreneurs without a public task. Unfortunately, unrestrained privatisation within an excessively released regulatory framework has led to unscrupulous profiteering and pillage by health care providers and unchecked utilisation by patients.[62]

The observed problems were closely related to the changes in the financial legal structure. Intended to increase the available financial resources, in 1992 a first attempt was made by transforming the legal basis of the right to health care: from a citizens' right into premium related entitlements. The introduction of a Social Insurance Fund and subsequently, the split into two separated funds provided the first institutional means of establishing a compulsory insurance based health care system. With the introduction of a National Health Insurance Fund, the *OEP*, the purchaser-provider split was formally realised. Although the law has effectuated the intended autonomous status of the National Health Insurance Fund, *de facto*, this autonomy has been limited due to structural budgetary deficits.

Efforts to improve the effectiveness of both collecting premiums as well as strengthening reimbursement methods of health services, had been introduced in 1993-1996 but could not prevent an ongoing debate started by the Ministry of Health about the re-nationalisation of ownership structures, and abolishing the compulsory health insurance system. Despite the unsuccessful efforts of the ministry, it remained its dominant position towards the National Health Insurance Fund in purchasing health care services. Attempts to reinforce the marginal role of voluntary *for*-profit health insurance (private funding, including co-payments) had been rejected due to highly political controversies, whereas *non-profit* health insurance, introduced in 1993, only included additional services for specific groups of the population.

Criticised by both national and international experts, the situation of "muddling through" in health financing legislation continued up until 1997. The government attempted to improve the distorted balance of excessive cost increases and decreasing revenues by introducing a package of legislative measures, of which the Compulsory Health Insurance Act is the most important. Although these new acts provide potentially useful initiatives to overcome the current crisis (contracting providers, a health benefit package, quality of care guidelines, *et cetera*), unclear formulated provisions and conflict of interests undermine the effectiveness of regulative intervention. More drastic changes such as limiting and specifying the scope of compulsory insurance entitlements[63] and simultaneously, legitimising a competitive scheme of *for*-profit insurance that

---

62 *L.c.*: 23.

63 NERA *o.c.*: 172.

provide a full range of services, and creating a universal system of co-payments have been suggested as essential elements in the health care reforms process.[64]

The renewed compulsory health insurance scheme impelled the government to revise the 1972 Health Care Act that was based on the principle of universal access to health care free of charge. The health insurance principle introduced a fundamental shift towards access based on compulsory contributions, *ergo*, health care not free of charge. By establishing an independent Health Fund collecting premiums, the government's withdrawal from both the finance and administration of the health care provision became apparent. The purchaser role of the National Health Insurance Fund substantially changed the relationship with both providers and consumers. Implementing underlying principles of solidarity, equality, patient autonomy and cost-efficiency created new tasks and responsibilities, rights and obligations both for providers and consumers. Therefore, the 1972 Health Care Act became rather obsolete. The government opted for a "matrix-act" that would regulate all sectors of health care, except health financing.[65] The decentralisation and privatisation process started earlier resulted in an unclear definition of tasks and responsibilities of the actors concerned. To give in faced problems, the Horn government opted for an extensive elaboration of the actors' role in the act itself. Such a detailed regulated act includes the danger of incorporating obsolete norms, since changing circumstances inevitably demand modification of the enacted norms, which is a time-consuming process. Its questionable whether it had not been advisable to opt for a general law with derived (ministerial) decrees regulating further details. Since the enactment, however, the delay in drafting by-laws to implement normative statements is considerable. This situation has been criticised since these by-laws should effectuate important issues such as the patient's right to complain.

The reorganization of governmental structures went hand in hand with the discussion on human rights in health care. Evolving public health notions emphasise respect for individual rights, trust between public health personnel and the community, conditions of non-discrimination, and adequate access to health care and education.[66] In this respect the enacted law on the Protection of Personal Data and Disclosure of Data of Public Interest can be considered as a first attempt at strengthening patients' individual rights in health care by regulating both privacy and access to (medical) data. The example of anonymous screening of HIV patients

---

64 Ministry of Finance *o.c.*: 70.

65 G. Kapócs, Deputy Director Health Policy Department, Ministry of Health, August 1997.

66 Gostin *o.c.*: 43.

made clear that there is still no consensus on the concept of human rights in health care. This attitude is, however, rapidly changing. The revised financing system impelled a further discussion on human rights in health care. The introduction of a premium related entitlement to health care necessitated the legislature to define the nature and scope of the benefit entitlements. Despite the primacy of equal access to basic health care, faced with structural funding deficits, infringements on this principle are potentially conflicting and need further regulation.

The reinforcement of the notion of human rights in health care also has an international dimension. Of crucial importance was the moderating role of European institutions, such as the Council of Europe and the European Court on Human Rights emphasising the respect of human rights and the *rule of law*. Ratification of the European Convention on Human Rights (1992) directly affected the paternalistic notion of the physician-patient relationship. Accordingly, new understanding in patients' rights needed an explicit statutory basis. Originally intended as a separate Patients' Rights Act, the 1998 Health Care Act adopted patients' rights as a leading benchmark in the doctor-patient relationship.

Grosso modo, the described enacted legislation correspond with the functional approach of law-jobs and confirm the ideal pattern of presumed health care legislative reforms. Nonetheless, a specific cluster of health care legislation is largely absent in this approach, *i.e.* quality control legislation. Certainly, both the Public Health Act 1991 and the Health Care Act 1998 refer to quality monitoring and the enhancement of quality standards, but fail to define and effectuate the necessary legal instruments.[67] In view of future enlargement, harmonization of Community quality legislation is one the preconditions of entering the European market. Incorporating European directives on equivalent professional qualifications and skills (as part of quality control) are particularly important when the common market will be open for Hungarian health professionals. Particularly for health professions, the Community has adopted specific directives concerning the mutual recognition of diplomas, certificates and other

[67] In addition, the 1998 Act on Pharmaceuticals stipulates some quality standards for dispensing new pharmaceuticals. Confirmed by Gulácsi, since 1990, successive governments declared their intentions to address the quality issue as an important policy theme. Though various institutions were established (the Council on Quality and Accreditation, the ÁNTSZ, the Health Insurance Fund Administration, and the Quality Assurance Department, peer review and audit have not been created so far, professional associations and the ÁNTSZ have performed a limited role in this respect. Finally, up to 2001, the Health Insurance Fund Administration did not have a policy on quality control. Gulácsi, 2001: 122-123. Hungarian insurance scholars confirmed the role of insurance funds in quality assurance and improvement, *e.g.*.. Z. Ajkay. Ot tanulmány az egészségbisztositási reformról, *OEP*, 1994 quoted by Gulácsi *o.c.*: 123.

evidence of formal qualifications to facilitate free movement.[68] However, up until 1998, the implementation of those European qualification standards has hardly been taken into consideration since the Hungarian Minister of Health does not expect a mass outflow of health personnel even with the present major differences in wage levels between Hungary and that of the EU Member States.[69] In view of the structural overcapacity of medical doctors and the intended drastic measures to reduce the number of hospital beds, nevertheless, such an outflow of physicians is more than likely. Conversely, the recognition of foreign diplomas and the licensing of health personnel who intend to start a (specialised) practise in Hungary has not been addressed either, although that might interfere with planning and allocation policy. Improvement of the effectiveness of legal interventions and reformulating responsibilities and competences is directly related to the methodological stages of law-making. Therefore, the final section will examine the discerned stages of law-making, notably the shortcomings in drafting legislation.

4. DEFICIENCIES IN THE LAW-MAKING PRACTISE

In "Parliaments as Policy-Making Bodies in East-Central Europe", Ágh analyses the role and function of the Hungarian legislature since the "first Hungarian parliament" (1990-1994). According to Ágh, the major obstacles of Hungarian policy-making are effectiveness and efficiency, and the implementation of legislation. One problem is the overloaded transitory stage of establishing institutional structures. Secondly, he mentions an over-concentration in power structure of the central government which does not leave any room for other social actors.[70] Ágh bases his conclusions on socio-economic legislation, while the development process of health care legislation is not very different. The emerged obstacles can be illustrated by outlining the main stages of the law-making method. Major difficulties have occurred in the preparatory and executive stage of law-making and are identified as: the unspecified legislative agenda (the setting objectives stage); lacking responsiveness (the problem analysis stage), and failing implementation and absence of systematic evaluation (the implementation

---

68 *E.g.*, doctors, dentists, pharmacists, midwives and nurses (chapter 8).

69 Á. Gögl, Minister of Health of the Republic of Hungary. Health and Enlargement of the EU: Views of a candidate Country. *Eurohealth* 1998, Iss 4: 18.

70 A. Ágh. Parliaments as Policy making Bodies in East Central Europe: The Case of Hungary. *International Political Science Review* 1997, Iss. 4: 418.

and evaluation stage). Ágh characterised these problems as "the pathology of law-making".[71]

Unspecified legislative agenda

The political changes in the early 1990s entailed a modernisation of the Hungarian health policy and legislative framework. With the acceptance of a new concept on public health and health insurance, shortcomings of Hungarian legislation became evident. These deficiencies imposed on the legislature to revise most of the legal acts of the previous system, with the priority of privatisation (Local Government Act 1990) and decentralisation (Public Health Act 1991) of public services. Both acts aimed at regulating primary care, the changed role of government in monitoring and controlling health care providers, improving the effectiveness and efficiency of provided health care and guaranteeing access to health care.

While both acts are in line with the sequence of health care clusters, nonetheless, a (mid- and long-term) strategic plan on constitutive steps of legislation is missing. Improving the health status of the population as an underlying notion requires an unambiguous framework of supportive and coercive legislation that enables the effectuation of opted objectives. Despite the dynamic start, some important (additional) acts were missing. At the same time the enacted legislation caused numerous complications due to ill-defined competences and responsibilities, which subsequently was the result of "over-politisised" ineffective decision-making.[72]

Only in 1995, the first government reform programme outlining new policy targets was called the "Programme of the Health Services Modernisation".[73] However, it was considered more as a "discussion paper" than prescribing the necessary legislative conditions. The legislative programme encompassed nearly two pages of the whole modernisation program, mainly stating the need for a new Health Act and Health Insurance Act.[74] With merely declaratory statements such as "decentralisation and deregulation consistently applied in addition to new regulations" and "out-dated and unnecessary, superfluous regulations need to be removed from effect", the legislative direction and content of the government modernisation

---

71 The use of this medical metaphor has been derived from B.W. Hogwood, B.G. Peters (eds). The Pathology of Public Policy. Oxford Claridon Press 1985: 1. Pathology is the branch of medicine, which studies the nature of disease, especially its structural and functional effects on the body.

72 L. Kiss. Rechtliche Vorbereitungen in der Republik Ungarn auf der Beitritt zur Europäischen Union in: Der Beitritt der Staaten Ostmitteleuropas zur Europäischen Union und die Rechte der deutschen Volksgruppen und Minderheiten sowie der Vertriebenen. D. Blumenwitz, G.H. Gornig, D. Murswiek. Köln Verlag Wissenschaft und Politiek 1997: 91.

73 Programme of Health Services Modernisation. Ministry of Welfare, Republic of Hungary, October, 1995.

74 *O.c.*: 183, 185.

programme is unsatisfactory in all respects. The government failed to define and underpin a legislative scenario and its objectives and means. As a consequence, legislative measures were proposed as soon as problems occurred, whereas anticipating potential conflicts did not seem to occur.

Lacking responsiveness

A second major problem concerned the lack of responsiveness and refers to the problem in the analysis stage. Frequent *ad hoc* legislative interventions undermine the legitimacy of law-making and impel further modification, though unrealistic time schedules and complexity of the problem do not allow a thorough and thus time-consuming problem analysis or priority setting debate. The cumulative deficiencies in law-making often concern disregarding relevant institutions and interest groups such as the Parliamentary Ombudsman, the Hungarian Medical Chamber and patients organisations, which complain about the lack of participation in the preparatory stages of legislation. The conception of monopoly on law-making induced the legislature to ignore particular organised interests since they dircetly represent national interests.[75] In this respect, explicit provisions in the Act on Law-making concerning the participatory role of social representative organisations in law-making appeared illusory.[76] Recent legislation, such as the new Health Care Act could mean a break with the past since it initiated some kind of consensus-based decision-making in which social actors had a participatory role. Due to the compromising character of this act, its effectiveness (compliance to the law) increased although it still includes controversial issues.

Inadequate implementation and absence of systematic evaluation

Finally, vaguely formulated policy objectives are accompanied by only a limited programme design. Thus at the implementation stage all the battles about conflicting objectives or values which were ignored or circumvented at the earlier stage will emerge.[77] This is exactly what happened with the programmatic declaration of a new Health Insurance Act (1993). Drafting the Provisions of Compulsory Health Insurance Act was not accompanied by a debate on, for instance, limiting health entitlements. Since it was, and still is, such a highly controversial issue, the government could do nothing else than preserve a comprehensive benefit package while ignoring the financial consequences. After enactment, the changing position and function of the *OEP* from a "passive" purchaser into a more proactive contractor has caused various conflicts on the reimbursement of

---

75 Ágh 1997 *o.c.*: 419.

76 Act XI. 1987 on Law-making, arts. 19 and 20.

77 Hogwood and Peters *o.c.*: 25.

entitlements and the types of contracted services. These disputes reflect the underlying dilemma between insufficient finances and practically unrestricted claims.

Furthermore, an extensive legislative production in a rather short period of time hinders effective realisation. Besides guidelines for those explicating the rules, administrative and judicial enforcement mechanisms are indispensable to effectuate legal standards. This aspect of the law-making circle has generally been neglected. Too often, enactment of a legal norm was considered to be as the final stage of the legislative process while self-implementing norms do not exist. Administrative enforcement, if present, frequently faced serious problems. Judicial review and legal enforcement was, however, not considered a serious option and happened sporadically. Mobilising public opinion is still more effective than starting a court procedure to enforce individual rights.[78]

Recently introduced complaint procedures may change this situation. With the introduction of statutory patients' rights, the Health Care Act simultaneously stipulates several (quasi) judicial procedures that enable the enforcement of enacted entitlements.[79] Furthermore, Parliamentary Commissioners' investigation competences, stipulated limitations of individual rights, legal rules concerning medical secrecy and professional liability, and legal standards on the registration of health related data provide a legal means of judicial review in concrete cases. By restoring the shortcomings of legal rules, these individual complaint procedures fulfil a key role in indicating and developing (recommendations for) legislative changes. Particularly in the field of company law, the law-making and law-developing function ("*richterliches Prüfungsrecht*") has been accepted. Since the 1988 Companies Act came into force, the Court of Registry practised their law-making and developing function in several cases.[80] The initiating role of judge-made law by the Court of Registry opens perspectives for other fields of law, in a way that open a conscious combination of legislative and judicial development of law.

Apart from the individual (quasi) judicial procedures, in Hungary, *systematic* monitoring and review of legislation is absent as during the first parliament, no scientific evaluation of the (key elements of) formal acts has so far undertaken. Indeed, annual parliamentary budget debates include some monitoring and evaluation aspects, but has its limitations. However, a systematic scientific assessment of the effectiveness of legislative

---

78 The Data Protection Parliamentary Commissioner. I Székely, August 1997.

79 *E.g.*, hospital complaint and mediation procedures.

80 A. Visegrády, Some problems of judge-made law in Central and Eastern Europe, in: Tanulmányok Benedek Ferenc Tiszteletére Pecs, 1996: 305. Studia Iuridica 123, Janus Pannonius Tudományegyetem. Act VI on Companies, 1988, modified in 1991, Act no. LXV.

experiences has not been done. Consequently, the review and correction of legislation and legislative policy based on evaluation studies do not take place.

5 CONCLUSIONS

In Hungary, health care system reforms have been introduced through a plethora of laws. Although the underlying Constitutional norm – the right to health – remained largely unchanged, initiated legal reforms fundamentally changed the legal structure that is embedded in the Hungarian health care system. It appeared that these reforms were mainly focussed on four selected clusters of health legislation, *viz*, public health, the organisation and planning of health care, financing health services, and patients' rights. In the field of public health, the dominant legal norm is the Public Health Act (ÁNTSZ 1991) that provided the government an important legal instrument to intervene in individuals' lives to protect community health. Simultaneously, government attempts to regulate the privatisation of (certain) health care services and the decentralisation of planning competences have been rather rash. The complexity of these developments caused many perverse effects and emerged as a threat to equal access to health care. As a consequence, further radical reform measures were postponed or cancelled in early 1993. This persisted until 1998 when new legislation came into force that attempted to revise the organisational structure of the health care system and to redefine regulatory and administrative competencies. Major controversial topics, however, remained unsolved, such as a substantial reduction of hospital capacities, limiting the volume of human resources, and choices in health care. Nonetheless, the legal reforms meant a shift away from Central Planning towards contracting health care services, which enabled the newly established National Health Insurance Fund to purchase health care services. Structural deficits of the National Health Insurance Fund introduced a new phenomenon, *viz*, the need for cost containment by means of priority-setting and limiting the scope of insurance entitlements. What is more, it addresses the discussion on private supplementary health insurance but despite the importance of priority-setting and its legal implications, the private health insurance concept as such cannot resolve the financial problems the Hungarian health care system is facing. The distorted funding also requires a modernization of the regulatory instruments levying premiums to overcome current deficits. Finally, Hungary faced an increased interest in patients' rights. Promulgated legal rights on informational freedom and privacy, combined with newly established (quasi) judiciary bodies such as the Constitutional Court and Parliamentary Commissioners directly affected the health care sector. Notably individual complaints procedures and *ex officio* investigations

of the Ombudsman revealed major shortcomings in respecting patients' rights. To strengthen the position of the patient in health care, the legislature adopted a chapter of fundamental patients' rights in the new Health Care Act. Nonetheless, annual reports of the Data Protection and Human and Civil Rights Commissioners made clear that effectuating these newly adopted rights remained problematic. Unmistakably, these reforms reflect not only an ideological break with the past, in terms of the underlying principles of the health care system, but also in terms of constitutional principles. The constitutional maxim of supremacy of the *rule of law* initiated a "legal revolution" imposing comprehensive reforms of previous "socialist" laws.

In sum, the initial analysis of the Hungarian legal framework revealed several lacunas, regulatory imperfections and even contradictions in different fields (public health, the organisation and planning, health care financing and quality control), whereas poor enforcement mechanisms and its consequences exposed a more methodological deficit.

Secondly, analysis of the legislative process, in terms of the developed methodology, enabled to put the legal reforms into perspective by identifying legal developments and examination of the legal consequences of newly defined legislation. Studying the patterns and deficiencies in law-making enabled to diagnose the pathological features (unspecified legislative agenda, lacking responsiveness, inadequate implementation and absence of systematic evaluation). The described disorders and consequences of invalid legal rules and its legislative strategy, justify the diagnosis of legislative "malnutrition" referring both to the method of law-making as well as the substantive concept of health law.

Following the model, the suggested treatment starts with strengthening the legislative role in the reform discussion by specifying objectives, legal preconditions, and selection criteria of necessary legal rules. Besides emphasizing a more rational decision-making on substantive norms, the quality of law-making may improve by introducing structural assessment of legislative results. A review to meta standards such as legality, legitimacy, effectiveness and efficiency enable the evaluation of outcomes with underlying targets that subsequently may entail alteration of the reform plan. As such, the underlying iterative and circular approach promote a circular approach of law-making and provide a cocktail of remedies, presenting a combined cure with a methodological conception of health care law. Intended to treat the disease, suppressing symptoms and alleviation of suffering are considered as supportive objectives. A second and third opinion in the Czech Republic and Poland enables the verification of the acceptability of the suggested therapy in a different Central and Eastern Europe setting.

CHAPTER 6: HEALTH CARE LEGISLATION IN THE CZECH REPUBLIC

1 INTRODUCTION

In the immediate aftermath of the collapse of communism, reinstalling democracy in the Czech Republic was supported by profound changes in the legal system. The new Constitution (1993) reflects important amendments of the Administrative, Penal, Civil and Commercial Codes. The leading principle was the need to protect fundamental human rights and freedoms. These legal changes have affected all fields of society, including the health care sector and relevant legislation. Besides strengthening individual rights of patients, from the very beginning Czech health care reforms were focussed on encouraging market reforms and competition. New legislation therefore seems to manifest corresponding tendencies, as observed in Hungary. The outcomes, however, give rise for concern. Symptoms such as legislative "hyperactivity" and the frequency of amended legal norms suggest identical legislative shortcomings as indicated in Hungary.

By identifying the main legislative changes, section 2 enables to position health care reforms according to the discerned clusters of the previous method. Subsequently, analysis of the main legal shortcomings may confirm the pattern, *viz*, the diagnosis of "legislative malnutrition" (section 3). Finally, examining the mutual relations within both the formal and substantive elements may strengthen the notion of a structured and more rational approach of legislative decision-making (section 4). As in the previous chapter, the theoretical model functions as the reference point.

2 SOURCES OF HEALTH LAW

2.1 Historical background

Until 1918, the Czechoslovak Republic, predecessor of the current Czech and Slovak Republics, was part of the Austro-Hungarian Empire. The origins of the major institutions of government and courts date from that period. Under the years of the First Republic (1918-1937), the Constitution established a bicameral National Assembly (*Národní shromázdení*) that acted as legislator; the national government (prime minister and ministers) as the supreme executive authority, and the judiciary. The Supreme Administrative Court was already established during the Austro-Hungarian period (1875) and played an important role in the development of administrative

law. The structure of the Czechoslovakian parliamentary model was mainly influenced by elements of French parliamentarianism. However, the development of a parliamentary system was curtailed with the dissolution of a democratic Czechoslovakia in 1938.[1]

Post-war development was further hindered by the political situation where the ruling Communist Party transformed the political and legal system based on "socialist ideological principles". This resulted in almost all property coming into state ownership. This situation influenced many fields including the health care system. The National Insurance Act of 1948, transformed the pre-war "Bismarckian" health and social insurance schemes into a compulsory system for all citizens, which came under the control of a new Central Social Insurance Institute. These developments were an important step in a gradual process of centralisation.[2]

The transfer from insurance to citizen's entitlement was effectuated under the Law on Health Care of the People, Act No. 20, 1966. In this regard, the most important provisions in this Act stipulate that "health care is provided by the State free of charge to all citizens" (Article V, Preamble) and "all enterprises, cooperatives and other organisations have the duty to take, within their competence, the necessary measures to create and protect healthy living and working conditions and are responsible for the implementation of these duties" (Article 1 section 1). Since its enactment, the Health Care Act had been amended frequently but is still valid.

The political turmoil in november 1989 started a period of democratic transition. It resulted in the ending of the totalitarian Communist Party rule; the reconstruction of the state administration and the centralist economic system; the first democratic parliamentary elections for the Federal Assembly, the Czech National Council and the Slovak National Council; the dissolution of the Federation (1992) and the subsequent establishment of a public administration for the newly independent Czech Republic. On January 1993, the Constitution of the Czech Republic came into force. It characterises the Czech Republic as a sovereign, unitary and democratic state (Article 1), based on the *rule of law* and founded on respect for human rights and freedoms. Legislative power is held by Parliament that reinstalled the bicameral system (Chamber of Deputies and Senate). From that period, Parliament started the modernisation of the legal system. As with other sectors, health care legislation in the Czech Republic has experienced radical changes, notably with respect to public health, the organisation and planning, financing of health care, and

---

1 A.P. den Exter, L. Prudil. The Czech Republic in: International Encyclopaedia of Medical Law. H. Nys (ed.) The Hague, Kluwer Law International 2001: 13.

2 M. Kaser. Health care in the Soviet Union and Eastern Europe. Croom Helm London, 1976: 114.

patients' rights. The following subsections (2.2-2.6) identify the emerged changes. Since statutory changes have been marked by a new constitutional order, the analysis will start with the applicable constitutional provision, the right to health protection, which is generally interpreted as a right to health care.

2.2 A constitutional right to health care

In January 1992, the Czechoslovak Parliament adopted the Charter of Human Rights and Freedoms (*Listina základních práv a svobod*, subsequently, the Charter).[3] This Charter incorporates a catalogue of human rights and freedoms having the force of a Constitutional Act. Consequently, this Charter is an integral part of the Czech constitutional order and falls under the protection of the judiciary.[4] Article 31 the Charter determines the constitutional basis to health care and reads:

"*Everyone has the right to protection of his health. Citizens are entitled on the basis of public insurance to free medical care and to medical aid under conditions provided for by law.*"

In concrete terms, access to health care has been guaranteed by a compulsory health insurance system that encompasses preventive care, curative care and care facilities. Based on this provision, the Health Insurance Act stipulates the individual entitlements and conditions.

The constitutional norm and own-payments in health care

The controversial phrase "*conditions provided for by law*" was the subject of continuous parliamentary debate between liberal ODS and left-wing Social Democrats. The political controversy concerned the intended introduction of patients' out-of-pocket payments by ministerial resolution (Ordinance). Members of Parliament (Deputies) brought the dispute before the Constitutional Court in 1996.[5] The Court resolved the case ruling that the procedure used for introducing patients' co-payments for basic health care services, violates the constitutional right to health care.[6] According to Article 41, section 1, the rights listed in Article [...] 31, [...] of the Charter

---

3 Officially referred as the Resolution of the Presidium of the Czech National Council of 16 december 1992 on the Declaration of the Charter of Fundamental Rights and Basic Freedoms, 2/1993 Coll., incl. 162/1998 Coll. Since the "velvet divorce" between the Czech and Slovak Republics, the Charter has been considered as part of both constitutional orders. Hereafter, subject of research is limited to the Czech legal framework. In Czech Parliament, the Charter was adopted together with the new Constitution (Act No. 1/1993 Coll.).

4 Articles 3 and 4 of the Czech Constitution, 1/1993 Coll., incl. 347/1997 Coll.

5 Based on article 73 sub 1 Act of the Constitutional Court (Act 182/1993 Sb).

6 Ruling Pl. US 35/95, July 10, 1996.

may only be claimed "within the confines of the laws implementing these provisions". Therefore, limitations of these specified constitutional rights require an explicit statutory base, i.e., the Public Health Insurance Act. Since the legal basis of this type of co-payments was considered insufficient, thus unconstitutional, the government was forced to repair the created unconstitutionality. By means of a statutory (positive) list, the government determines which health care services are wholly or in part covered by the compulsory health insurance scheme, *ergo*, introducing patients' co-payments by statutory law. From legislative technical-perspective, a laborious and time-consuming procedure, particularly since the type of services and scope of contributions may be altered in time. At that time, two other cases were brought before the Constitutional Court concerning full reimbursement of incontinence materials. Although the main issue of dispute seems to be the *source* of financing, again, patients' out-of-pocket money are still highly debated.[7]

Own payments in education: The school tuition case

Where the introduction of cost sharing measures is concerned, a parallel may be drawn with the right to education. Albeit different in outcome, the reasoning behind it could be relevant to the concept of cost sharing in health care. In 1993, the Constitutional Court decided on the right to free education stipulated in Article 33 section 2 of the Charter. As mentioned before, according to Article 41 section 1 the right listed in Article [...] 31, 33 [...] of the Charter may only be claimed "within the confines of the laws implementing these provisions". In the so-called *School Tuition* case, the Court annulled a parliamentary amendment of the School Act No. 29/1984 Sb introducing free elementary and secondary school education "unless otherwise provided by statute".[8] The quoted clause was ruled as in blatant conflict with the core of the right to education free of charge, and therefore viewed as unconstitutional. Even Article 41 of the Charter, which includes the rights enumerated in Article 33 as one of the rights that "may be claimed only within the confines of the law implementing these provisions", could not save it from being declared unconstitutional. A statute which calls into doubt the very principle that education must be "free of charge", undermines the entire right, so that it is not one justified by the proviso under Article 41 and is, thus, unconstitutional.[9]

---

7 A.P. den Exter. Health legal reforms in the Czech Republic and Hungary in: Health Care Reforms in Central and Eastern Europe: Outcomes and Challenges. E. Krizova and J. Simek (eds) Charles University Press, Prague 2000: 28.

8 Pl. ÚS 35/93, 1 Sbirka c. 7, published also under 49/1994 Sb.

9 M. Gillis. The Relationship of Ordinary Courts to the Constitutional Court in: The Czech Legal System in European Contexts SOCRATES/ERASMUS Programme 1998/99. The Czech Constitutional Court, Charles University Prague, Prague 1998: 17.

How to cope with the diverging constitutional rulings on health care and education? A possible explanation for the contradictory outcomes could be the more "individual" character of the education right, *i.e.* a more absolute character although both rights are traditionally characterised as social rights. Apparently, a hierarchy of these social rights can be deduced from Constitutional Court rulings that subordinate health care to education.

In a way, different reading of both constitutional provisions reflect the difficulties of the judiciary with the "internationalisation" and changing perception of a health care right. As such, the unwillingness of ordinary courts to comply with constitutional rights has been mentioned as symptomatic evidence.

Judicial failure to comply with constitutional rights

Despite its incorporation in the Constitution, the application of the Charter's rights and freedoms show a rather ambivalent situation. The role of ordinary courts has particularly been questioned. According to Holländer, absence of a tradition of the direct applicability of the Constitution has been explained by the mere programmatic character of particularly social rights, meaning that violations were not able to be sanctioned by courts.[10] A second reason is the currently prevailing low level of expertise of the judiciary, which is a consequence of the long-persisting low level of legal education, as well as of a number of negative stereotypes. Holländer considers the orientation on the formal approach of law as the most important item in relation thereto. Precisely by refusing to apply substantive and adjective law in a manner sensitive to values, judicial bodies unfortunately provide the weightiest evidence of their lack of preparedness to apply the Constitution.[11]

Besides the Charter's rights, as concerns the applicability of international treaty rights, the situation seems even worse. This can be illustrated as follows. Article 10 of the Basic Law makes constitutional a (highly debated) provision, which binds the Czech Republic on ratified and promulgated human rights and fundamental freedoms treaties.[12] Such treaties are immediately binding and prevail over domestic law.[13] As such,

---

10 P. Holländer. The Role of the Constitutional Court for the Application of the Constitution in Case Decisions of Ordinary Courts. *Archiv für Rechts- und Sozialphilosophie* 2000, Iss. 4: 552.

11 Holländer *o.c.*: 552.

12 The debate is mainly focussed on the question of "what is a human rights treaty"? In practice, it is not always clear which criteria should be used in deciding what type of treaty it concerns.

13 The Czech legislature used the generic term "treaty", which is able to cover different treaty instruments, such as the Covenant, Convention, Protocol, etc. but not resolutions, declarations of international organisations since they do not represent consensus but one-sided acts. D. Jilek. Human Rights Treaties and the New Constitution in: Survey of Lectures on Czech Law, Brno, Masarykova Univerzita, 1995: 111.

these treaties are self-executing, meaning that Czech citizens can appeal directly to international treaties provisions, notably disputes on human rights and fundamental freedoms. This is different from the previous Constitutional doctrine. Those who at that time (1960s) were considered as prominent representatives of the Czechoslovak socialist doctrine of international law took the view that treaties regulated relations exclusively between the persons of international law and, as such, were not susceptible to domestic application.[14] Czech scholars now support a more extensive interpretation of human rights treaties, whether it regulates human rights exclusively, dominantly or individually.[15]

In practice, however, ordinary courts do not feel bound by decisions of the Constitutional Court.[16] Consequently, the *de facto* primacy of domestic law above international law is still asserted and may cause legal problems. The antagonistic behaviour of ordinary courts may give rise to

---

14 H.E.J. Malenovsky. Treaties in the Czech Republic: Unresolved "division of labour" between Parliament and the Constitutional Court in: Constitutional Reform and International Law in Central and Eastern Europe. R. Müllerson, M. Fitzmaurice, M. Andenas (eds). Kluwer Law International, The Hague 1998: 279.

15 Jilek *o.c.*: 112; also: R. Bernhardt. Europäische Grundrechte in der zweiten Hälfte des 20. Jahrhunderts in: Das künftige Mitteleuropa Tradition und Perspektiven. Karolinum Univerzity Karlovy (Charles University) Prag 1998: 56-58. For a dissenting opinion see: F. Weyr, a leading Czechoslovak constitutional scholar who considered "from the juristic point of view [...] decisive preference has to be given to the German theories", which consider "the pertinent constitutional provisions on civil rights and liberties and their guarantees as mere academic principles", "monologues of the law-giver", which in practise, do not have significance of norms binding for courts and administrative bodies. F. Weyr. Ceskoslovvenské ústavni právo (Czechoslovak Constitutional Law), Prague 1937: 248. Weyr's interpretation of the conception of constitutionally enshrined rights and liberties corresponds with the positive law tradition of the Weimar Constitution in which many of the fundamental rights were placed as non-judicable, programmatic phrases.

16 Holländer *o.c.*: 537. Article 89(2) of the Constitution provides that enforceable decisions of the Constitutional Court are binding on all public authorities and persons. The Supreme Court took the position that ordinary courts are not counted among "public authorities" and that the Constitutional Court stands outside the ordinary court system, therefore the Constitutional Court is generally not entitled to review their decisions. The Constitutional Court had repeatedly made reference to Article 87 para. 1, sub d of the Constitution, according to which the Constitutional Court also has the jurisdiction over constitutional complaints against final decisions and other actions of public authorities violating constitutionally guaranteed fundamental rights and freedoms. According to the Constitutional Court and the doctrine, the term "public authority" encompasses state bodies and self-governing authorities, including the ordinary judiciary. Constitutional Court judgement No. III ÚS 337/97, november 1997. The binding character includes both Constitutional Court decisions in matters of norm control as well as in cases of constitutional complaints. However, ordinary courts and several constitutional law scholars reject the precedential nature of Constitutional Court judgements in cases of constitutional complaints. V. Mikule, V. Sládecek. Ústavni soudnictvi a lidská práva: Predpisy – documenty – komentáre – poznámky (The Constitutional Judiciary and Human Rights: Legl Texts – Documents – Commentaries – Notes), Prague 1994, quoted by Holländer *o.c.* 545.

concern related, for instance, health care particularly in view of the ratified European Convention on Human Rights, including additional protocols.[17] This Convention is pre-eminently an Article 10 treaty and has therefore direct effect. Subsequently, violations on *individual* human rights and freedoms can be directly based on the Convention. Incorporating individual rights and freedoms, recent European Court case law includes a *rapprochement* of individual and social, and socially related rights (chapter three) and therefore, enhancement of these rights within the framework of the Convention and thus also making them of relevance to the Czech situation. Notably the *López Ostra, Tavares* and *Guerra* cases explicate the role of national (health) authorities in ensuring applicant's rights.[18] In view of these rulings, by denying the direct effect, ordinary courts seem to deprive Czech citizens the right of appeal to legal causes that could potentially strengthen claimants' right to health care. Inconsistencies in reasoning and outcomes between the Constitutional Court and ordinary courts also gave rise to concerns. Improvement of the judiciary's level of expertise in order to remove its negative perception towards constitutionally enshrined rights should be given priority in the near future. Furthermore, the need for domestic legal norms matching supra-domestic law is evident. This is primarily a task for the legislature, meaning, a revision of the statutory framework. Hereafter, it will be apparent whether or not, and in what respect, the legislature has succeeded in this assignment with regard to four selected clusters of health care law, starting with public health law.

2.3 Public health

Historical perspective

Before 1945, the country had a relatively strong and effective public health system. A network of District and Regional Hygiene Institutes founded later is still responsible for epidemiological surveillance (including infectious diseases), immunisation logistics and safety measures concerning environmental hazards, food, and other sectors. As they share public health duties with other parts of the former state health care system, the hygiene services are not directly equivalent to a public health network. Primary care

---

17 Protocol No. 11 to the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 155) of 11 May 1994 was ratified by the Czech Republic on 28 April 1995.

18 *Lopez-Ostra* 9 december 1994 Application no. 303-C; *Tavares* decision of the Commission, Decision of 12 september 1991 Application no. 16593/90, and *Guerra and others v. Italy* 19 February 1998 Application no. 14967/89.

facilities, for example, are responsible for preventive services, immunisation and antenatal services (financed by health insurance funds).[19]

Despite this network of public health services, when compared to international standards, health conditions have decreased dramatically since 1960. The state of public health was in a downward spiral due to bad environmental (working) conditions, depression and alcoholism. Apart from compulsory and free vaccination programmes to reduce communicable diseases, public health was generally neglected.[20] The centralist, and in many cases, rigid system was not able to respond to new health problems.

A fragmented restoration of the Health of the Nation-Agenda

To overcome the environmental and public health crisis a health care reform plan was launched in 1989 aimed at strengthening the national health system.[21] The most essential changes concerned the removal of state monopoly in providing health care and introducing private health care. Reforms were primarily focussed on changes in the financing, reimbursement and privatisation of *individual* health care services. In practice, however, these types of services have only limited impact on the health status of the population. Key determinants of health include both *collective* health care (*e.g.*, epidemiology, vaccination programmes) and circumstances outside the health sector, policies in sectors such as housing, employment and education. As far as public health is concerned, health policy and legislative issues of health promotion and disease prevention were only accepted in a later stage of the reform process (1995). Before that time, a medium-term programme to enhance the national health status had failed to stipulate normative rules. Such legal norms had to support the direction and enforcement of a "restoration of health and health promotion agenda". Health in the Czech conception, however, was continued to be regarded as primarily the responsibility of health professionals and problems of health and of health care are viewed as identical.[22] The consequent subordination of public health resulted in the absence of relevant legislation in this field.

---

19 European Observatory on Health Care Systems. WHO Regional office for Europe. Health Care Systems in Transition: Czech Republic 1999: 15.

20 A. Albert, C. Bennett, M. Bojar. Health Care in the Czech Republic. A System in Transition. *J. American Medical Association* (JAMA) 1992; 267: 2464.

21 Reform of Health Care in the Czech Republic. Draft of a New System of Health Care. Ministry of Health, Prague, 1990 and accepted in december 1990 as Resolution 339/90 of the Czech government. The project defines the principles and steps essential for the new system. All are exclusively concerned with the health care system. However, the problem of improving the health status of the population was not discussed.

22 National Health Programme: A Long Term Strategy. Ministry of Health of the Czech Republic, Prague 1995: 12-13.

The launch of the 1995 long-term National Health Programme was meant to be a landmark in public health. This promising programme on public health analysed the main priorities in enhancing the population's health status and translated the outcomes in a long-term policy strategy. Strategy priorities were supposed to be rationally defined according to criteria such as social relevance, the extent of potential intervention and economic/financial consequences. Subsequently, based on health indicators as morbidity and mortality causes various health issues were selected as priorities (*e.g.*, positive change in nutrition habits, reduction of the prevalence of smoking, improvement of reproductive health, reduction in alcohol consumption).

Besides some successful regional and local health promotion programmes,[23] the concomitant legal support to promote a healthy lifestyle, however, remained segmented[24] and rather ineffective due to missing linkages with the curative care and health funds.[25]

Apart from the separate documents regulating health promotion and disease prevention, in the current legal setting, public health is still centred on health protection.[26] In this respect the archaic Health Care Act, which is still in force, incorporates the functions and organisation of the Sanitation (former Hygienic) Services heavily involved in health protection.

The Act on Health Care

Under the previous Constitution, the most important law in Czech health care was the Health Care Act (1966).[27] After the introduction of a separately regulated health insurance system in 1992, the Health Care Act 1966 remained in force. This comprehensive act sets the legal conditions which attempts to regulate various facets of health care. The focus of the Health Care Act is setting regulatory conditions for preventive protection and strengthening population's physical and mental health (Articles IV and VI). These conditions cover basic relations with respect to the provision of care, set principles for the physician-patient relationship, obligations of all organisations and bodies *vis-à-vis* the protection of healthy life conditions, health care management, the system of health care facilities, science and

---

23 Based on the WHO healthly city, region, school, and enterprise programmes.

24 Regulation on nutrition patterns, control of advertising tobacco products. Newly developed legislation on prevention and public health promotion will be covered by Act No. 258/2000 Coll. on the Protection of Public Health, which will come into force mid 2001.

25 J. Jarós, K. Kalina (eds). The Czech Health Care System. Delivery and Finance. Czech Association for Health Services Research, OECD Study 1998: 42.

26 Recently, Act No. 258/2000 Coll., on the protection of public health confirmed the traditional role of the public health services ("hygiene services"), divided in district and regional public health stations. This Act came into force in 2001.

27 Health of the Population Act, No. 20/1966 Coll. Since 1990 frequently amended, most recently in 1996 Amendment 206/1996.

research and other issues concerning health care. Due to frequent amendments, the present form of the law insufficient for the revised health care organisation (hereafter). It does not correspond to the problems of modern medicine, *inter alia*, research on embryos, scope of informed consent.[28] The successor of the Health Care Act is currently being debated in parliament. Two less comprehensive draft bills modernising the general public health conception were rejected since they did not include a well-defined implementation strategy to realise the National Programme of Health Promotion. Although in an embryonic stage for six years now, the overall concept still does not differ from the previous conception on public health. According to sceptics, the name of the draft Law on Public Health is therefore misleading since it does not propagate the WHO's notion of public health.

Apart from public health, major regulatory changes focus on the organisation and planning of the health care system.

2.4 *Organisation and planning of health services*

In the immediate aftermath of the change of political system, the Czech government presented a document called "Draft of a New System of Health Care".[29] This ambitious government plan was launched as a first step to revise the overall health care system, starting with the modernisation of the organisational and financial structures of health care services. This official policy document was dominated by achieving objectives such as de-monopolisation and decentralisation of health facilities, establishing multiple source financing, strengthening patients' freedom of choice, and strengthening health providers' autonomy.[30] The realisation of these targets had major consequences for the, at that time, most important act, the 1966 Health Care Act.

Simultaneously, a compulsory health insurance scheme was introduced by the Public Health Insurance Act. Both the revised Health Care Act and the Public Health Insurance Act reflect the core of the current legal framework. As concerns the organisation and planning of health care, both aspects have been regulated by the Act on Health Care. To understand the regulatory framework of notably primary and secondary care, the legal setting will be examined hereafter.

---

[28] Den Exter and Prudil *o.c.*: 27.

[29] Reform of Health Care in the Czech Republic. Version II Draft of a New System of Health Care. Ministry of Health. Prague. October 28, 1990.

[30] J. Veprek, Z. Papes, P. Veprek. Czech Health Care in Economic Transformation. CERGE-EI, April 1994: 16.

The Act on Health Care

Despite various amendments, Health Care Act 20/1966 remains the fundamentum for the organisation and planning of the overall health care system. As mentioned before, this law sets the legal conditions which attempts to regulate numerous aspects of health care, *inter alia*, the protection and prevention (part one), role of health care actors (part two), organisation of health services, competencies of health personnel, and the Ministry of Health (part three), *et cetera*.

As in many other countries, the Ministry of Health has a dominant role in conceptualising the health care system. Besides its regulatory and facilitative function in prevention and protection, the ministry sets conditions regarding the health care delivery system, health personnel and technologies, and it supervises administrative competencies. Changed notions regarding the ascendant role of the Ministry in health care required drastic revision of the Health Care Act. However, the frequency and content of amendments have affected the ratio of this act considerably. Furthermore, annulment of relevant provisions, in many cases, caused withdrawal of prototypical regulatory tasks of the legislature. From the initial stage of reforms, decentralising and privatising the provision of health care services dominated the political and legislative agenda.

Decentralisation of competences and privatisation of health care services under the Health Care Act

The first step in de-monopolising and deregulating the health care provision was the decentralisation of managerial competences of former state regulated institutions followed by developing legal conditions that legitimised private health care facilities.[31] Consequently, more than 500 facilities, such as diagnostic centres, ambulatory clinics, and hospitals, have since become legally and financially autonomous.[32] To diversify services, non-profit private facilities were encouraged to operate alongside with publicly owned facilities.

Low salaries in public hospitals and ambulatories and the conception of increased professional autonomy attracted many health professionals

---

31 Act No. 160/1992 on Health Care in Non-Governmental Health Care Facilities, amended by Act No. 161/1993. Preceding this act, the general legal basis for private property was adopted as a central element in the Charter (article 11) and Act on Private Enterprise (No 23/1990). Modernisation of the Commercial Code and income tax defined further conditions for private structures established by national and foreign investors. According to the new Constitution all types of property would be treated equally. The main idea of the government was to re-establish dominance of private property. P. Kranzusch. Die Reformen in tschechischen Gesundheitswesen und deren wirtschaftliche Folgen. *Osteuropa Wirtschaft* 1996, Iss. 4: 340.

32 OECD *o.c.*: 2464.

to the concept of the privatisation of health practise. In primary care, the establishment of private practise became popular among general physicians and specialists. Before 1992, to operate their own practise was prohibited by law. Since then, practically all became self-employed practitioners, working in single practises or health clinics (polyclinics).

Both the decentralisation and privatisation of the health care provision required adequate control and redistribution mechanisms to regulate the supply and allocation of health care services and facilities. The District Health Department (registration) controls the entry of physicians into primary care through licensing by the Medical Chamber and the issuing of permits.[33]

Apart from a licence to practise a medical profession, no further regulatory conditions are required to start a private practise. In practice, however, a contract with one or more health insurance funds (HIFs) is a necessity for reimbursement of provided services. Intended to reduce the oversupply of physicians, recently, HIFs have been entitled to contract physicians more selectively according to their accreditation policy. The practice of selective contracting was only introduced in 1997. Article 17 of Act 48/1997 introduced freedom of contracting providers and resulted in a decrease of contracted physicians, at least in theory. Practically, it appeared that the largest insurer, controlling about 75 percent of the health insurance market, does not contract selectively. Only in exceptional cases, existing contracts with individual practitioners have been cancelled, for instance in certain malpractice cases or fraudulent behaviour. Here, freedom of contracting providers has been interpreted as freedom to choose for continuation of contracting, *sec.* Originally, practically all providers (both individual practitioners and health care institutions) were contracted. Since annulment of contracts is scarce, selective contracting with providers is only a theoretical option. In case of annulment, non-transparent arbitrary procedures often resulted into continuation of contracting due to ministerial pressure *casu quo* public opinion. Since the enactment, it appeared that selective contracting as an instrument to reduce the number of providers has not been successful, at least in the case of the largest insurer.

Differing from primary care, privatising secondary care facilities such as specialised ambulatory medical services and commonplace hospital care was not the main objective. Here, privatisation interpreted as an exchange of assets to private enterprises hardly occurred, except for attractive balneal therapy facilities (spa baths) and a few specialised hospitals. Most of the public institutions were "sold" to local governments that became financially

[33] *Mutatis mutandis* the Stomatological and Pharmaceutical Chambers.

and legally responsible for often poorly equipped facilities. This decentralisation of competences also included managerial responsibilities (Article 39 Health Care Act). Further reform plans are primarily oriented towards increasing efficiency. Capacity planning of health care services however, maintains the competence of the Ministry of Health (Article 42) setting nationwide principles concerning allocation, norms and standards of equipment, *et cetera*. Furthermore, the Ministry is authorised to prohibit the establishment, construction or provision of a health care facility that would conflict these principles (section 2). As such, the accreditation procedures for health facilities remained a ministerial affair whereas licensing of individual providers has been attributed to the Medical Chamber.

Re-introducing professions associations

Practising a medical profession, membership of the Czech Medical Chamber is compulsory as stipulated under the Czech Medical Chamber Act.[34] In 1991, the Czech Medical Chamber was established as an independent organisation that had been abolished by the communist government in the early 1950s. Apart from the Medical Chamber, the Act also established the Czech Stomatological (Dental) and Pharmaceutical Chambers with identical tasks and responsibilities. Furthermore, there was a re-emergence of medical professional societies, nurses' societies and other health care professional *gremia*.

Established as a statutory professional body, the Chamber's tasks and responsibilities concern "monitoring and the improvement of the quality of professional care" by means of, *inter alia*, licensing, accreditation procedures, disciplinary procedures, developing training programmes for medical physicians, developing professional, ethical standards and guidelines, and representing physicians in negotiations with both the government and insurance companies, although the Chamber does not act as a trade union. Attempts by the Klaus administration in 1994 to abolish compulsory membership have failed. According to the Medical Chamber, maintenance of quality control requires compulsory membership to the non-governmental organisation of all physicians, *i.e.* the Medical, Dental or Pharmaceutical Chamber. Voluntary membership to newly established associations would fail sufficient self-regulative competencies in this respect. In 1996, the government withdrew its privatisation reform plans of the Chambers. The decentralisation of competences and privatisation of the delivery of (primary) health care services correlate to

[34] Act on the Czech Medical Chamber No. 220/1991 Coll.

another development, *viz*, the introduction of a social health insurance scheme.

2.5 Health care financing

Under the pre-reform health care system, the National Health Service model was administrated centrally and financed solely from the state budget. General dissatisfaction with the system's shortcomings impelled drastic reforms. From a financial point of view, the transformation started from a general taxation funded system into a model financed by multiple sources. In addition to the state budget, the health care system would be financed by health insurance premiums (both to be paid by employers and employees), local taxes and patients' own payments. The introduction of a compulsory health insurance system, and simultaneously, a modified reimbursement system (initially, fee-for-services) can be considered as the most important element of the 1990 health care reform programme. The current outcomes are largely inspired by the Czechoslovak pre-war health insurance system, as well as present systems in Germany, Austria and the Netherlands.[35]

The Act on Public Health Insurance

The legal basis for the Czech health insurance includes: (i) the General Health Insurance Act (Act 48/1997) which sets the basis for health insurance;[36] (ii) the General Health Insurance Company Act, (Act 551/1991) which establishes the General Health Insurance Fund (*Vseobecna Zdravotni Pojistovna, VZP*);[37] (iii) the Insurance Premium for General Health Insurance Act (Act No. 592/1992) which regulates the setting of premiums, penalties, method of payment, supervision and registration of premium payers,[38] and (iv) the Sectorial, Professional, Corporate, and other Health Insurance Offices Act (Act No. 280/1992) which establishes branch health insurance companies (specialised sickness funds) appealing to the tradition of plurality of insurance funds.[39] Originally, these sickness funds were intended for employees of certain government agencies (*e.g.*, police and

---

[35] Albert, *o.c.*: 2463. While health care is covered from insurance funds, sickness benefits, however, are paid by the state-run social security fund, which is not part of the health care budget. Some proposals for the unification of both systems have been made, but it will surely not take place in the short term. OECD *o.c.*: 32.

[36] Amended by Act No. 592/1992, 10/1993 and 60/1995, 149/1996 and most recently Act No. 48/1997, the Act on Public Health Insurance. Practically, the later replaced the basic elements of the original act.

[37] Amended by Act No. 592/1992, 10/1993, 60/1995, 149/1996, and 48/1997.

[38] Amended by Act No. 59/1995.

[39] Amended by Act. No. 10/1993, 15/1993, 60/1995, 149/1996 and 48/1997.

the army), economic sectors (*e.g.*, miners), large industries and banking employees only. But as free choice of insurance fund was guaranteed by law, these employer-based funds are, in theory, open to all applicants (open enrolment) and compete with each other for the insured. In practice, not all insurance funds operate nation-wide which restricts patients' freedom of insurance.[40]

As far as the funding of health care services is concerned, the most important provisions can be found in Act No. 48/1997 on Public Health Insurance that replaced the original Law (Act No. 550/1991). The Act on Public Health Insurance defines the persons who are obligatorily insured (personal scope) by the public health insurance, *viz.* persons with permanent residence in the Czech Republic and persons without permanent residence in the Czech Republic but who work for an employer who is resident in the Czech Republic. According the Act, the insured, employers and the national authorities are responsible for the payment of premiums. The government is responsible for children, students, pensioners, the unemployed, the military and recipients of social security. By law, the insured receive a wide range of therapeutic and preventative services, whether or not conditionally.[41] Therefore, the health insurance funds contract with individual providers, collect contributions and remunerate contracted providers. Payments for provided medical services are based on a service list with a relative value scale determined by the Ministry of Health. Since 1997, the Ministry of Health has published a new List of Procedures (items of services) with corresponding new point values. Annual negotiations between the Ministry of Health, health insurance funds, the professional Chambers and providers decide on the range of services and medications to be covered and the value of the reimbursement points.

Cost containment measures

Concern about the open-ended financing system encouraged the government to develop cost containment measures. Since 1994, carefully introduced attempts have been made to contain costs by limiting the *de facto* unlimited volume of the contracted services. From that moment, instead of "passive payers" that reimburse the delivered services, health insurance funds (HIFs) were entitled to act as more active purchasers.[42] An even more effective measure was introduced by the 1997 Public Health Insurance Act specifying the funds competencies to impose volume limits in contracts and introducing alternative reimbursement methods that are different from fee-for-services (Article 17, section 3).

---

40 Den Exter and Prudil *o.c.*: 29.

41 Arts. 13 section 2, and 15 Act No. 48/1997.

42 Den Exter, *supra* note 7: 31.

Since its introduction in 1992, the health insurance system has caused considerable changes in health care financing. As a result of the contracting procedure, contracting providers has proceeded by public tender (Article 46, section 2). In these selection procedures, contract criteria concern, *inter alia*, the necessity of provided care, (geographical) accessibility and quality of equipment. Figures in 1997 show that the largest health insurance fund, the *VZP*, refused to conclude new contracts with 176 providers and terminated contracts with 130 others.[43] Although not yet a significant number, the tender mechanism includes a potentially effective instrument to reduce the number of health care facilities. To a certain degree, the new Health Insurance Act is considered as the first adequate legislative measure that actually enables health insurance funds to regulate both the volume of care as well as the number of contracted providers. Before its inception, the liberal approach of the legislature allowed providers perverse and uncontrolled expansion of services provided.

On the demand side, limiting the scope of the health services package and cost sharing attempts have been made, but were not very successful. At this moment, cosmetic procedures, acupuncture and certain stomological procedures are excluded from the health benefit package,[44] while certain prescribed pharmaceuticals introduce patients' out-of-pocket payments. On the other hand, however, there are still no barriers to access secondary, specialised health care since the concept of the general practitioner (GP) as gate-keeper has not been successfully implemented.

Changes in the providers' reimbursement system

Changes in the financing sphere were combined with the modernisation of reimbursement methods. The system of providers' reimbursement appeared to be the most complex and controversial result of the health care reform. The open-ended fee-for-services point system reimbursement had a profound impact on the health care system. At the time it was introduced (1993) total expenditures increased rapidly.[45] At that time, overcharging by physicians was quite common and was possible due to insufficient and weak control mechanisms. In order to contain costs, Act 48/1997 enabled the replacement of the fee-for-services reimbursement system by a more controllable per capita payment system for GP care and

---

[43] The total number of concluded contracts was 22,791 (December 1997). Annual Report of the General Health Insurance Fund of the Czech Republic, 1997, 35. Annulment or refusal is based on Article 17, section 2 Act 48/1997.

[44] Article 15 sections 2, 7, 9.

[45] Figures on total expenditures on health care, as a percentage of GDP, increased from 5.3 (1991) to 5.5 (1992) to 7.6 (1993) and 8.1 (1994). Source: Ministry of Health of the Czech Republic. One of the reasons mentioned was the introduction of the FFS reimbursement system.

other services. Certain GP services, however, such as preventive services were reimbursed according to the existing fee-for-services system. At the same time, historical budgets for residential care were introduced combined with a (future) DRG reimbursement method. Prices were the negotiating element between representatives of health insurance funds and providers of health care.

Towards a new risk adjustment scheme
Finally, with the establishment of multiple health insurers, the Czech government also introduced a redistribution system of contributions to avoid risk selection among the insured.[46] Health insurance funds retained forty percent of the collected contributions, and the remaining percentage, plus all governmental contributions, were subject to redistribution. The risk adjustment scheme is very simple with a weighted redistribution, dividing insured persons into two age categories, *viz*, one share for an insured under the age of 60, and three shares for an insured of 60 and above.[47,48] A new more sophisticated redistribution scheme has been developed yet but has to be implemented through new legislation.

2.6 Patients' rights

The current Czech legal status of human rights, more particularly patients' rights, is rather disappointing, at least, from a domestic perspective. Although the Charter on Human Rights and Freedoms (1993) includes several human rights such as the right to life (Article 6) and integrity of the human body (Article 7), it does not cover patients' rights as such. Instead, existing legislation defines certain specific rights but these are far from complete. Consequently, patients' rights have only been incorporated fragmentally and incompletely into legislation. For instance, the 1966

---

[46] The concept of risk selection or cream skimming is inherent to a competitive health insurance market. Cream skimming refers to an insurer's selection of so-called preferred risks, that is, those insured members expected to be profitable given the risk-adjusted capitation payments and the regulatory regime for setting additional premiums. An effective way to prevent cream skimming is to redefine risk-adjusted capitation payment formula so that insurers cannot predict which insured persons will be profitable or unprofitable. W.P.M.M. van de Ven, R.C.J.A. van Vliet, E.M. van Barneveld, and L.M. Lamers. Risk-Adjusted Capitation: Recent Experiences in the Netherlands, *Health Affairs* 1994: 13: 130; see also J.P. Newhouse. Rate Adjusters for Medicare under Capitation. *Health Care Financing Review.* Annual Supplement 1986: 45-55.

[47] OECD *o.c.*: 32.

[48] This weighting probably exceeds the true average costs of health care for those over 60, so the distribution tends to favour the *VZP*, which insures most of the elderly. In spite of this, as individuals can change insurers and insurers can effectively select their clients, there is considerable potential for adverse selection. European Observatory *o.c.*: 8.

Health Care Act defines two basic rights, namely: the right to information (Article 23, section 1) and informed consent (section 2), whereas sections 3 and 4 include a proviso on informed consent in case of incompetence (mental illness, minors and in an emergency). However, the scope and the extent of information to which the patient is entitled to is highly debatable.

The Health Care Act also includes the physician's duty to confidentiality (Article 55). Health care professionals have to maintain confidentiality about all the facts they are informed on in relation to the exercise of their profession. There are also exceptions when, for example, the person concerned agrees to allow a third party to be informed or when the health care professional is relieved of his duty by a higher body in the interests of the state. However, this last option is virtually unheard since neither the higher body nor the interests of the state are clearly defined.[49] Recently, the patient's right to privacy has been strengthened by the adoption of a new law on Personal Data Protection.[50] In addition to article 55 of the Health Care Act, this new law is aimed at protecting the collection and automatic processing of personal (medical) information. In principle, the data may only be processed in accordance with the purpose of collecting, which conforms to the Council of Europe's Convention on Data Processing.[51]

Finally, both the Health Care Act and the Health Insurance Act guarantee the right to health care. Access to health care services has been regulated a social right and guaranteed by a social health insurance system.[52]

Apart from the Charter and separate legal provisions in the Health Care Act, the Central Ethical Committee developed a Code of Patients' Rights in Health Institutions which states that patients are conditionally entitled, *inter alia*, to be informed, to refuse treatment, to have their privacy respected, and to confidentiality.[53] Furthermore, the Ethical Code of Physicians stipulated physician's duties and indirectly addresses patients' rights.[54] Since both codes include norms that are not binding in law, its legal impact is limited. In 1997, the Code of Patients' Rights in Health

---

49 Den Exter and Prudil *o.c.*: 53.

50 Act on Personal Data Protection No. 101/2000 Coll. In addition, the latest revision of 1966 Health Care Act addressed the issue of medical records (Act No. 260/2001 Coll.). It defines certain rules on access to medical records (e.g., the persons granted access to medical records, issues that should be recorded, *et cetera*).

51 Officially, the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, ETS no. 108, Strasbourg 1981.

52 Article 9, section 1 Health Care Act; article 11, section 1 sub d Public Health Insurance Act which also refers to newly emerged rights as freedom of choice of insurer subsequently physician (section 1, sub a-b).

53 The Central Ethical Committee of the Ministry of Health, 1992.

54 The Ethical Code of the Czech Chamber of Physicians, 1992.

Institutions was evaluated to determine the degree to which Czech patients were aware of both its existence and patients' rights in general. It appeared that only a small majority of the patients questioned had been informed about their (legal) rights. Apart from general public announcements posted at the institutions' entrance, physicians did not inform patients about their rights, unless requested to do so.[55]

The absence of a legal framework of patients' rights characterises an approach that opts for a non-legislative strategy, *i.e.* apart from the basic right of informed consent, patients' rights will be promoted at institutional level. Health care institutions then create their own charter based on legal provisions, as well as on documents prepared by professional bodies. Where this is the case, the charter is developed following rulings of the court but is, nevertheless, vulnerable to the hazards inherent to individual situations. Countries opting for this alternative primarily rely on case law.[56]

Inadequate information mechanisms and the voluntary basis and non-enforceability of the non-statutory Codes reveal legal pitfalls in the current situation of patients' rights. Although most countries suffer from gaps in implementation to one degree or another, and errors in implementation are found in even the most developed systems, the gaps in the Czech system are so systematic and serious that they undermine, to an unacceptable degree, the realisation of patients' rights. In view of the internationalisation of patients' rights and emergence of international mechanisms for their protection, the Czech Republic can be exposed to legal and political risk as patients would hold the government accountable for violations.[57]

Consequently, the non-legislative approach will be difficult to maintain in the current setting and even more so given that the Czech Republic ratified the European Convention on Human Rights and Fundamental Freedoms in 1992.[58] Since national legislation is largely missing, offences committed against patients' rights must be directly determined from the European Convention. It can provide a judicial basis for infringement of patients' rights in case of, for instance, unlawful detention (contravening the right to liberty, Article 5 of the Convention), requests to be heard within a reasonable time by an independent and impartial tribunal (the

---

55 E. Krizova. The Patients' Rights as an Important Issue in the Process of Civic Emancipation in the Czech Republic in: The Right to Health Care in Several European Countries. A.P. den Exter and H.E.G.M. Hermans (eds) Kluwer Law International, The Hague 1999: 161, *et seq.*

56 B. Wijnberg. Patients' Rights and Legislative strategies. Medical Law. 12: 137-140 (1993). The other alternative is a separate act on patients' rights such as in Finland (1993) or the Netherlands (1995).

57 Den Exter and Prudil *o.c.*: 54.

58 Date of ratification 7 May 1992, whereas the Convention entered into force on 1 October 1994.

right to a fair trail, Article 6 of the Convention), or claiming respect for individual's privacy (the right to respect private life, Article 8).[59]

The prospect of the Bioethics Convention (1997) may prompt legal changes by regulating "the protection of human rights and dignity of the human being in biology and medicine". Even though the Convention does not provide for an individual right to complaint before the European Court.[60] Despite being unable to lodge a complaint based at the Bioethics Convention, its not unlikely that the European Court may include the Bioethics Convention in proceedings under the European Convention, if they also constitute a violation of one of the rights contained in the latter Convention.[61]

3 PATTERNS IN LEGISLATIVE REFORMS

In the previous section, it appeared that the modernisation of the Czech health care legal framework is still *in statu nascendi.* While policy reform programmes specify health targets, legal norms to implement and enforce these objectives, they are still insufficiently developed or missing. Analysis of the main omissions indicates the position of current legislative reforms based on the analytical discerned clusters of health care law.

Public health law

One of the striking features of the Czech reforms since 1990 is the lack of (adequate) legislation on collective health care. The most important law is the Health Care Act, 1966 that addressed serious omissions with respect to new understanding on public health law. Although the 1995 health policy programme proclaimed (legislative) measures to improve the health status of the population, the legislature has not been very successful in this

---

59 The European Convention is generally considered as an Article 10 Treaty, *i.e.* an international treaty on human rights and fundamental freedoms, duly ratified and promulgated and therefore directly binding to the Czech Republic taking precedence over statutes.

60 Officially, the Convention on Human Rights and Biomedicine, 1997. The treaty has not yet come into force yet. In March 2001, the Czech Republic ratified the Convention, which entered into force in October 2001. The impact of this Convention in the Czech legal setting is not quite clear. Since the Convention includes various fundamental human rights and freedoms it can be considered as an Article 10 treaty. Nonetheless, Member States can make claim an exception a reservation in respect of any particular provision of the Convention where the Convention does not conform with national law (Article 36 section 1 Convention). Reservations of a general character that are worded in terms too vague or broad for their exact meaning and scope to be determined, are not permitted. According to the Explanatory report referring to the European Court's interpretation, the concept of "law" must be interpreted extensively, including secondary regulation. Explanatory Report to the Convention on Human Rights Medicine No. 174). Directorate of Legal Affairs, Strasbourg, May 1997.

61 Explanatory Report No. 165.

respect. Apart from anti-tobacco and smoking programmes, the legislature failed to enact protective and promotional legislation on environmental pollution, unhealthy foods, *et cetera*. As such, anti-pollution and occupational preventive legislation highlights the recent importance of public health and therefore future legislative strategies. Nonetheless, legal intervention was mainly focussing on general practise, hospitals, health insurance and pharmaceutical services since that was considered more lucrative.[62]

Organisation and planning of health services

Drastic privatisation of health care services and the deregulation of managerial competencies was a main issue of early Czech health care reforms. Driven by the leading principle "private provision, public financing", legal problems were manifold and show various similarities with financing legislation.

Since the first wave of decentralisation, national administrative functions have been transferred to District Health Officers without proper definition of its administrative tasks and competencies. As a consequence of inadequate and unclear administrative procedures (decentralisation) and increased autonomy of health facilities (privatisation), massive acquisitions of advanced medical technologies took place. Quite often, the need for such technologies was primarily based on medical prestige without medical necessity. The liberal approach of the legislature with respect to health services can be cited as a major cause of explosive cost increases in health care. Whereas privatisation of primary care has been largely completed, the current Czech government changed its policy with respect to secondary and tertiary care facilities. Nowadays, privatisation of these services is practically impossible since the Ministry of Health nullified previously decentralised competencies and is reluctant to privatise health services. Instead of privatisation, the Ministry of Health is more focussed on rationalising health care practise. In co-operation with the Czech Medical Chamber and Czech Medical Association, the Ministry attempts to establish clinical guidelines to rationalise decision-making.

Besides the postponement of further privatisation and efforts to introduce transparent decision procedures and decision-making, the Ministry has attemped to force a reduction of hospital bed capacity through the Public Health Insurance Act, 1997. This illustrates attempts by the Czech legislator to move towards stricter supervision of continuing decentralisation and privatisation tendencies within the health care

---

62 M.A. Vienonen, J. Springett. Public Health, Primary Health Care and Health Insurance: How to bring the quest for health gain into the health sector reform in central and eastern Europe? *Eurohealth* 1998/1999. Winter Iss. 6 (special issue).

system.[63] Through the suggested measures, the Ministry of Health intends to revise or even reverse several measures that have already been implemented (self-regulation). According to the Ministry, "self-regulation cannot be applied in health care, since it did not work. Instead, the government will take its responsibilities, meaning bringing public services under public control". However, self-regulative imperfection should be more differentiated. First, self-regulation is not similar to unconditional discretion of powers. The legislature should create sufficient legal conditions *within* which the actors can operate. Since the legal conditions that introduced market competition (as self-regulative mechanism) in health insurance regulation were not effectively realised,[64] regulated market competition as such, never had a chance of being successful. In this respect, the Ministry's proposal, maintenance of a compulsory health insurance system while abolishing plurality of health insurers in the near future, is rather disproportional given the suggestions concerning improving competitive incentives among insurers. Apart from possible legal claims caused by such a "denationalisation" measures, its questionable whether a single health insurance fund as opted would operate more cost effectively and efficiently without, at the same time, removing existing legal imperfections.

Regulation of financing and tariffs: Inadequate public resources control and price control mechanisms

Czech health care system reforms were dominated by abolishing the national health system, introducing a separate financing system based on insurance principles and establishing a public/private mix of health facilities and services, whether or not profit-based. Needless to say, problems arising from a desire to achieve these aims were manifold. Major omissions in the legal framework regulating the health insurance funds concern insufficient accountability of the funds towards state administration, which makes it difficult for both the Ministry of Health and the Ministry of Finance to receive information from the funds for adequate control of public resources.[65] As a consequence, social health insurance funds behave much more like private, for-profit companies.

---

63 The Conception of the Ministry of Health 1998-1999. The main ideas and objectives of the most recent document of the Ministry of Health are: (i) the ministry will increase its influence in health insurance, meaning strengthening its supervisory powers over health insurance funds and quality of provided care by health professionals; (ii) the privatisation of health services will come under more strict public control; (iii) re-introducing previously abolished administrative structures on health facilities at regional level; (iv) developing quality standards (guidelines) concerning medical technologies and professional qualifications; and (v) maintaining a compulsory health insurance system while abolishing plurality of health insurers in the near future.

64 OECD *o.c.*: 34.

65 OECD *o.c.*: 32.

Legislative mistakes surrounded the introduction of a fee-for-service reimbursement system that were not supported by adequate price and volume regulation. The fee-for-service is the universal system of reimbursement of all types of providers and helped to define and price medical services. It has stimulated the privatisation of primary care and a rapid development of formerly neglected services, such as haemodialysis. Apart from some positive developments, it caused a dramatic increase in the production of medical services and therefore defaulted expanding medical expenditures of health insurance funds. Consequently, the absence of adequate price regulation is considered as a main reason for the inflation of high-priced services.[66] The need to regulate prices in health care is based on the argument of imperfect information. Given patient's dependency on the physician's judgement concerning the kind of necessary care and its costs, price regulation of these services is a prerequisite. Obviously, such regulation should be transparent and efficient which was definitely not the case in 1995.[67] Up to 1997, initial attempts to change this development failed when historical budgets for residential care were introduced combined with a (future) diagnostic-related group (DRG) reimbursement method. Furthermore, general practitioners are reimbursed per registered basis (capitation), except for certain selected services (*e.g.* vaccination).

The modifications of the reimbursement system are part of the "managed" or "regulated" competition concept among insurers and providers, derived from early experiences in several western European countries. "Managed competition" attempts to combine solidarity and competition in health care while dissolving deficiencies in both purchasing and providing health care services.[68] According to the managed competition model, the government (or some independent agency) should provide insurers with the following incentives to invest in managed care and to abstain from risk selection. First, the government should institute an adequate system of risk-adjusted compensation of health insurers. A system of risk-adjusted compensation is necessary to convert fixed contributions by subscribers into risk-adjusted payments to health insurers. In addition to a risk-adjusted payment mechanism, the government should prescribe an annual open enrolment period and a standardized benefit package, should create opportunities for price competition among insurers and should enforce an effective competition policy to counteract anti-competitive conduct. In addition to appropriate incentives, health insurers should

---

66 O. Vyborná. The Reform of the Czech Health Care System. *Eastern European Economics* May-June 1995, Iss. 3: 90.

67 *L.c.*: 90.

68 The concept of "managed competition" was originally developed and subsequently refined by A.C. Enthoven. Theory and Practice of Managed Competition in Health Care Finance. North-Holland, Amsterdam 1988.

be furnished with sufficient tools to manage care. Specifically, individual health insurers should be allowed to selectively contract with providers and should be involved in health care facilities and manpower planning. Finally, the government should vouch for a systematic gathering and evaluation of process and outcome data for quality assessment, and for the dissemination of information about quality of care to the general public.

The Czech interpretation of managed competition was not very successful in satisfying these conditions. Although the key principles have been introduced by law (e.g., open enrolment, freedom to select a provider, rudimentary risk-adjusted payment mechanisms, and liberal price setting measures), rigid legislation failed to enforce effective implementation for a long time. For instance, competition among health insurance funds (by means of open enrolment) was not successful since legal conditions did not allow differentiation in health benefit packages; therefore competition in services is hardly possible. Only recently, minor differentiations are possible concerning additional, outside the benefit package services or "amenity" care. The concept of competition *an sich* was not a failure. Instead, the absence of adequate legal norms such as a properly defined health benefit package and low point value of services did not enable sufficient (regulated) competition. Strengthening regulated competition by ameliorating legal norms should therefore be a priority of the legislature. In more concrete terms, this means, *inter alia*, anticipating on European competition law since future accession to the European Union may effect contractual relations in Czech health care. Given the dominant position of the largest health insurance fund (about seventy-five percent of the health insurance market) effective antitrust legislation is necessary to enable competition among health insurers. At the moment, such legislation is non-existent. However, the preliminary question that should be answered is whether, and to what extent, is the European Community competent in dealing with matters concerning social security systems.[69] As in other countries, in the Czech legal debate on European law, opinions are also divergent. A middle position is that members have a certain degree of freedom in their choice of a particular system of health insurance (the organisation aspect) based on the principle of subsidiarity and the relationship between private and social health insurance.[70] Freedom is limited, however, where the content of the system is concerned. On content, the EC Treaty, and the Community regulations and directives based upon the treaty, circumscribe the conditions to maintain competition (with private health insurance) but also conditions governing the introduc-

---

[69] H.E.G.M. Hermans, I. Tiems, "Convergence in the Dutch Health Insurance: Possibilities and Obstacles in a European Perspective", *European J. Law and Economics* 1997, Iss. 4: 375.

[70] *O.c.*: 376.

tion of competition in social health insurance.[71] Despite the compulsory and social character of insurance and premia levied on the basis of solidarity, a social health insurance system can take on features of private insurance and lose its original character. For instance, the situation in the Netherlands where the free choice of insurer by the insured or when elements of solidarity are replaced by an equivalent principle by which premiums are fixed in relation to the degree of risk. At the moment, similar measures are under discussion in the Czech Republic. There is, therefore, a certain risk for the government in trying to intervene, through legislation, in the character of social insurance.[72]

Furthermore, selective contracting of providers has not been successful due to limited discretionary powers of health insurers in dissolving contracts. Amending the Public Health Insurance Act may solve these problems by liberalising the tender procedures for contracting providers. On the other hand, selecting providers requires a transparent and verifiable (administrative) complaint and appeal procedure since it could mean a violation of providers' civil rights (Article 6, section 1 ECHR). In view of the need to further decrease the volume of contracted providers, it is quite likely that potential conflicts between insurers and providers will concern this aspect. In a way, European norms may function as a catalyst in defining domestic conflict regulation procedures.

Another reason why managed competition among health insurance companies failed was the absence of adequate government regulation preventing *cream skimming*. Cream skimming (or preferred risk selection) is the selection by the insurer of so-called preferred risks, *i.e.* the insured for whom risk-adjusted per capita payment the insurer considers will be far above the expected cost level.[73] At the moment branch health insurance funds were introduced, this form of competition took place. Employees left the General Health Insurance Fund (*VZP*) to become members of the newly established funds, leaving many unhealthy insured to the General Health Insurance Fund. To compensate the General Health Insurance Fund, the premiums collected by other health insurance funds became subject to redistribution. Since the risk-adjustment formula is based on age and sex,[74] it is not very successful. Research findings suggested a more advanced (partial) capitation formula extended with gender, region and

---

71 B.H. ter Kuile, F.M. du Pré, K. Sevinga. Health Care in Europe after 1992: The European Dimension in: H.E.G.M. Hermans, A.F. Casparie J.H.P. Paelinck (eds). Health Care in Europe after 1992, Dartmouth: Aldershot 1992: 16-17.

72 Hermans and Tiems *o.c.*: 379.

73 W.P.M.M. van de Ven and F.T. Schut. Should Catastrophic Risks be included in a Regulated Competitive Health Insurance Market? *Soc. Sc. Med.* 1994, Iss. 10: 1459-1472.

74 Recently, it was solely based on age discerning two subcategories (below and above the age of 60).

disability to reduce the disadvantages.[75] Although a new redistribution plan has been developed, it has not been effectuated by legislation.[76] The current ineffective capitation formula, in combination with the prohibition for insurance funds to set their own premiums, deprives them of the ability to negotiate effectively. As a consequence, the Czech health insurance reforms have been described as "the worst of all world".[77] New incentives to realise competition among insurers require a certain freedom of premium setting that is less strictly regulated by the Public Health Insurance Act and, simultaneously, introducing a more sophisticated capitation formula to prevent cream skimming.

Apart from the rigid premium setting of the health benefit package, the Public Health Insurance Act does not forbid health insurance funds to develop alternative delivery systems such as Health Maintenance Organizations (HMOs). On the provision of health care, the law allows a certain degree of self-management (decentralisation) concluding more innovative contracts between hospitals and insurers, employers and hospitals or group practises. The contracts being used include a risk element for both hospitals and primary physicians with the health insurance fund. Innovative elements concern the introduction of efficiency incentives such as primary physicians acting as gatekeepers, re-investing cost savings, the selective contracting of providers, the enhancement of quality of care by introducing peer review, guidelines and protocols, and individual complaint procedures. These managed care projects have been initiated by branch health insurance funds (e.g., bank employees) in Prague and inspired by the British fund holding system. Although from a financial perspective preliminary results are promising, branch health insurance funds easily exclude high-risk applicants from insurance.[78] This emphasises the need for effective legislation that discourages risk selection.

Quality control

Traditionally, regulatory norms on quality control address qualifications of health professionals and health facilities. In order to maintain these norms, the Czech Medical Chamber Act (1991) introduced an independent Medical Chamber with considerable self-regulative competencies concerning licensing, developing medical guidelines and drafting and implementing disciplinary rules involving individual physicians. Nonetheless, the CMC

---

75 J.P. Newhouse. Patients at risk: health reform and risk adjustment. *Health Affairs* 1994. Iss. 13: 132-146: NERA June 1996: 125; L.M. Lamers. Capitation payments to competing Dutch sickness funds based on diagnostic information from prior hospitalization. Erasmus University Rotterdam (dissertation) 1997: 8.

76 OECD *o.c.*: 32.

77 NERA *o.c.*: 125.

78 P. Veprek. Rizenou Péci (RIP). Prague. April 1999.

has been criticised for neglecting its supervisory role in quality control, as formulated in the act.[79] Non-transparent disciplinary procedures and an unwillingness to practise and enforce its legal competences undermine the patient's confidence in disciplinary proceedings.

As far as controlling the quality of care is concerned, the marginal role of health insurance funds is worth mentioning. By means of contractual stipulations, health insurance funds can play an additional role in controlling and enhancing the quality of care provided. Acting as prudent purchasers, their influence on quality control and improvement has been underestimated for a long time. This seems to have changed with the "managed care" experiments. By including statutory quality provisions in individual contracts, health insurance funds can be entitled to set quality conditions to contracted care.

Other legal instruments to control quality of care include Civil and Penal liability rules. Civil liability is regulated by the Civil Code.[80] It does not, however, include any special provisions on the liability when providing health care services. According to Article 415, the basic rule is that everybody is obliged to act in a manner that would not damage human health, property, nature and the environment. Each person is responsible for damage caused by breach of his/her legal responsibilities. Criminal liability is regulated by the Penal Code.[81] As with civil liability, no specific liability exists for medical professionals practising their profession.

Finally, mention should be made of the quality of the medical education programmes. Since the regulation on medical education is based on obsolete pre-reform principles, the modernisation of these norms is a new challenge for the Czech national authorities. Raised by the future enlargement, compatibility of formal qualifications of diplomas with current EU standards is a necessity.[82] European integration imposes on the national legislator a duty to facilitate the freedom of movement of persons, i.e. physicians, through mutual recognition of diplomas. At the moment, the Ministry of Health has not succeeded in harmonising national licensing and accreditation criteria to Community norms. Following a period of

---

79 Czech Helsinki Committee. Report on the State of Human Rights in the Czech Republic 1998: 85.

80 Act No. 40/1964 Coll., as amended.

81 Act No. 140/1961 Coll., as amended.

82 Of relevance here are two important Directives, *viz.* concerning medical qualifications and training (Directives 75/362 and 75/363). The first Directive concerned mutual recognition of primary medical qualifications and specialist medical qualifications within the EU. The second Directive covered the minimum standards of training required in order to be awarded such qualifications. Both directives have been superseded by the consolidated Directive 93/16 "to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications", commonly referred to as the "Doctors Directive".

expenditure regulation and cost containment measures, it is evident that the harmonisation of such quality standards should be a next priority.[83]

Patients' rights
As mentioned before, major international events such as the ratification of the European Convention for the Protection on Human Rights, the Biomedicine Convention and the publication of national evaluation studies on human rights in health care (the Czech Helsinki Committee, patients' rights organisations) emphasise the need for further codification of patients' rights and adequate legal enforcement mechanisms.[84] Apart from the right to information and consent, newly emerged patients' rights do not have a basis in statutory law. There is not even consensus on whether the law should regulate patients' rights and if this is the case, and what type of law – administrative or civil law – should be enacted. In view of the number and seriousness of violations on patients' rights,[85] the Czech legislature should take these rights seriously and finally comply with its international obligations, i.e., to establish patients' rights by law, enforceable by the courts.

4 DEFICIENCIES IN THE LAW-MAKING PRACTISE

In the course of the transformation several shortcomings in the outcomes of lawmaking became manifest. These deficiencies can explained partly by means of the analytical model of law-making descripted in chapter two. The differentiation of subsequent stages of law-making enable the analysis of (potential) legal implications drafting legislation, whereas the subsequent iterative stages of law-making systematize the normative decision-making process and reveal deficiencies in the legislative outcomes. *Ergo*, such a theoretical approach of mutually related stages has certain relevance rationalising the lawmaking process in health care.

In general, it can be concluded that the Czech legislative activity faces similar symptoms as identified in Hungary ("pathology of law-making", chapter five). The observed deficiencies such as a repeated change of Ministers of Health,[86] frequent *ad hoc* interventions, defective legal norms are inherent to underpinning shortcomings such as the overloaded legislator and embryonic institutional structures. At the same time, there is no clear long-term conception of how to cope with the initiated health

---

83 OECD *o.c.*: 28.

84 L. Prudil, Patients' Right in the Czech Republic in the Last Decade in: European Centre for Advanced Legal Studies Yearly (in press).

85 Czech Helsinki Committee Report 1998: 85; The Association for the Protection of Patients (OSOP).

86 Since the beginning of 1990 five ministers have been in the office.

care reforms. Problems such as the unstable and poorly functioning legal and institutional framework for privatisation, unclear ownership constructions, and slow and inadequate financial restructuring and modernisation have also been observed in Hungary.[87] In a way, the following comment from the Constitutional Court's confirms the criticism on the current law-making practise. "*Within two weeks they* (Deputies of Parliament) *know already that the Law does not work. After enactment, the Constitutional Court has been asked for its opinion by the same Deputies and repair the damage.*"[88]

Nonetheless, an important exception to the limited time horizon of government reform programmes was the "Draft of the New System of the Health Care, 1990", formulating the conceptual framework for transforming health care. However, its legal underpinning has only partially achieved. The main reason was the lack of well-defined aims of law-making and the subsequent reform steps. It appeared that a well-considered and elaborated plan of approach was absent (strategic planning). Predominantly, identified legal priorities (i.e., privatisation and deregulation) reflected personal interests of the main actors involved. This explains numerous inconsistencies in legal decision-making.

Further, the legislative drafting process has been gravely hampered by frequent changes of Ministers of Health. Although the Constitution grants the Chamber of Deputies the right to initiate and draft legislation, in practise, most Bills are drafted at governmental, respectively ministerial level. The political instability at the Ministry of Health, invited other political actors to adopt short-term policies, but then lacked the capacity to enforce the respective laws. Furthermore, the influence of external actors such as the General Health Insurance Fund (*VZP*) and the Chamber of Physicians on both legislative policy-making and the legislative drafting process itself is substantial. For instance, various Bills on Public Health Insurance have been largely drafted by the legal department of the health insurance fund (*VZP*), including "generous" provisions for the *VZP* that were not always in favour of the general interest.

Finally, where systematic review of legislation (*ex ante* or *ex post*) is missing, judicial review notably by the Constitutional Court assesses the practical implications of the current legal framework. Czech Constitutional law acknowledges an individual right to complain (*actio popularis*)[89] but only when other legal remedies before the ordinary court have been completed. The Czech Constitutional Court has encountered serious difficulties,

---

87 M. Potucek. Not Only the Market. The Role of the Market, Government and Civic Sector in the Development of Postcommunist Societies. Central European University Press, Budapest, Hungary, 1999: 31.

88 Chief Justice Z. Kessler, Czech Constitutional Court, Brno, April 1999.

89 The Constitutional Court does not have the competencies to initiate a case *ex officio*, therefore, it depends on lodged complaints by individuals.

notably in relation to ordinary courts, which Holländer characterised as the "paradox of the acceptance and rejection of Constitutional Court decisions".[90] As one of the underlying causes Holländer mentioned the narrow legal positivism that rejects constitutional judgements as source of law.[91] Otherwise, the Czech judiciary is facing practical problems such as the speed of court procedures, and its corollary, trust in the courts. Based on practical experiences over the last few years, the Czech Helsinki Committee is concerned about the actual attainability of legal protection for a person by means of a timely court ruling. In its reports, it is stated that postponement of court proceedings (*e.g.* in family disputes) and the lack of a functional and organisational complete administrative judiciary (absence of Supreme Administrative Court) weakens citizen's trust in the law.[92] In this respect, quasi-judicial institutions such as a Ombudsman could play an important, although complementary, role in strengthening citizens' trust in the law by revealing instances of poor legislation and raising awareness among public officials of public's expectations. The informal and relatively short proceedings have appeared quite successful in other countries, for example in Hungary. Despite limited competences, particularly *ex officio* investigations reveal many executive and legislative shortcomings. Quite often, the exposed deficiencies necessitate subsequent regulatory or legislative revision. In a way, the Parliamentary Ombudsman evaluates (the absence of) administrative and normative interventions. Unfortunately, up to 2001, such an institution did not exist in the Czech Republic.[93] The absence, or the ineffectiveness, of supervisory and enforcement mechanisms explains the lack of feedback of legal norms.

5 CONCLUSIONS

Analysis of the Czech legal framework revealed profound changes, notably with regard to the organisation and financing of health care. This is in contrast with public health were apart from policy programmes, public health law, *cum annexis* has not been changed substantially. Minor changes include newly developed anti-tobacco and alcohol regulation and occupational preventive measures, but legal norms remained rather obsolete. This justifies the conclusion that public health policy, at least from a legal perspective, has so far been unsuccessful. Instead, legal reforms were dominated by the introduction of a "Bismarckian" health insurance system

---

90 *Supra* note 16.

91 Holländer *o.c.*: 548, 552.

92 Czech Helsinki Committee. Report on the State of Human Rights in the Czech Republic in 1995, Prague, 1996: 5; confirmed by: Report on the State of Human Rights in the Czech Republic in 1998, Prague 1999: 104-105, 107.

93 Just recently (January 2001), the Act on the National ombudsman came into force.

and necessary organisational changes (e.g. the privatisation of health services). Despite major imperfections, the framework of compulsory health insurance legislation introduced an almost unrestricted entitlement to health care for the insured. At least in theory, since legal options to realise and enforce such a right by law are practically absent. Continuous modifications have attempted to limit the volume and scope of legal entitlements, which raised constitutional concerns. Though the Constitutional Court did not question the legitimacy of these measures as such, it appeared that cost containment measures could conflict with international law providing minimum standards (e.g., ILO Conventions). Consequently, (constitutional) complaints can invoke the constitutionality of far-reaching health insurance reforms. Organisational changes on primary and secondary care imposed major revisions of the original Health Care Act (1966). Due to the frequent amendments, the Health Care Act lacks a coherent organisational structure of health care services and facilities. Emerging problems such as an effective resource allocation policy of private practices will complicate this issue and demands the reconsideration of the rather obsolete law.

It appeared that the dominant role of the (central) government in the provision, organisation, planning and financing has largely been exchanged for the *laissez faire* principle. By abandoning crucial regulatory mechanisms from the Health Care Act, rigorous decentralisation and privatisation tendencies have occurred. It seemed that the Czech legislator "threw the baby away with the bathwater". In a certain way, this explains the difficulties in public health law and the field of patients' rights. The withdrawal of important organisational regulatory provisions affect an adequate realisation of access to collective services, which violates the equality principle. Due to the emphasis on privatising health care, the legislature was not so much interested in enhancing patients' rights. Only recently has this changed due to the ratification of the Biomedicine Convention. The phrase "[e]ach Party shall, in its internal law, take all necessary measures to effect the provisions of this Convention" has urged the Czech government to provide an adequate legal framework to stipulate and effectuate patients' rights, including curtailments "necessary in a democratic society in the public interests". As such, current non-binding Patients' and Ethical Codes can be considered as a preliminary stage to the codification of a specific law on patients' rights, including effective (judicial) enforcement mechanisms according to European standards.

Generally, the legal reforms face an imbalance in terms of the discerned clusters of health law. Dominant are the introduction of a statutory social health insurance model and the privatisation of health care services, while public health, quality of care and the rights of patients received hardly any legislative attention until quite recently. Subsequently, in the stages of law-

making there emerged several important deficits in the process of legislative drafting and anomalies between the theoretical model and the practise of law-making. Similar to Hungary, the most important deficits focus on the initial legislative stages (elaboration of a legislative strategy, formulation of legislative objectives and the in-depth data analysis). Particularly in the data-analysis stage, lessons could be learned from foreign experiences with cost containment measures and the selective contracting of health care providers. Impact assessment studies concerning the introduction of market forces in the field of health insurance could provide relevant information when considering changes in health insurance law. The absence, or insufficient level, of analysis of this kind of data does not contribute to the quality of legislation. It is even more likely that the absence of such information and subsequent analysis is caused by the poor legislative decision-making process.

Omissions were also found in the "post-legislative" stages, i.e., the evaluation and modification of legislative norms. The omissions concern the absence of systematic ex-ante and ex-post assessment, feedback legislative policy and the subsequent revision of legislation. Instead, *ad hoc* constitutional review evaluates legal norms. Consequently, the Constitutional Court partly replaces the legislature as evaluator of legislation ("judicial evaluation"). On one occasion, constitutional review required the legislator to revise the formal procedure of in casu patient co-payments. However, substantial revision of a legal norm due to its unconstitutionality has not occurred, at least as far as health care legislation is concerned. Therefore, legislative practise did not entirely confirm to the hypothesis of revision through evaluation. Nonetheless, it can be concluded that judicial evaluation may require a reconsideration of (the nature of) a specific legal norm. In contrast to Hungary, the Czech Republic until quite recently failed to establish the institution of an Ombudsman. Given the Hungarian experiences, the establishment of this important quasi-judicial institution will increase normative feedback.

CHAPTER 7: HEALTH CARE LEGISLATION IN POLAND

1 INTRODUCTION

The 1980s were a decade of protracted crisis within state socialism in Central and Eastern Europe, most manifestly in Poland. Poland became a trendsetter and model for changes, not only during the crisis of state socialism but also afterwards, during the pre-transition crisis and breakthrough from one system to another system and during the first period of democratic transition. Poland, therefore, experienced both the advantages and disadvantages of being a pioneer.[1]

As in the previous chapters, research on Polish legislation analyses the legal problems experienced during the transformation of the system, more specifically in the health care sector. Therefore, a descriptive analysis of the current legal framework will identify the main legal changes that have occurred in the post-communist period. Such an analysis enabled to position the main sources of health care legislation (section 2). The analysed patterns and observed shortcomings further enable the prioritisation of additional legislative activities in health care based on criteria such as national needs and international legal standards. The analysis of both the sequence of legislation, emerged deficiencies, concomitant newly developed or modified legal norms (section 3), as well as examining the methodological stages of law-making (section 4) may contribute towards inserting and directing regulatory and policy modifications based on more scientific arguments. As such, the applied approach could confirm the underpinning rationality conception of health care law-making.

2 SOURCES OF HEALTH LAW

2.1 Historical background

Poland was the first Eastern European state to break with the USSR and to re-establish a democratic government in 1989. Political reforms introduced major changes in the legal system, such as the revival of the *rule of law* (*praworzadnosc*), the definition of a new Constitution enshrining fundamental human rights and freedoms, and newly established institutions such as the National Ombudsman. Before these post-communist reforms, the latest regime had already started the process of adjudication by establishing the Constitutional Tribunal in 1985. Judicial review of

[1] Á. Attila. The Politics of Central Europe. Sage Publications London. 1998: 141.

administrative decisions was already introduced as a result of the "round table negotiations" between the central government and the Solidarity trade union. The competent judicial institution was the Supreme Administrative Court although its competences were limited.[2]

The restoration of democracy also revealed the need to restructure the health care system. Under communist rule after the Second World War, a Ministry of Health was established and health care was declared a public responsibility. The administration of the health care system was strongly centralised, as was the administration of the economy in general. Poland developed an extensive health care system over the next decades, which resisted some aspects of the Soviet model. Unlike other countries in the eastern hemisphere, private practise was never formally abolished and certain primary care services remained under communism. In the post war period, three major sets of health care sector reform can be discerned.[3] The first set of reforms aimed to develop free and universal public health care. Health care services were nationalised in 1948 and offered their services to all state employees. The initiated process of nationalisation continued through new legislation that introduced an exclusive state monopoly on the production and distribution of pharmaceuticals.[4] Free health care in rural areas was only restrictively available but this situation improved after 1972 when coverage was extended to include agricultural workers. Secondly, reforms aimed to merge comprehensive health and social services in each district. The administrative changes were initiated by the renamed Ministry of Health and Social Affairs. In 1972, the integrated health care management units, the ZOZ (*Zespól Opieki Zdrowotnej*) were established, which managed hospitals, outpatient clinics, specialist and primary health care, as well as some social services. The third reform cluster aimed to decentralise public administration. Health sector reforms in the 1980s were linked to efforts to decentralise the administrative structure of the country by strengthening the position of *voivodships* (provinces) and later the *gmina* (communes). In 1983, the powers of the Ministry of Health and Social Welfare were reduced and the voivodships and the ZOZ were given greater policy and administrative powers.

---

2 The jurisdiction of the Supreme Administrative Court (NSA) is based on the protection of individuals' rights, only on request of the individual. The court has no competence to rule upon general normative administrative laws, decrees and orders. Its competencies are restricted to individual administrative acts from central, regional, local, and other competent organs in cases of pubic administration. D.J. Galligan, D.M. Smilov. Administrative Law in Central and Eastern Europe. Central European Press, Budapest 1999: 215.

3 Health Care Systems in Transition (HiT), Poland 1999 European Observatory in Health Care Systems WHO Regional Office for Europe, Copenhagen: 5.

4 S. Pozdzioch. New legislation in the field of public health law in Poland. *EJHL*. 1995, Iss. 2: 262.

The inherited socialist health care system was criticised for its misconceptions. One of these misconceptions concerned the dominant role of the Ministry of Health in the delivery, organisation and financing of health care. Newly emerging interest groups, such as the Medical Chamber urged for more freedom in proving health care by lobbying for legislation that legalised private ownership constructions in health care. Successive reforms propagated a partial withdrawal of the central government in the health care sector by further decentralisation and the introduction of a social health insurance scheme.[5] Embarking on the latest reforms, the two most important legal documents were the Acts on Health Care Institutions (1991) and General Health Insurance (1999). The following sections examine the main legal aspects of the health care system reforms more extensively, starting with the underlying constitutional basis.

2.2 A constitutional right to health care

The present Polish legal order was established after the political transformation processes that occurred in Central and Eastern Europe in 1989. As most post-communist countries, Poland had to change almost its entire legal system. The legal reforms started with pivotal concepts such as constitutionality and legality. The first important step was the enforcement of the so-called "Small Constitution" (*Mala Konstytucja*) in 1992, which outlined the powers and structure of the major institutions in the country.[6] It was, however, a temporary substitute for a basic law since it did not provide a Bill of Rights and upheld the socialist provisions on citizens' rights. In the socialist conception of constitutional human rights, they were generally not directly applicable, but solely considered as declaration norms.[7] The "Small Constitution" left a large number of constitutional issues to be settled by an entirely new Constitution. The old communist

---

5 A.P. den Exter. Legal reforms of the Polish health care system in view of accession the European Union. *EJHL* 2001, Iss. 2: 5-25.

6 Dziennik Ustaw (Official Journal of Poland, abbreviated *Dz. U.*), 1992, No. 84, Item 426; 1995, No. 38, Item 184, No. 150, Item. 729; 1996, No. 106, Item 488.

7 P. Hofmanski. Menschenrechtenschutz in Polen. Neue Dimensionen nach 1989 in: Demokratie Gestern und Heute, 1995: 264; K. Dzialocha, Bezposrednie stosowanie Konstytucij PRL przez sady (Direct applicability of the Constitution in the People's Republic of Poland by the Judiciary). Studia Prawicze 1988, No. 4, quoted by T. Diemer-Benedict. "Die Grundrechte in der neuen polnischen Verfassung". *ZaöRV* 58/1, 1998: 206. *Cf.* for instance, W. Osiatynski. Social and Economic Rights in a new Constitution for Poland, in: Western Rights? Post-Communist Application. A. Sajó ed. Kluwer Law International, The Hague 1996: 258.

Constitution of July 22, 1952,[8] therefore remained partly in force to prevent a legal vacuum in the areas left open by the "Small Constitution".[9]

In October 1997, the newly drafted Polish Constitution came into force.[10] It replaced the transitional Constitution including three constitutional documents, *viz*, the "Small Constitution", remnants of the 1952 Constitution, and the Act preparing the new Constitution.[11] The 1997 Constitution meant a fundamental change with the past, enshrining both the *Rechtsstaat* principle as human rights and freedoms.[12]

The right to health care in the new Polish constitution

The 1997 Constitution has maintained the right to health care as one of the constitutional social rights. The health care right is headed under the title "Economic, Social and Cultural Freedoms and Rights", chapter two, "Freedoms, Rights and Obligations of Persons and Citizens", reading:

> *"Everyone shall have the right to have his health protected"*, Article 68 (1).

This right includes equal access for all citizens to health care services, financed from public funds and to be ensured by public authorities (section 2). With respect to specific groups (*i.e.*, children, pregnant women, handicapped people and persons of advanced age), public authorities shall ensure special health care (section 3) and control epidemic diseases and prevent the negative health consequences of degradation of the environment (section 4).

Article 68, however, does not provide an absolute right to health care. Section 2 limits the contents in a way that the conditions, scope and availability of social and medical services are defined "*by statute*". By including this phrase, the Polish legislature has attempted to solve the problem of rather undefined norms. It means that curtailments to the social right to health care will be further operationalised by statutory law, *i.e.* the Health Care Institutions Act (1991) and the General Health Insurance Act (1997). The latter act defines, *inter alia*, the conditions and

---

8 Constitution of July 1952. *Dz. U.* 1952, No. 33, Item 232 as amended.

9 D.J. Galligan, D.M. Smilov. Administrative Law in Central and Eastern Europe. CEU Press, Budapest 1999: 211.

10 *Dz. U.* 1997, No. 78, Item. 483.

11 *Dz. U.* 1992, No. 67, Item 336; 1994, No. 61, Item 251.

12 Despite the socialistic approach, nonetheless, a shift towards a more individual conception on human rights and freedoms has been adopted in 1989 when the Constitution enshrined, *inter alia*, an individual constitutional property right (Article 7). Furthermore, at that time, the Constitutional Tribunal ruled several cases from which several individual constitutional rights-principles can be derived such as the prohibition of retroactivity, decision 16 January 1996, W 12/94, OTK 1996, Item 10, and decision 25 June 1996, K 15/95, OTK 1996, Item 7. Furthermore, the protection of acquired rights U 3/95, 245 and K 25/95, 501.

scope of benefits. Further specification of the health care right imposes on the government to develop special health care programmes for certain categories of beneficiaries. Finally, this article also refers to what can be considered as typical public health functions (to protect, prevent and promote).

Although the Constitutional norm itself does not create a subjective right, operationalised by statutory act, it may entail individual (enforceable) entitlements. At the moment, the Tribunal's rulings do not confirm this thesis. However, it should be emphasized that the relevant cases concern the situation before the General Health Insurance Act came into force (January 1999).

Former Constitutional judgements denied the conception of subjective rights, stating that the 1952 Constitution leaves the legislator a substantial "margin of discretion" to define the nature and scope of the constitutionally enshrined health care right.[13] On several occasions the Constitutional Tribunal confirmed this interpretation, based on the former Constitutional provision, Article 70, section 1 and 2.[14,15] In general, the Tribunal considered the referred provisions as providing citizens a guarantee towards social risks, such as sickness, old age, *et cetera*. At the same time, the Tribunal accepted the subsequent obligation of the government to realise such a guarantee. However, the obligation includes guaranteeing a *minimum* level of services. Furthermore, according to the Tribunal, Article 70 did not constitute an underlying principle for individual entitlements. Instead, it provides the legislature a far-reaching discretionary power to mould the necessary regulation, within the condition of considering other constitu-

---

13 *E.g.*, Constitutional Tribunal ruling K 7/90, OTK 1990, Item 5 quoted by T. Diemer-Benedict. Die Grundrechte in der neuen polnischen Verfassung. *ZaöRV* 1998, Iss. 1: 211-2.

14 Article 70 reads as follows: (1) Citizens of the Republic of Poland shall have the right to health protection and to assistance in the event of sickness or inability to work, and (2) this right shall be implemented to an increasing degree by (i). the development of social insurance to cover sickness, old age and inability to work, and by enlargement of various forms of social assistance; (ii) the development of state-organised protection of health and by the raising of health standards of the population, free medical assistance for all working people and their families, a steady improvement of safety conditions, protection and hygiene at work, extensive prevention and treatment of disease, and care for the disabled. Upheld pursuant to Article 77 of the Constitutional Act 1992 of the Constitution 1952. Although health care was in principle universal and free, in practice queuing for certain services and side-payments or gifts to medical staff were both common. During the 1950s, occupational health clinics were set up at work sites, primarily for workers in large industries, miners and the railways. Many of these developed into parallel health systems, which still exist. Limited free health services were provided in rural areas, although private primary health care continued and rural coverage fell short of universality for many years. National Centre for Health System Management, Health Care System in Transition (HiT) Profile Poland, Warsaw 1996: 5.

15 *E.g.*, K. 1/88, 94; K. 7/90, 55; K. 6/91, 62; K. 14/91, 132; K. 14/92, 330 – 331.

tional principles and norms.[16] The legal basis for individual entitlements can only be derived from concrete constitutional norms achieved by means of legislation.[17] More recent case law confirm this interpretation ... "this means that the legislator can modify social rights, both in favour or to the detriment of individuals as long as it does not deprive the right from its essence, *i.e.* guaranteeing a right or benefits necessary for a basic minimum of existence".[18] According to the Tribunal, the right to health care includes an obligation ... "to provide health care facilities and services which, however, does not exclude the individual from its own responsibilities."[19] Otherwise, such an interpretation would transfer the full risks to the government, practically creating a subjective right.

Moreover, with respect to other social questions (old age and pension benefits), the legislature's margin of discretion has been confirmed. In these cases, however, the Tribunal refers to other constitutional principles and norms (equal treatment and the rule of law-principle), to define limitations in restricting individual's claims. Reviewing the legitimacy of potential legislative limitations, the Tribunal concluded unconstitutional legislative modifications that *fully* deprive the insured from exercising his/her social security right or receiving a payment below the subsistence level.[20] This, however, does not exclude modifications of rights as such, only those restrictions, which make social security rights illusory. In another case, the Tribunal accepted the argument that exceptional economic circumstances can justify legislative impediments on social rights on the condition that it does not violate the *rule of law*, meaning the prohibition of retrospective effect and the condition of a transitional period or *vacatio legis*.[21] The legal reforms referred to concerned the system change of the pension scheme that violates future pension benefits.

The discretionary competences of the legislature concerning the organisation, financing and delivery of health care system underlie the reforms that have since occurred.

---

16 L. Garlicki, Soziale Rechte in der Rechtsprechung des Verfassungsgerechtes, in: Grundrecht im Umbruch: Das Beispiel von Polen und Deutschland. G. Manssen, B. Banaszak (eds). Berlin Verlag, Berlin 1997: 98.

17 K 7/90, 55.

18 Constitutional Tribunal ruling K 8/96, 275 and K 7/95, 414.

19 K 7/95, 414. This is in line with the intention of the legislator at that time, to create a civil state, meaning, individuals should, to certain extent, take their responsibility in society. B Banaszak *o.c.* 1997: 78.

20 K. 1/88, 95; K 8/96, 275, and K. 7/95, 414.

21 K. 10/98, 57.

2.3 Public health

The National Health Programme

The deep economic crisis (1989) made the fulfilment of previously formulated health goals impossible. Morbidity and mortality increased for circulatory system diseases, injuries and poisonings, mental health problems. Morbidity from communicable diseases also rose (*e.g.*, measles, viral hepatitis and sexually transmitted diseases).[22] At the same time, over-centralized allocation, finance and provision of resources made health care subject to political intervention. Little attention was paid to cost reduction and efficiency improvement, whereas defective strategic planning contributed towards inequalities in the regional accessibility of health services.

Although this health crisis had been acknowledged in the past, it was not until the collapse of the socialist system that large-scale reforms were proposed to address these problems in the health care sector. It imposed on the Polish government to dismantle the socialist health care system. Various democratically elected governments suggested drastic health care reforms as a attempt to overcome the occurred deficits and its consequences. In 1990, the Polish government presented a detailed document that outlined a strategy for the reform process. Overriding goals of launched reform proposals were: (i) to stop and reverse detrimental tendencies in health status; (ii) to improve the quality of provided health care services, and (iii) to enhance the efficiency of used resources. This plan was seen as a long-term, rolling programme which drastically changed the organisation and financing of the health care sector.[23] The main features of this reform plan were:

- a shift in emphasis from a centrally-planned institutional model towards a decentralised primary health care system;
- supplementing state financing of health care with the introduction of an insurance scheme;
- the introduction of a performance-based reimbursement system where services are paid for after they are provided rather than by a fixed annual budget, and
- the introduction of a National Health Programme (NHP), based on the WHO "Health for All" policy targets was accepted by the government.[24]

---

22 Biuletyn statystyczny: Ochrona zdrowia 1991 (Statistical Bulletin. Health Care Statistics) National Centre for Health Systems Management, Warsaw 1991.

23 Ministry of Health and Social Welfare. Directions of Change in the Organisation and Financing of Health Care Services (in Polish). Ministry of Health and Social Welfare, Warsaw 1990.

24 Ministry of Health and Social Welfare, National Health Programme (in Polish), Ministry of Health and Social Welfare, Warsaw 1990. Since that time successive NHP's have been developed: 1994 and 1997.

This NHP put an increased emphasis on health promotion and preventive health care. The current NHP policy objectives have resulted in several legislative initiatives aimed at implementing the defined targets. By describing the main, legislative reforms in previously discerned clusters of health care law, it will be examined in what respect this policy has been successful.

Redefined public health objectives

An important part of restructuring the health care system was the modernisation of the concept on health preventive and promotional care according to international standards (e.g., Health for All 2000 recommendations). In the Polish tradition, these health preventive and promotional services represent the main features of public health, which is focussed on traditional collective health care services and facilities as well as environmental and occupational health care. Due to the reorientation of prevention and promotion, public health objectives have been elaborated in the National Health Programme and are focused at changing the lifestyle of the population, improving working and living conditions, and reducing differences in health status and access to health services and facilities. Disease prevention and health promotion have been prioritised as intermediate programme objectives.[25] One of the outcomes of this programme was, *inter alia*, the introduction of restrictive anti-smoking legislation in 1996, as an attempt to control smoking. It imposed limitations on advertising and strict requirements for health warnings on packaging, and prohibited smoking in all public buildings. Apart from anti-tobacco regulation, prevention and promotion in mental health is another major public health concern and required new mental health legislation.

Act on Mental Health

The introduction of statutory norms on psychiatric care was a direct consequence of the "Small Constitution" that came into force in 1992. Although the main concern of the 1994 Act on Mental Health[26] is the regulation of the individual rights and freedoms of mentally disturbed people (see section 7.2.6), the act also regulates typically public health activities such as the promotion of mental health and prevention of mental disorders, regulating the organisational structures of mental health and providing mentally ill persons with a comprehensive scheme of universally accessible primary health care and specialised psychiatric facilities (Article

[25] The programme priorities include: a cardiac diseases prevention programme; a cancer prevention programme; reform of the emergency services; mother and child health, and transplantation, dialysis and purchase of high technology equipment, *o.c.* NHP: 10.

[26] *Dz. U.* 1994 No. 111, Item 535. Mental Health Act, 1994.

2). Regional and local authorities (voivodships and gminy) play a key role in establishing and running mental health facilities in accordance with the national developed framework, which has been developed by the Ministry of Health. Apart from the Act on Mental Health, new legislation on disease prevention and health promotion focussed on occupational health was launched in 1997.

Act on Occupational Health Services

The Occupational Health Services Act is based on the provisions enshrined in European Union directives, including Directive 89/391/EEC that refers to the measures necessary to improve workers health and safety at work, and on ILO Conventions, notably numbers 155 and 161.[27] The Act establishes occupational health services (OHS) in order to protect the health of those exposed to hazardous conditions at work and to provide preventive health care at work. The tasks of the occupational health service cover a wide range of activities intended to reduce the harmful effects of the work environment on employee health, provide consultation on occupational pathology, and provide various activities aimed at protecting employees' health.

In general, the Law on Occupational Health Services covers a major part of the public health legislative framework since it updates occupational health services' structures and modes of operation, and stresses the prophylactic function, thereby supporting those trends which have been revealed as priorities (i.e., the functioning of occupational health services under circumstances of free-market economy, ensuring equal chances of health protection for all employees, irrespective the type of job or sector of economy in which they are employed). Detailed provisions guarantee an indispensable degree of government intervention, first of all by ensuring the possibility of conducting consultations, supervision by means of quality assessment, as well as by enhancing the level of postgraduate education and training of occupational medicine professionals (Arts. 17-20).

Apart from newly developed legislation on mental health and occupational health, public health legal reforms are rather moderate compared to the legal changes in the organisation and financing of health care.

---

[27] *Dz. U.* 1997, No. 96 Item 593. Act on Occupational Health Services, as amended (Ustawa o sluzbie medycyny pracy, 27 June 1997); EC Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers. OJ No. L 183, p. 1, 1989 June 29th; ILO Convention concerning Occupational Safety and Health and the Working Environment (C-155, August 11th, 1983), and ILO Convention concerning Occupational Health Services (C-161, February 17th, 1988).

2.4 Organisation and planning of health services

The principle shift from a centrally planned and organised health care system started when the Law on Health Care Institutions came into force in 1991. This Act introduced drastic reforms aimed at decentralising and privatising the provision of (primary) health care with major consequences for the financing of health care.

Act on Health Care Institutions

The Act on Health Care Institutions officially repealed the former state national health care system.[28] The Law opened the way for establishing private activities including, for example, the provision of health care, the pharmaceutical industry, medical supplies, ambulatory diagnostic services and a wide range of hospital services that could be contracted. By virtue of Article 4, health care institutions or individual persons who hold appropriate professional qualifications may provide health care services. Health care institutions may be established by various entities, such as the central government, voivodships, local communities and gminy, non-profit and for-profit private entities (churches, foundations, associations and insurance companies). Article 2 defines "health care institutions" as hospitals and other facilities for persons in need of care, delivered in an appropriate permanent facility; health centres and clinics; clinics for accidents and emergencies; diagnostic laboratories; orthodontics and dental prothetical facilities, and rehabilitation facilities. These institutions can have a private or public character, in the latter case they are established by governmental bodies and publicly funded. This enabled the government to modify the previous organisational structure of the health care system since the purchaser may contract private health care institutions to provide health care services.[29] Of further relevance is that the act enshrines various patients' rights (e.g., the right to health care, confidentiality and access to medical data, information and consent).[30] Finally, both chapter two and three stipulate detailed provisions concerning hospitals and ambulatory health care institutions.

The second part of the Health Care Institutions Act (articles 33-62) deals with administrative, financial and contractual matters concerning public health care institutions, for instance, the establishment of supervisory boards. The competences vary from the right of consultation (*e.g.*,

---

[28] *Dz. U.* 1991 No. 91, Item 408 as amended (Ustawa o Zakladach Opieki Zdrowotnej, 30 August 1991)

[29] C. W. Wlodarczyk, I. Koprowska. Health Care Reform in Poland in: Health Care Reforms in Central and Eastern Europe: Outcomes and Challenges. E. Krizová and J. Simek (eds). Charles University Press, Prague 2000: 110.

[30] Arts. 18-19a.

investment plans), to the appointment and dismissal of board members, whereas part three includes provisions on inspection and control (articles 65-67a). For instance, article 65 *et seq* provide detailed competences of the Minister of Health with respect to control, supervision, and inspection of health care institutions. Whereas according to article 66(1) the Minister and provisional authorities are empowered to order professional inspections to be performed by various bodies, including professional chambers of physicians, *et cetera.*

Unmistakably, the Health Care Institutions Act has played a key role in the institutional reforms since it legitimised the private provision of health care services. However, the very first step shifting away from a centrally planned and provided health care system was a law that enabled physicians to organise themselves in independent associations.

Act on the Chamber of Physicians

The Law on the Chamber of Physicians reintroduced the chamber's right to self-government, which had been abolished for over ten years.[31] The Law established the Chamber of Physicians as a legally constituted public body with regulatory competences and regionally organised (Article 1). Two years later, the Chamber of Pharmacists was restored and the Nurses' and Midwives' Chamber was established.[32] Regulatory competences concern the formulation of principles on professional ethics and deontology binding to all physicians. Furthermore, the Association has important administrative and executive competences in various issues concerning the medical profession (*e.g.*, the registration of physicians, negotiating working conditions, and payment) and participating in a range of public health matters (Article 4). Apart from the conditions for membership, the act stipulates the rights and responsibilities of member-physicians (Arts. 12-18).

A novum is the introduction of medical disciplinary courts and relevant disciplinary procedures (Arts. 41-57). All registered physicians (including dentists and pharmacists) are subject to medical disciplinary law (Article 41). Therefore, the Act established the Medical Disciplinary Court that, in the first instance, can issue several penalties in case of "conduct contrary to principles of professional ethics and deontology", as well as "violating regulations regarding the practise of the medical profession". These principles of professional ethics and deontology have been stipulated in

---

31 *Dz. U.* 1989 No. 30, Item 158. Act on the Chamber of Physicians, as amended (o izbach lekarskich, 17 May 1989).

32 *Dz. U.* 1991 No. 41, Item 179, Act on Chamber of Pharmacists (o izbach aptekarskich, 19 April 1991); *Dz. U.* 1991 No. 41, Item 178. Act on the Chamber of Nurses and Midwives, as amended (o samorzadzie pielegniarek I poloznych, 19 April 1991).

a separate rule, *viz*, the Code of Medical Ethics. Disciplinary penalties include a reprimand; warning; temporary suspension for practise, and prohibition from practising the medical profession (Article 42, section 1). Section 2 opens the physician's right to appeal to the Supreme Disciplinary Court. Apart from the Physicians Chamber Act, of further relevance is the Medical Professions Act.

Act on Medical Professions

A new act on the medical profession was adopted in december 1996.[33] The new act repeals the former medical professions act (October 1950),[34] and the Presidential decree on dental practise (June 1927).[35] Consequently, a single act regulates the status of both physicians and dentists. It also strengthened physicians' self-governmental competences. This, however, was also a main point of criticism in relation to the act.[36] The regional self-governmental bodies are entitled to license physicians to practise the profession after verifying the legal conditions, although not all are clearly defined by law and regulation (Arts. 5-10). The regional boards are also entitled to periodical review of medical skills and qualifications (Arts. 16, 19). The new act also regulated the conditions for foreigners to practise a medical profession.

Furthermore, the law includes provisions with regard to the admissibility of medical experiments on human beings and medical treatment only with patient's consent, the practise of scientific experiments (Arts. 21 ff), the rules of practise, including the scope of the physician's duty to provide medical care (Arts. 30 ff). Such a duty occurs whenever a delay may cause loss of life, health, and physical damage to the patient or any matter of great urgency (Article 35). The act also stipulates the physician's obligation of medical secrecy and other patients' rights (respecting patient's privacy, maintain medical records). Finally, the act entitles physicians to start a private practise, supervised by regional boards of physicians (art. 54).

Apart from the increased role of decentralised bodies in the field of the planning and organisation of health care services, a second major reform issue was the introduction of a purchaser-provider split.

2.5 Health care financing

Of the many challenges facing health care reforms during the transition process, in addition to decentralisation tendencies, the introduction of a

---

33 *Dz. U.* 1997, No. 28, Item 152.
34 *Dz. U.* 1950, No. 50, Item 458.
35 *Dz. U.* 1934, No. 4, Item 32.
36 *Dz. U.* 1997, No. 28, Item 153.

compulsory health insurance system can be characterised as the most problematic. It imposed major legal changes, notably in the field of health financing. The introduction of a "Bismarckian"-based health insurance system marked the second phase in Polish health care reforms that still, however, including unique elements. The typical Polish elements refer to the particular coherent organisational structure characteristic of the pre-war period. Besides the reflection to the past, the developed General Health Insurance Act introduced new elements such as patient's own contributions for pharmaceuticals and sanatoria services.

Act on General Health Insurance

Based on the new Constitutional right to health care, in 1997 the Polish Parliament adopted the Act on General Health Insurance.[37] The Law introduced a compulsory health insurance system for the entire population. Due to political disputes, the act only came into force in January 1999. The underlying principles of the Act on General Health Insurance (hereafter, the Health Insurance Act) are solidarity; non-profit social health insurance; equal access; self-financing; free choice of provider and purchaser; and good managerial practise. Subsequent provisions have attempted to operationalise these principles, starting with defining the beneficiaries, and the nature and scope of the benefit package. Based on Article 3, the insured are entitled to equal access to a standard package of services ensured by different funds irrespective the insurance premium, the chosen fund or place of residence. The benefit activities are aimed at preservation, recovery and improvement of health. Therefore, the health insurance benefit package covers a wide range of services in kind, *inter alia*, medical examination and advice; diagnostics; treatment (both in and out-patient care); rehabilitation; maternity care; pharmaceuticals; vaccinations and other preventive activities.[38] However, certain services (e.g. specific diagnostic tests and pharmaceuticals) require patient co-payments or are excluded from the health insurance fund benefit package (e.g. certain types of dental care, extra-standard services, high technology care, and medical treatment abroad).[39]

The Act further established sixteen regional and branch health insurance funds (*Kasy Chorych*), organised more or less similar to the German "Krankenkassen". The legally constituted health insurance funds sign performance-based contracts with (both public and private) health care institutions and individual health professionals (Article 53, section 1).

---

37 *Dz. U.* 1997, No. 28 Item. 153 (ustawa o powszechnym ubezpieczeniu zdrowotnym, 6 February 1997), as amended.

38 Article 31 section 1 sub 2.

39 Articles 31a, 31f and 37.

These contracts determine, in particular, the type and scope of services provided, terms and conditions of providing services, (maximum) health service cost settlement, principles of service quality, quality monitoring and control mechanisms, as well as principles of supervision, documentation and complaint procedures (section 4). Within this framework patients have the freedom of choice of both provider and insurer (Article 60). The funds will be responsible for collecting and distributing the resources, which should promote efficiency. The freedom of contracting providers should create an incentive for providers to enhance services.

By virtue of Article 66, the health insurance funds are autonomous legal entities, regulated by Civil Law. Therefore, (non-litigious) disputes can be initiated by the insured based on Civil Law rules.[40] Article 147 of the act generally stipulates that in matters related to health insurance coverage and establishing the right to services, Sickness Funds decisions will be brought for the Court of Labour and Social Insurance within the terms and according to the rules determined in the provisions of the Code of Civil Proceedings. This provision provides the insured with an important instrument to enforce individual benefit claims.

Regional and branch health insurance funds

The Health Insurance Law outlines the framework for a system of regionally based and sector based health insurance funds. The act continues to follow the existing parallel health schemes set as independent systems. Resources are allocated by the respective branch insurance fund, which is being financed in a similar manner to the regional insurance funds. The parallel systems operate their own hospitals and clinics, signing contracts with providers. Those eligible for services under the parallel systems can choose between their regional provider and the parallel system provider (Article 69b). If a regional provider has an appropriate contract with the parallel system provider, patients are able to use facilities of the other. As such, the parallel system offers a minimal amount of competition as branch funds, but the consumer choice of providers will only be available to those eligible for parallel services.[41] In some cases, access to certain specialist and diagnostic procedures under the parallel health systems is better than under the public health care system, and waiting times are often shorter.

---

40 Article 147 generally stipulates that in matters related to the health insurance coverage and establishing the right to services, Sickness Funds decisions will be brought for the Court of Labour and Social Insurance within the terms and according to the rules determined in the provisions of the Code of Civil Proceedings concerning the separate procedure for social insurance matters.

41 National Economic Research Associates (NERA). Financing Health Care with Particular Reference to Medicines. The Health Care System in Poland. London, november 1998: 137.

However, not all services are provided within the parallel health systems, in which case patients have the right to use publicly provided facilities.[42]

Although the parallel health systems have provided an alternative source of health care services for the eligible employees and dependants, the lack of any co-ordination between them and the public health care system has led to several problems, such as, many parallel systems offer services without a clear mandate or responsibility to provide health care. This lack of accountability means that the Ministry of Health has virtually no control over how health care funds are spend by other ministries. Secondly, there are no formal procedures for co-ordinating the function, administration, and budget processes of the parallel systems with those of the Ministry of Health. This has led to unnecessary duplication of facilities and excess capacity. Thirdly, patients use the public network when the parallel system does not offer the required services with any financial transfer to the Ministry of Health for providing such coverage.[43] Up until now, the Health Insurance Act does not provide any provisions attempting to solve these obstacles.

Private health insurance

Besides compulsory health insurance, since 1990 Poland has had limited experience with private (voluntary) health insurance. Before that time, private insurance was virtually absent under socialism in Poland. The most common way of substituting (or complementing) social benefits in cash was to create transfers simply through saving for, for example, old age ("rainy days"). Buying individual insurance was permitted although private companies were not allowed to operate. The only two national companies were dealing with different types of insurance. One of them, the State Insurance Company (*PZU*) offered life and accident insurance policies, and pension plans for individuals. However, health insurance was not offered.[44]

During the transition period, a legal norm was developed for the private insurance sector, and implemented by the Insurance Act in July 1990.[45] In fact, the Law of 1984 that allowed the establishment of co-operative insurance institutions had already legitimised this possibility of private insurance. The act was rather restrictive and discouraging, but it resulted in the establishment of the first – in recent decades – non state-owned

---

42 NERA *o.c.*:16.

43 World Bank Health System Reform. The World Bank, Washington D.C. 1992: 61-62.

44 I. Topinska. Public vs. Private Safety net, past and recent trends in Poland in: Social Protection for Countries in Transition from Planned to Market Economy. Jate Press Szeged 1994: 136. International Symposium Colleque International, Szeged, 7-11 October 1992.

45 *Dz. U.* 1990, No. 59, Item 344 Act on Insurance Activity, 1990 with subsequent amendments.

insurance company.[46] Since the Act came into force, the insurance market has grown rapidly although the experiences with private health insurance are still moderate.[47]

2.6 Patients' rights

Apart from the revision of health financing legislation, the dissolution of the socialist health system marked a new approach to the issue of human rights. Since the Central and Eastern European countries have accepted the concept of fundamental human rights and freedoms, they have made substantial progress towards implementing and guaranteeing these rights and freedoms.

Taking rights seriously Poland, as other Central and Eastern European countries, has stipulating a catalogue of mainly individual rights and freedoms in the Constitution (Chapter II). Apart from the inalienable right of human dignity (Article 30), the Constitution does not include a separate framework of patients' rights. Instead, the Ministry of Health and Social Welfare proposed a single statutory act on patients' rights. After questions raised by the Polish Ombudsman, the Ministry presented a "Charter of Patients' Rights" in december 1998 which had been severely criticised. The Charter is merely an incomplete and incomprehensive collection of patients' rights, stipulated in various legal acts related to health care which are currently into force. Furthermore, this document does not include expected guarantees nor does it provide any additional support for the effective protection of patients' rights. It is also doubtful whether the Charter will become legally effective.[48] Until that time, patients' rights can be found in various (legal) documents. Firstly, in the Health Care Institutions Act and, more extensively, the Physicians Code of Deontology and the Mental Health Act.

Act on Health Care Institutions

Strengthening the position of individuals in health care starts with regulating the rights of patients. In Poland, it was a revolutionary idea to include such issues *expressis verbis* in statutory law. The Health Care Institution Act strengthened the patient's legal positions with respect to health care institutions by stipulating the following rights: to be informed of his/her health condition; the notion of informed consent; the right to refuse medical treatment; access to medical records; privacy; confidentiality,

---

46 Topinska *o.c.*: 137.

47 K. Tymowska. Health care under transformation in Poland. *Health Policy*. Vol 56 2001:93.

48 Annual Information 1998: 16.

and the right to die in peace and dignity (Article 19).[49] The protection of these rights has been improved by means of private legal actions. In case of the negligent breach of the patient's rights, s/he may claim indemnity based on Article 448 of the Civil Code. In case of the violation of the right to die in dignity, certain relatives can claim damages (Article 19a Health Care Institutions Act). Nonetheless, in certain circumstances the curtailment of these rights has been excepted. Furthermore, the act stipulates that the unauthorised disclosure of personal data is to be considered a violation of patient's privacy. Subsequently, the patient may claim indemnity from the health care institution.[50]

Physicians Medical Code of Ethics

Besides the Health Care Institutions Act, a general source of patients' rights is the Physicians Medical Code of Ethics (*Kodeks Etyki Lekarskiej*).[51] The Code includes ethical values to all members of the Chamber of Physicians. Formulated as physicians' duties, such ethical standards primarily include the protection of human life and health. More significantly, the Code formulates explicit patients' rights, such as respecting patient's personal dignity and privacy; the right to be informed; the need to obtain consent before treatment; the right to request a second opinion; medical secrecy, which pertains to the Act on Medical Professions; and rights in specific medical interventions (transplantation, procreation, research and biomedical experiments). Although no particular reference to abortion is made, Article 39 demands that "when undertaking any medical procedures on pregnant women the physician is equally responsible for the health and life of her child. For this reason, it is the duty of the physician to maintain the health and life of the child before its birth. Nonetheless, the Act on Family Planning legitimises abortion in specified circumstances.[52]

Finally, regionally Disciplinary Boards of self-governing physicians associations are the competent authority to supervise compliance of ethical standards (Article 5). However, both the Ethical Code and the Act of Medical Professions do not foresee complaint procedures in which patient's complain about physicians violating the above mentioned rights.[53] In this

---

49 *Dz. U.* 1997, No. 104, Item 661, as amended.

50 Art. 415 *ff.* Civil Code.

51 Medical Code of Ethics, Warsaw, April 1994, accepted by the General Assembly of the Chambers of Physicians and Dentists.

52 Law on 7 January 1993 on Family Planning, Human Embryo Protection and Conditions of Legal Pregnancy Termination, as amended by december 23, 1997.

53 The Physicians Medical Code of Ethics, by virtue of Article 4(1), Article 41 and, in particular, Article 63(2) of the Act on Medical Chambers (*Dz. U.*, No. 30 , Item 158), has been incorporated into the system of law, thus becoming rules of conduct binding on physicians.

respect, the effect of the Ethical Code on enforcing patients' rights is rather limited. The Mental Health Act is more successful by introducing a number of legally enforceable rights for persons with mental disorders.

Act on Mental Health

Article 31 (3) of the 1997 Constitution stipulates that "[a]ny limitation upon the exercise of constitutional freedoms and rights may be imposed only by statute, and only when necessary in a democratic state for the protection of its security or public order, or to protect the natural environment, health or public morals, or the freedom and rights of other persons. Such limitations shall not violate the essence of freedoms and rights." The possibility of the legislature infringing a person's rights is therefore severely restricted. Only for the purpose of protecting his or her values will it be possible to impede or limit a person's rights and freedoms, and only by statutory act.

In psychiatry and related disciplines, referred legal impediments concern the inalienability of human dignity (Art. 30) and have been stipulated in the Mental Health Act.[54] Absence of a statutory basis and lacking judicial review on infringements of patients' rights was the main reason for drafting the Act on Mental Health. Until 1994, rules for involuntary treatment had been partially stipulated by means of ministerial regulation.[55] At the same time, it did not envisage judicial control on infringements of patients' rights and freedoms. Ratification of the European Convention on Human Rights and Fundamental Freedoms (ECHR) urged Poland to provide a statutory basis for involuntary admission of psychiatric patients (Article 5).[56] Consequently, chapters II–VI stipulate detailed provisions on (in)voluntary admission, examination, treatment, rehabilitation and assistance of mentally disordered patients. More specifically, the Act codifies fundamental principles such as informed consent procedures for court review in case of involuntary admission, and conditions for applying of physical restraint measures (Arts. 18, 23). To safeguard the rights of mentally incapacitated patients the Guardianship Court has been introduced for minors and mentally incapacitated persons (Arts. 42-49).

In 1997, the Supreme Chamber of Control evaluated the functioning of psychiatric (wards of) hospitals with respect to guaranteeing the rights

---

54 *Dz. U.* 1994 No. 111 Poz. 535, and subsequent amendments.

55 Instruction No. 120/52 of the Minister of Health of december 10th, 1952 on admitting and discharging patients from psychiatric hospitals. Official Gazette of the Ministry of Health, 1952, No. 24, Item 240.

56 *Dz. U.* 1993, no. 61, 284. Government Statement of April 7th, 1993 concerning ratification of the Republic of Poland of the European Convention for the Protection of Human Rights and basic Freedoms, *Dz. U.* 1993, No. 61, Item 285.

of compulsory admitted patients in psychiatric hospitals.[57] The audit revealed several violations of patients' rights, varying from insufficiently information to the patients on their rights, diagnostic, therapeutically and preventive proceedings before requesting consent. It further reported several irregularities concerning procedural requirements for involuntary admission. Enforcing these rights by the supervisory boards in public health care institutions did not appear effective, which was the reason for the Polish legislature to introduce judicial review by means of Article 19a, Health Care Institutions Act.

The results have been passed to the Ministry of Health and Social Welfare. According to the Supreme Chamber, improvement in the enforceability of patients' rights depends both on the increase in financial resources and on rational changes in the organisation of institutions and the physician's compliance with legal and ethical norms. The Commissioner for Civil Rights Protection (Polish Ombudsman) and the judiciary have confirmed these conclusions. Notably the Ombudsman has frequently acted as patients' advocate in individual complaints and general cases on violations of law.

Act on the Commissioner for Civil Rights Protection

Poland was the first country in Central-Eastern Europe that has appointed a parliamentary Ombudsman. The office of the Ombudsman (officially, "Commissioner for Civil Rights Protection") was established in 1987 and functions as an independent institution, accountable to Parliament.[58] Guaranteeing citizens' rights and liberties as set forth in the Constitution, the Commissioner shall investigate whether the law and/or principles of community life and social justice have been violated, due to any action or default on the part of agencies, organisations or institutions responsible for compliance and implementation of such rights and liberties (Article 1). Irrespective its traditional functions, the Commissioner can also appeal to the Constitutional Tribunal against parliamentary Acts and (derived) regulation (Article 16, section 2 sub 3).

The ombudsman institution in Poland has been strongly influenced by the Scandinavian model, promoted by Polish scholars. The institution has

---

57 The Supreme Chamber of Control (Polish abbrev. "NIK") is a central body of government control, its members are appointed by Parliament. It supervises the activities of governmental administrative organs, organs of governmental legal bodies, local self-government bodies, other subjects performing tasks assigned or entrusted by the government when using central or local self-government assets. "Information on the results of an audit by the Supreme Chamber of Control on the implementation of the Mental Health Protection Act." A. Ciecierska and D Gajdus, Department of Health and Physical Culture. Supreme Chamber of Control, Poland 1997: 75-79.

58 *Dz. U.* 1991 No. 109, Item 471.

become quite popular since its establishment given the number of individual complaints on violations of citizens' rights and freedoms by governmental authorities that have been addressed.[59,60] As with other Ombudsmen throughout Europe, the Commissioner has had to reject a large number of complaints since they fall outside his jurisdiction. Presenting its 1996 annual report to Parliament, the Commissioner concluded: "numerous complaints filed at the Commissioner's office have shown that the right of citizens to health care in public institutions, free of charge has been infringed."[61] The Commissioner has addressed many occasions in which a violation of the right to access to health care involved in charging patients for selected services or surgical activities, so-called "voluntary donations". Breach of the right to free health care services occurs also in maternity wards (...). Women entitled to free services are charged for being treated during hospital admission or when they are not assigned to the administrative district of the hospital (...). The situation presented shows that the legal principle of universal access to health care services does not correspond with the daily practise.

3 PATTERNS IN LEGISLATIVE REFORMS

It is evident that the legislative reform process is not without its problems. Analysis using the theoretically discerned clusters revealed certain omissions and shortcomings in the process. While the foundations of a revised health care system in the direction of a decentralised health insurance system have largely been laid, major problems have appeared with the (lack of) implementation and enforcement of statutory acts. Of particular concern is the absence of regulations implementing the Health Care Institutions Act and Medical Professions Act. Secondly, since the initial steps towards a decentralised health insurance system have been achieved, it appeared that the Polish legislator has changed its priorities towards the "approximation of laws" in the light of accessing the European Union. This process has raised legal problems, also in the field of health. Up until now, adopting the *acquis communautaire* (the legal framework of EC law) in the area of health has not been very successful. The identified deficits and problems that have occurred in the reform stage have been classified

---

59 E. Letowska. The Polish Ombudsman and Human Rights in: Ombudsman in Europe – The Institution. Engel Verlag, Kehll am Rhein, 1994: 61.

60 In 1988: 52, 867 complaints; 1989: 29,031; 1990: 22,764; 1991: 22,340; – 1997: 31, 122; 1998: 30, 251. In: Commissioner for Civil Rights Protection. Annual Information. Warszawa 1998: 101.

61 Stenographic account of the 14th session of the Parliament of the Republic of Poland, 27-29 August 1997, Warsaw, quoted by Baginska and Nesterowicz. The Polish Solution to Realise the Right to Health Care: in: Den Exter and Hermans 1999 *o.c.*: 121.

according to the discerned clusters of health care law-making and concern public health legislation, the organisation of health services, and financing legislation. Apart from approximation of domestic public health law, even more problematic is the alignment with the European Union's internal market. Since the internal market legislation constitutes the very core of the substantial European law, the emphasis is on the consequences for the freedom of movement, *nominatim* patient flows.

Approximation of public health law

Accession to the European Union will have implications for the health systems in the existing Member States, especially due to the trans-national mobility of persons.[62] In view of the lower life expectancy and poorer health status in accession countries, there will be a need to assist these countries in adapting to Community policy in the field of public health. Since the latest amendments of the EC Treaty, the new public health provision in the Treaty identifies three strands of action: improving information for the development of public health; reacting rapidly to threats to health; and tackling health determinants through health promotion and disease prevention (Article 152 EC). Based on this provision, the Commission has set out a new framework for action in the field of public health in its "Communication on the development of public health policy".[63] The proposed actions take into account the emerging health threats, increasing pressures on health systems, and the enlargement of the Community. Although this Commission's public health action programmes are open to candidate countries, the orientation in Poland, however, has evolved into the treatment-oriented. This has led to public health being given low priority, with inadequate funding and therefore less successful in health promotion and health education activities.[64] The limited interest of the Polish government for public health issues at national level does not correspond with the Community public health policy. What is needed is a reconsideration of its national public health policy including the impact of European health policy. Concrete actions should start with the definition of legal instruments and implementing action programmes on aids and other communicable diseases, cancer, drug dependency, health promotion,

---

62 Alignment with the Internal Market must be distinguished from accession to the Union, which will involve acceptance of the *acquis communautaire* as a whole, even if it is obvious that Internal Market legislation constitutes the very core of the substantial law of this *acquis*.

63 Communication on the development of public health policy in the European Community. COM (1998) 230 final, building on the communication of the 24th november 1993, Com (1993)559 final.

64 National Centre for Health System Management. Study concerning adaptations of the Polish Health Policy and Legislation to the requirements of EU Membership (Polish). Warsaw 1995: 176.

pollution-related diseases, injury prevention and rare diseases.[65] To certain extent, the National Health Programme 1993 has already prioritised these issues in the new health policy framework.[66] However, the legal basis to coordinate and implement the required activities is missing. Strengthening the legal status of the National Health Programme in enforcing its stipulated objectives, in addition to amending relevant Health Care Institutions Act provisions, has been suggested to overcome the main legal shortcomings.[67]

Absence and delay organisational by-laws

Several problems that have been observed concern serious delays in executive regulations pertaining to the domain of health care.[68] This is particularly true of the 1991 Act on Health Care Institutions and subsequent amendments in 1997. Despite the fact that the Act came into force seven years ago, at the present time, various regulations derived from the law have still to be implemented. Referred regulations should specify, *inter alia*, standards of medical procedures, principles of certifying medical equipment and devices, minimum standards for the employment of persons performing basic activities, rules and procedures for obtaining specialist titles, rules for the accreditation of health care facilities, principles of storing and disclosing data from medical files, the functioning of health care institutions of governmental departments, *et cetera*. Where the accreditation conditions of health care facilities is concerned, the Polish Ministry of Health started to develop a regulatory accreditation system based on foreign experiences, notably the Netherlands.[69] Currently, there are no major legal restrictions to starting and managing a hospital facility. In order to regulate both the volume and allocation of hospital facilities, a licensing system will be introduced. Without a license it will be forbidden to start or run a hospital. The licensing system will be based on a national and regional planning norms, and based upon needs. This licensing system will be founded on the Health Care Institutions Act, notably the licensing by-law.

---

65 OJ No. L 95, 16.4.96, p.16; OJ No. L 95, 16.4.96, p.9; OJ No. L 19, 22.1.97, p.24; OJ No. L 95, 16.4.96, p. 1; OJ No. L 155, 29.4.99, p.7; OJ No. L 46, 20.2.99, p.1, and OJ No. L 155, 29.4.99, p.1.

66 It is expected that Poland will participate in the year 2000 in four public health action programmes: AIDS and other communicable diseases, cancer, drug dependence and health promotion. Participation in other action programmes is being discussed.

67 National Centre for Health System Management *o.c.*: 179-180.

68 Commissioner for Civil Rights Protection. Annual Information 1998, Warsaw 1999: 16-17.

69 J. Both, J. Czeczot, and A.P. den Exter. The Certificate of Need Development: Elaboration of a licensing system according to needs and its Implementation, in: Standards of Health Services Purchased in the National Health Insurance System. TNO Prevention and Public Health 2001.

More significant delays in issuing by-laws on the Act on Medical Professions have limited or frustrated the implementation of many provisions of the Act and the introduction of new rights and obligations of physicians (e.g., related to certifying doctors for practise, post-graduate training, new specialisations and activities and activities outside the health care sector).[70] The issuing of executive regulations which limit blood donor rights, as stipulated in the Act on Public Donation of Blood, has also been delayed.

The impact of EC law on health care services and financing legislation

Approximation of laws is a major aspect in the integration of the internal market. The Polish Europe agreement[71] already contains an explicit reference to approximation, which is seen as "an important condition for economic integration into the Community".[72] Progressive alignment with internal market rules and practices necessitates the adaptation of the basic rules laid down in the Treaty. More detailed secondary legislation has also been required where wide differences between rules and practices in the Member States present obstacles to free movement. The large body of secondary legislation includes key areas such as the co-ordination of social security provisions for migrant workers. In view of expected migration flows,[73] both from acceding to present members and among the acceding members themselves, the exportability of social security benefits will increase in importance. Of particular relevance are Co-ordination Regulations 1408/71 and 574/72.[74] Regulation 1408/71, which is based on Article 42 EC (ex Art. 51), guarantees EU citizens acquired rights accumulated under one national social health insurance scheme, when

---

70 RPO/271538/98/1, RPO/272393/98/1, RPO/285128/98/1, RPO/287545/98/1.

71 For a more extensive analysis about the Europe agreements, see also the next chapter (section 8.1). The legal base of this Agreement is Art. 310 EC Treaty (ex Art. 238 EC) and has the legal character of association agreement. Originally, Europe Agreements are not designed to prepare CEE countries for EU accession. Europe Agreements basically deal with free trade and political dialogue, not with law approximation. This changed as a direct consequence of the political re-interpretation of these agreements at the 1993 Copenhagen European Council M-A Gaudissart, A. Sinnaeve. The Role of the White Paper in: Enlarging the European Union. Relations between the EU and Central and Eastern Europe. M. Maresceau (ed.) Longman. London 1997: 42-44.

72 Arts. 68, 69. O.J. L 348, 31/12/1993, p. 2-180.

73 In view of the wage differentials, and the limited freedom of movement before accession. Agenda 2000: Impact Study. The Effects on the Union's Policies of Enlargement to the Applicant Countries of Central and Eastern Europe (Chapter 5.1).

74 Council Regulation (EEC) No. 1408/71 of 14 June 1971, O.J. No. L 149 of 5 July 1971. Apart from regulation 1408/71, there is regulation 574/72, laying down the procedure for implementing 1408/71; officially: Regulation (EEC) No. 574/72 of March 1972, O.J. L 74 of 27 March 1972. Both regulations have been revised several times and which remain valid to this day.

staying permanently or temporarily outside the territory. The social protection guaranteed by one national social health insurance scheme would be guaranteed irrespective of the place of residence. Since Regulation 1408/71 is directly binding, it is valid without being ratified by any national parliament. Article 22(1)(c) of Regulation 1408/71 will enable certain categories of persons who are ensured under Polish legislation to go to another Member State for the purpose of receiving medical treatment there, at the expense of the competent institution (i.e. the Polish Ministry of Health). However, the insured must obtain an authorisation from the competent institution. By virtue of Article 22(2), the authorisation must be given only if both the following conditions are fulfilled: (i) the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides, and (ii) the treatment cannot be given within the time "normally necessary for obtaining the treatment in question in the Member State of residence" taking account of the person's current state of health and the possible course of the disease. When these conditions are met, Polish social insured are entitled to cross-border care. At the same time, the directly binding effect urges the candidate Member State to harmonise national legislation. Possible obstacles restricting the free movement of cross-border care need to be removed.

Such an obstacle is the pre-authorisation criterion, *i.e.*, the "availability-criterion" in Article 31a(2) of the General Health Insurance Act, which does not correspond with the time "normally necessary for obtaining the treatment in question in the Member State of residence", Article 22(2). Article 31a(2) stipulates that "the Minister of Health may refer the insured for diagnostic examination or treatment abroad in case such services are not available in Poland." Such cross-border health care will be financed by the state budget.[75] At the moment, it is unclear how to interpreted "not available". It could mean "*physically*" not available whether due to absence of technical capabilities or financial reasons, or secondly, interpreted as not available "*within reasonable time*". The Ministry of Health uses a restrictive interpretation, *ergo*, physically not available instead of normally necessary, interpreted as not available within reasonable time. This hinders cross-border care and violates fundamental freedoms of EC law (both pensions and services).[76]

In case of extensive interpretation of the authorisation criterion, the insured may also claim cross-border care when, for instance, there are waiting lists for certain services or there are likely differences in the quality

---

[75] Article 31a section 2.

[76] A.P. den Exter. Legal reforms of the Polish health care system in view of accession the European Union. *EJHL* 2001, Iss. 2: 16.

of services available. Consequently, relevant questions are how to define "unreasonable time"; who will decide (most likely the Minister of Health); based on what criteria; may such a decision be contested; which should be the relevant committee? Cross-national experiences on access to health care services might also be relevant to Poland. Although mainly focussed on accessibility of national health care services, the criteria used are also applicable in the case of cross-border health care. Comparative legal research in various western countries indicates that courts have attached the principles of medical necessity, of urgency or non-deferability and the freedom of choice of provider by patients. However, these principles are not applied in an absolute or abstract fashion but on a conditional basis.[77] One conditions that is emerging is financial resources. With increasing frequency, the courts in Italy and the Netherlands have had to make judgements on the right to health care with explicit reference to questions of the costs of care. In these countries, the courts emphasize the principles of medical necessity, urgency and freedom of choice of providers by patients.[78] However, in these two countries, as well as in the UK, conditions have been formulated and the courts have accepted that the right to health care, in this case access to health care services abroad, has to be judged within the scope of the limited resources.

However, even when a more extensive interpretation would be accepted, it is questionable whether the increase in cross-border flows of Polish patients will be significant. Although article 22(1)(c) of Regulation 1408/71 enables the person to go to the Member State where the service is provided, this does not necessarily mean that the costs related to medical care provided in the Member State B have to be born by the competent institution of Member State A where the "beneficiary of the service" is insured. In fact, there is still a close link between the financing of the national health insurance system, to be paid out of taxes or contributions, and the health care (hospitals, physician, *et cetera*) to be provided under these systems.[79] In more concrete terms, this means that the competent institution in Member State A (i.e., Poland) will reimburse the costs according to tariffs valid in Member State A. Since the institution that

---

77 *E.g.*, H.E.G.M. Hermans, G. France. Choices in Health care in Italy and the Netherlands: II. Legal dimensions in: Leidl R (ed.) Health care and its financing in the single European market. Amsterdam, IOS Press 1998: 265-282. G. France, H.E.G.M. Hermans. Choices in health care in Italy and the Netherlands: I. Economic and financial dimensions in: Leidl: 254-264; A. den Exter, B. Hermans. Constitutional Rights to Health Care: The consequences of Placing Limits on the Right to Health Care in Several Western and Eastern European Countries. in: *EJHL* 1998, Iss. 3: 261-289.

78 Den Exter and Hermans *o.c.*: 284-285.

79 R. Cornelissen 25 years of regulation (EEC) No 1408/71, its achievements and its limits, in: European and International Social Security Law, Institute of Social Law, Catholic University Louvain, 1999: 122.

provides the service has to be fully compensated,[80] the difference has to be paid by the "beneficiary of the service". Due to the relatively low wages, the majority of the population in Poland will not be able to finance (substantial) price differences. Particularly since it is not (as yet) an insurable risk. Consequently, cross-border care can be considered as a serious option only for those who can afford it. As such, cross-border care may put the principle of solidarity incorporated in the health insurance scheme under pressure.

To overcome the differences in real cost of treatment and tariffs, agreements with neighbouring institutions and health purchasers concerning the level costs to be reimbursed, particularly in border regions, is suggested. Establishing collaboration with neighbouring institutions can be based on positive experiences with border regions and so-called Euregions.[81] These experiences emphasise common interest where highly specialised treatments requiring very expensive equipment, highly specialised staff and a sufficient level of patient demand are concerned. Systematic referrals for these specific pathologies to the so-called centres of excellence throughout the EU would not only allow the member states to refrain from investing in the same type of care, it would at the same time ensure a more optimal use of these centres.[82]

Another lesson to be drawn from these experiences is that, if borders in health care are to be torn down, this should first be done in border areas. Indeed, as the transaction costs are often lower in these areas, the inhabitants of border areas are better placed to experience the limitations imposed by the application of the territoriality principle in health care protection. In some cases, this could be an obstacle to closer or more convenient health care delivery across borders. This should lead us to reflect upon subjects such as interregional health care planning in border areas and specific agreements between health care providers and health insurance institutions so as to facilitate cross-border referral based on cross-border complementarities in health care supply.[83]

Apart from financial and organisation implications, a third lesson to be drawn is that cross-border collaboration in health care can stimulate the

---

80 By virtue of Article 93 Regulation 574/72.

81 These Euregions were established within the interregional (INTERREG) programme. This programme was set up to remove internal market impediments among Member States. For several reasons, these activities have extended to the field of health care, strengthening cross-border health care. One of the most active Euregions in health care is the Euregion Meuse-Rhine. At this moment, the European Union counts more than 60 Euregions, although not all of them are collaborating in the field of trans-national health care.

82 J. Hermesse, H. Lewalle, W. Palm. Patient mobility within the European Union. *EJPH* 1997, Iss. 3 supplement: 9.

83 Hermesse *o.c.*: 9-10. B. Starmans, R. Leidl, G. Rhodes. A comparative study on cross-border hospital care in the Euregio Meuse-Rhine. *EJPH* 1997, Iss. 3 supplement: 40.

realisation of patients' rights, particularly the right on cross-border health care. When patients are being informed about (potential) benefits of cross-border care they may opt for the most attractive purchaser, i.e. purchasing cross-border care in other Euregion countries. This means that, in addition to the purchasers and providers, patients and consumers will have to be considered as a newly emerging countervailing power aimed at improving access to cross-border health care.[84,85,86] Supported by relevant European Court rulings, this development requires changes in organising health care and rules strengthening the position and influence of patients/insurees.[87] The citizen's voice and choice should make a contribution towards shaping health care services as the decisions taken at other levels of economic, managerial, and professional decision-making. It means that citizens should be heard on issues such as the content of health care, contracting, quality of services in the provider-patient relationship, the management of waiting lists and the handling of complaints. The exercise of choice and of other patient's rights, require extensive, accurate and timely information and education. This entails access to publicly verified information on health services' performance.

These principles and priorities could also be chosen as major benchmarks for the creation of cross-border alliances in current Polish Euregions (Neisse-Nisa-Nysa, Spree-Neisse-Bober, *et cetera*).[88] Such alliances may function as "laboratories for accession", or a major attempt towards future integration with the European Union. Clearly, such alliances will be bounded by certain limitations. For instance, collaborative partners have been subjected to different legal norms of various legal systems. Further-

---

84 D. Light. Countervailing powers. A framework for professions in transition In: T. Johnson, G. Larkin, M. Saks (eds) Health professions and the State in Europe. London/New York: Routledge, 1995: 25-41.

85 H.E.G.M. Hermans, A.P. den Exter. Cross Border-Alliances in Health Care: International Co-operation between Health Insurers and Providers in the Euregio Meuse-Rhine. *CMJ* 1999, Iss. 2: 267.

86 See also, Draft Recommendation No. R (99) of the Committee of Ministers to Member States on citizen and patient participation in the decision-making process effecting health care. It defines several guidelines to ensure citizens' participation in all respects of health care systems. From the ability to influence the overall administration of the health care system and to participate in the decision-making process.

87 *E.g.*, C-120/95, C-158/96 confirmed by C-368/98 and C-157/99, *infra* chapter 8.

88 The oldest Euregion in which Poland is involved is the Euregio Neisse-Nisa-Nysa, including Polish, Czech, and German partners. Established in 1991, this Euregio deals with, *inter alia*, trans-frontier environmental issues. The second Euregio, Spree-Neisse-Bober was set up between Germany and Poland. Besides environmental issues, other fields of cross-border collaboration include traffic and economic development. Other important Euregions are Pro Europe Viadrina in (1993) and Pomerania (1995). Such types of trans-frontier co-operation can be based on various bilateral treaties, or on the European Outline Convention on Trans-frontier Co-operation between Territorial Communities or Authorities, 21 May 1980, ETS No.106 aimed at promoting trans-frontier co-operation.

more, partners cannot terminate agreements that conflict with national health policy. Consequently, trans-frontier collaboration requires trans-frontier authority, locally and nationally. Formalisation of collaboration could contribute to provide the "political willingness" of the competent authorities. Finally, administrative centralism and concentration of cross-border decision-making at national level could create institutional difficulties.[89] This is particularly the case where the planning of health care services, financing and tariff decision-making processes are concerned. The suggested answer includes a combination of decentralisation and cross-border subsidiarity.[90] With the establishment of regionally quasi-autonomous health insurance funds on both sides of the Polish-German border, a main obstacle for trans-frontier collaboration has been eliminated.

4 DEFICIENCIES IN THE LAW-MAKING PRACTISE

The legal framework is a defining element of effective reforms as it determines the rules for both the public and private sector in health care. The quality of legislation can strongly influence economic development and the well being of the citizen. Poland has exerted considerable effort towards create the institutional and regulatory environment necessary for a market economy and pluralistic democracy. In that process, Poland has encountered various legal problems, many concern the law-making process caused by prevalent instability in statute law and regulations. The existing law is a patchwork of pre-reform legislation together with statutes and regulations passed by successive governments and parliaments since the ancient regime. In consequence, there is a large body of incoherent and rapidly changing legal norms that are difficult to apply consistently. In this way, the role of court and judicial decisions has now become more important in shaping and ameliorating normative acts. Further analysis of the law-making process according to the discerned stages has identified several major legal deficiencies, in particular with respect to the implementation and evaluation stages of law-making.

Irregularities implementing legal norms

The Human Rights Commissioner observed a deepening tendency under which authorities not authorised to issue executive regulations do so and said regulations are issued in forms not provided for by the Constitution. If this tendency solidifies it may constitute a threat to the protection of civil

---

89 J.W. van der Meulen. Euregions across the Polish borders (in Dutch), Netherlands Institute for International Relations "Clingendael", The Hague 1997: 11-12.

90 *L.c.*: 12.

rights and to the efficient functioning of government.[91] The Commissioner has frequently taken action in response to complaints that legislative authorities have been exceeded. "Even if the effective statute – *in casu* the Act of State Police – contains gaps, loopholes and shortcomings, it is not the prerogative of government agencies to rectify them through the issuance of an executive regulation". In several cases, the Constitutional Tribunal confirmed the Commissioner's grievance.[92] In other cases of exceeding competencies, the Commissioner's conclusions were applied by the competent Minister to rectify specific irregularities.[93] Unfortunately, such requests are not always successful. Despite pledges from the Minister, *i.e.* the Minister of Health and Social Welfare, the problem of preventing, diagnosing, treating and combating infectious diseases by means of annual occupational check-ups still has to be properly regulated. Current regulations are not only outdated in terms of their content but are incompatible with current constitutional requirements (for instance, in the manner in which they place obligations on citizens).

Judicial evaluation: Lacking tradition of applying international law

Promoting human rights mainly concern the International Covenants on Human Rights (the Covenant on Civil and Political Rights and the Covenant on Economic, Social and Cultural Rights) as well as the European Convention on Protection on Human Rights and Fundamental Freedoms. In 1994, Commissioner Letowska firmly criticised the lack of knowledge of the Covenants manifested by a number of perverse examples.[94] Letowska bluntly concluded: "[a] *lthough its existence is known in Poland, it is limited to restricted groups, viz, lawyers. The accessible literature is more of a theoretical nature; it does not concern the practical effects of the existence of such instruments. Wide circles of judges and administrative officials simply do not know the Conventions. The fact that Poland signed the European Convention only in 1991 also results in ignorance in judicial practise ensuing from that Convention. The shortcoming is quite significant since it is on the basis of that instrument, through judicial practise, that more concrete standards of law are established.*"[95]

This attitude stems from the uncontested heritage of the *ancien régime.* International law was not accepted as a relevant criterion that could be used to evaluate domestic law. There was also no tradition of making direct use of the Constitution as a basis for a decision or even for reviewing regula-

---

91 Commissioner for Civil Rights Protection. Annual Report 1998. Warszawa: 12.

92 *E.g.*, RPO/253237/98/V August 12, 1998; decision december 8, 1998 file no. U 7/98.

93 *E.g.*, RPO/284617/98/V August 6, 1998 and RPO/288649/98/V september, 24, 1998, RPO/234309/98/V september 3, 1998; RPO/253067/97/I; and RPO/283823/98/I August 6, 1998.

94 Letowska *o.c.*: 61.

95 Letowska *o.c.*: 60.

tions as the basis for decision-making in the court. However, this situation has changed. Ratification of International and European Human Rights Covenants and subsequently necessary constitutional amendments have revealed an increased interest in the direct application of international law.[96,97] Since the 1997 Constitution came into force (ratified) international law unambiguously constitutes part of the Polish legal order (Article 91, par.1, 1997 Constitution), and is valid *ex proprio vigore*.[98] In view of the entrenched provisions and substantial case law of supreme judicial bodies, Poland became open for the first time in the post-war period to international legal obligations derived from the Vienna Treaty Convention (application of treaty provisions).[99]

The increased relevance of international sources of law has also highly influenced the methods of interpreting law by the courts and for their legal thinking. The court's role was restricted to the settlement of particular disputes based on uncritical adoption of positive law. This narrow positivist conception of the law affected the court's approach towards interpreting law. The exclusion of international law, as well as the weakening of the control function of the courts, caused the judiciary to develop a tendency towards an excessive preference of a purely linguistic interpretation. Simultaneously, a distrust of a systemic (including reference to international law), axiological (contrary to instrumental) and functional interpretation became manifest.[100] Acceptance of the notion of the *rule of law*, the establishment and practise of the Constitutional Tribunal, and ratified human rights conventions have entailed a more critical attitude of the courts towards the legislature and executive. The awareness of these

---

96 *Dz. U.*, 1993, no. 61, Item 284-285, including the Protocols No. 1-5, 8-10 (ratified), Protocol No. 7 signed but not ratified, Protocol No. 6 was not signed by Poland.

97 *E.g.*, the High Administrative Court, the Supreme Court and later the Constitutional Tribunal. Cf. Decision I SA 799/90, SA/Wr/14/91,I SA 35/91, III CZP 48/92, Syg. Akt. II. KRN 274/91, V KRN 109/90, III AZP/9/92, III ARN 28/90; Syg. akt. K 8/91, OTK 1992, I, Item 5, 82-83.

98 The question of the direct applicability of international law was matter of doctrinal and judicial dispute, notably in the early 1990s. One concern raised in the debate was that ratification would impose unfamiliar values and ethics on the Polish nation. S. Waltos, in: Introduction to the Collection of Penal Law. Park Publ., Bielsko-Biela 1993, quoted by Hofmanski. The direct applicability is, however, limited to specific international agreements which include agreements, *inter alia*, on human rights, political and military alliances, and Poland's membership in an international organisation, Article 89(1).

99 Convention on the Law of Treaties, 23 May 1969, ratified by Poland in 1990: *Dz. U.* 1990, no. 74, Items 439 and 440 which states, *inter alia*, that "Every treaty in force is binding upon the parties to it and must be performed by them in good faith" (Article 26) and "A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty ..." (Article 27).

100 E. Letowska, J. Letowski. Transformation of the law: A "craving" for judge-made law. In: Poland towards to the Rule of Law. Polish Academy of Sciences, Warsaw 1996: 124.

changes has inspired the courts to apply various methods of interpretation, including axiological interpretation.[101] Both the normative frame of reference of (inter)national sources of law and changing methods of interoperation by the courts have increased their countervailing power in evaluating the legislature. In this spirit, it is also worth mentioning the role of the Commissioner for Citizen's Rights. He is concerned with the legality or otherwise of administrative actions. In consequence, he has extensive powers to submit cases to the Constitutional Tribunal or the Supreme Administrative Court. The Ombudsman has become involved with problems caused by serious delay (or failure to act) in defining adequate regulation. He expressed his concern at delays to legislation that invokes the danger of arbitrariness of decision-making.[102] The Commissioner also indicates the Sejm areas where new legislation is needed. He has also developed an "early warning principle" by which he tries to anticipate possible violations of civil rights in present or proposed legislation and recommend action through formal reports to Parliament and government, including further legislation. His purpose in doing so is "to strengthen the perception of the legal framework in social life and in the life of individuals"[103] and hence to persuade legislators to amend legislation or introduce new statutes or regulations to avoid possible breaches of civil rights.[104] As such, the Commissioner is becoming a cathartic force in transforming legislation.

5 CONCLUSIONS

The transformation of the Polish healthcare system initiated profound changes in national health legislation, for instance the enactment of the Law on Health Insurance and Health Care Institutions. Although new legal norms strengthened the position of the individual in health care, new problems emerged. Major weaknesses in legislation concern disparities with European law in the light of adopting the *acquis communautaire*. Harmonization of legislation revealed several problems in terms of the theoretically discerned stages of law-making. Key deficiencies have occurred in the development stages and concern the formulation of clearly legislative objectives, problem analysis and priority setting. Although the expertise to identify and diagnose legal problems and, subsequently, to select legislative priorities is available, successive governments lacked the capacity to develop a consistent and comprehensive legislative reform strategy.

---

101 Letowska *o.c.*: 125.
102 Commissioner's Annual Report 1993: 17.
103 Commissioner's Annual Report 1992: 27, 29.
104 Commissioner's Annual Report 1993: 111.

Consequently, the newly developed legal framework has be characterised by harshly drafted legislation without reasonable time schedule. Subsequent and frequent amendments have also been observed in other countries in transition. The lack of time and capacity to plan necessary regulatory instruments has considerably contributed to the deficits in legislation.

Identifying and diagnosing legal problems related to the alignment of international, notably European, law has received only theoretical consideration. The role of international covenants and the Europe agreement in particular has been highly underestimated in identifying latent legal conflicts and setting law-making objectives in the field of health care. The premise that Poland will transform its foundation based on a market economy, democracy, *rule of law* and human rights (Preamble of the Europe agreement) did not result in successive legal steps. Apart from the Mental Health Act, as a direct consequence of ratifying the European Convention on Human Rights, compatibility with the EC public health provisions and internal market principles did not result in re-defining the law. European Commission documents (e.g. Agenda 2000, "Development of Public Health Policy" and "Health and Enlargement"), however, provide valuable materials to help identify actions, draw up a programme of priorities, over and above the transposition and implementation of the *acquis communautaire*, in the context of the future enlargement of the European Community.

Up to this time, a national programme drawing and defining regulatory priorities, including an in-depth data analysis on the legal implications of adopting the "acquis" has remained absent. Limited knowledge and experience with Community law and its implications to health care law could explain this absence. Secondly, fearing the consequences of open markets and unlimited trans-boundary flows may also explain the interest for supra-national legal aspects.

The iterative analysis revealed several difficulties in the implementation stage. When the legislative basis is missing or unclear, alternatively, the administration issues (unauthorised) regulation or applies an extensive margin of discretion in decision-making. This phenomenon has been observed by the Ombudsman and threatens the legal security principle. Secondly, when the legislature failed to transform and implement supra-national law, the Constitutional Tribunal and Supreme Court have appealed to its responsibilities. Occasionally, these courts have concluded that the legislature is bound by international obligations (evaluation stage). In other words, by appealing to international and European legal standards, these courts impose the legislature and government to transform national legislation according to supra-national law. In view of the increased importance of international law and the accepted direct applicability of international human rights treaties (article 89(1) Constitution), it may be

expected that the Tribunal and the Supreme Court urge the prioritisation of legislative activities when national patients' rights have not been regulated adequately.

Apart from national judiciary bodies, in view of future enlargement, the European Court of Justice will also enforce the "human rights acquis". For instance, illustrative cross-border health cases confirm the (conditional) patients' right of free movement which subsequently impose on Member States the removal of national (regulatory) barriers. In the case of Poland this would mean, *inter alia*, a revision of the current pre-authorisation provision conform Article 22(1)(c) of regulation 1408/71. Modification of the national pre-authorisation procedure makes clear that alignment with European law goes further than legislative reforms necessary to put in place a market economy, it also aims to safeguard patients' rights such as access to (trans-boundary) health care. Otherwise, where pending cases confirm such a right, it will have serious implications for the financial position of recently established sickness funds. It is therefore likely that overall evaluation of the Court of Justice's rulings will have direct legislative policy implications. More than ever, it would mean a reappraisal of patients' rights as a principle issue on the national health policy agenda. Secondly, the incorporation of the acquis in legislation as an integral and living part of the legal decision-making process.

Part Three

The relevance of the analytical model in transposing EC law

GENERAL INTRODUCTION

Since the ratification of the Europe (Accession) agreements with the European Union and its Member States, all the candidate Member States embarked on harmonising national legislation to European legal standards. For the time being, this has primarily been focussed on specific themes such as "health and safety at work", "health, environment and food" and "various public health action programmes". However, more radical legal changes are required in relation to the implementation of the internal market and the *acquis communautaire*. Particularly the (in) direct effects of the internal market to the health (care) sector has, until recently, remained *terra incognita*. The "White Paper on Enlargement" and "Agenda 2000" launched a pre-accession strategy specifying, *inter alia*, internal market priority directives and regulations that need to be transposed.[1] More detailed accession strategies can be found in "national programmes for the adoption of the acquis" (NPAA) in which each candidate country sets the legislative (policy) agenda and timetable on the approximation of the legislative process.

Within the framework of this research, the author addresses the relevance of the legal-theoretical model of law-making applicable to health legislation. This methodological approach reflects the legislative process as a circular conceptual model. Part one described the underlying principles and objectives of that model, more particularly its relevance to health care law-making. In part two, the actual situation of health care legislation in three selected countries was examined according to the approach of theoretically discerned stages and clusters of health care law-making. This approach enabled the classification of the principal features of health care legislation as well as the identification of legislative deficiencies in terms of the conceptual framework of health care law. Subsequently, such observations would initiate judicial and/or policy incentives amending and/or introducing legal norms. In line with this approach, part three will apply the analytical model of law-making to European Community law, more specifically, to assess the European legal implications of transposing the principle of the *acquis communautaire* into domestic law. The impact analysis and subsequent review of the "approximation of laws" process enable the identification of possible gaps in the country's transposition process, which could necessitate candidate countries to modify the national

---

[1] The term "transposition" refers to the process of adjusting Member States' national legislation to those parts of EC law which have acquired legal force for that Member State. Transposition is therefore an activity that has to be performed, mainly by the national authorities. D.M. Curtin, R.H. van Ooik, Revamping the European Union's Enforcement systems with a view to Eastern Enlargement. Scientific Council for Government Policy (WRR), The Hague, October 2000: 39.

accession policy targets and strategy. The underlying assumption is that this approach may contribute towards structuring and analysing (potential) European legal problems, transform them into legislative objectives, and subsequently, to define legislative standards; *ergo* an attempt to rationalise the acquis transformation process. Such a more rational approach should enhance the capacities of candidate Member States to implement common European legal standards as part and parcel of the submitted health care reform process. From a scientific perspective, however, the applied approach enables the verification of the tenability of the underlying thesis, *i.e.* the theoretical model as explanatory instrument of both the process and content of health care legislation.

Reviewing the consequences of EC law raises the question of whether the underlying principles (the right to health care and patient autonomy) and selected indicators (public health regulatory reforms, the organisation and financing legislation and patients' rights) are applicable to the European law setting. It will be argued that the specific nature and origin of EC law will impose further modification of the original model by including European legal principles.

CHAPTER 8: THE RELEVANCE OF THE ANALYTICAL MODEL TO EC LAW APPROXIMATION

1 INTRODUCTION

From the previous chapters it has become clear that the legal systems selected, just as with other Central and Eastern European systems, have experienced major changes. These reforms were initiated by (re)installing constitutional concepts such as parliamentary democracy, the *rule of law* and respect for human rights. Besides internal impetus, the transformation towards a "western" democracy that respects fundamental economic and legal principles has been strongly stimulated by the European Union (EU) and its Member States. From the beginning, the EU was aware of its responsibility to support the necessary institutional changes. Substantial financial and technical assistance has been provided in the framework of the PHARE-programme.[1] Originally intended to support economic reforms in Central and Eastern Europe, the Copenhagen Summit (1993) shifted its aim to assist candidate countries in helping them to prepare for joining the EU as quickly as possible. The basic legal instrument to realise this objective is the Europe agreement (EA) concluded with the accession countries individually. Apart from these Europe agreements, the Accession Partnerships constitute the central pillar of the reinforced pre-accession strategy. It sets out the key short and medium term priorities to be met by the candidates in order to prepare for membership. It also indicate the financial assistance available from the EU in supporting of these priorities and the conditionality attached to this assistance.[2] In addition to the Accession Partnership, each country has prepared a "national programme for the adoption of the acquis" (NPAA) which indicates the resources and the timetable foreseen for the implementation of the accession priorities. Given the divergence in (institutional) development, most applicant countries have defined their own priorities for accession. Most of these programmes include (public) health as one of the priorities. The emphasis, however, is on incorporating the EC internal market principles.

---

1 Originally, PHARE represented: *P*oland and *H*ungary: *A*ssistance to the *R*econstruction of the *E*conomy. Set up in 1989, Phare had by 1996 been extended to include 13 partner countries from the region (including (non) candidate member states).

2 Council Regulation (EC) No. 622/98 of March 1998 on assistance to the applicant States in the framework of the pre-accession strategy, and in particular on the establishment of Accession Partnerships, OJC No. 85 of 20/03/1998, Article 1.

Incorporating EC law requires the approximation of national laws to European legal standards. This will have major consequences for the domestic health legislation in candidate countries. Within the framework of this research, the question is raised of whether, and in what respect, the previously developed model could contribute towards the law approximation process. Since the previous chapters confirmed the value of a structured and systematised approach of law-making, it is quite likely that the analytical model can also be of relevance in aligning national law to EC health law. To verify that assumption, the model of law-making will be applied to examine the "approximation of health laws" process. Since the model's underlying values (right to health care and patient's autonomy) do not necessarily correspond with Community legal principles, the original model of health law needs to be amended. This requires, for instance, the inclusion of the principles of Community law and their incorporation in the analytical model. Since the community values underlie and restrict Community law and policy, these principles affect the discerned clusters of health care law and health policy. The first step is, therefore, to discuss the impact of EC law on the analytical model of health care law-making (section 2). Following the theoretical stages of law-making, the analysis begins by describing the relationships between the European Union and applicant countries since the concluded agreements formulate the objectives and normative framework to be incorporated by candidate member states. Paving the way for accession, concluded Europe agreements and national accession programmes function as important guidelines to initiate legal reforms (section 3). Subsequently, the analytical stage of problem-analysis addresses the priorities more extensively which enables the examination of the consequences of Community law on the domestic legal order (section 4). Since candidate countries have already started the law approximation process, the final section therefore addresses the outcomes (section 5). In terms of the model, this section addresses the progress in transposing the health acquis ("definition of the ultimate means") and subsequent stages. It is argued that by further analysing the path to accession, the adapted analytical model provides a feasible instrument in manifested reform processes. It indicates the successes and deficits in regulatory norms. Moreover, it enables the (re)definition the objectives of the legislative harmonisation strategy.

2 RATIONALIZING THE LAW APPROXIMATION PROCESS

By examining health legislative reforms in several selected countries, the previous chapters examined the theoretical tenability of the developed model. It appeared that the introduced legislative changes followed, *grosso modo*, the same pattern. This pattern is based on the functions of health

law as discerned in the doctrinal debate.[3] The subsequent theoretical model reflects in a simplified manner the stages in the health legislative process. The political dimension in the lawmaking process has been expressed by the constant interaction between law and policymaking.[4]

What has been examined from a national legal perspective (part two) can, *mutatis mutandis*, also be discussed from an European perspective. The theoretical model of lawmaking can also be a valuable instrument in rationalising the approximation of laws process. From a methodological perspective, incorporating European Community law by means of approximation of laws does not fundamentally differ from reforming the health care system by transforming the legislative framework. Although the motives and objectives differ, the methodology and, therefore, the iterative stages in the lawmaking activity are identical. The Community legal approach, however, necessitates modification of the original model since its underlying principles differ from the health care legal values (the right to health care and self-determination).[5] The adjustment concerns the incorporation of Community legal principles within the original model. Within the framework of Community law, principles are interpreted as "guiding legal principles" of the common market.[6] But principles also seem synonymous with "conditions" and "objectives" of the common market and its core component, the internal market. This is achieved by equal treatment,[7] economic and social cohesion[8] and the *acquis communautaire*

---

3 *Supra* chapter 3, section 3.

4 Figure 4.4, chapter 4.

5 Despite the difference, this does not exclude any overlap between European and health legal principles. For instance, the right to access to health care has also been interpreted as access to health care services abroad, in particular in EU member states (see the *Decker* and *Kohll*-rulings). This right has been incorporated in European free movement principles (persons and services). With the Treaty of Nice (2000), a "Charter of Human Rights of the European Union" was adopted, including the healthcare right.

6 The notion of the common market is a pivotal element of numerous objectives imposed by the Treaty. The establishment of the common market covers three aspects, notably, first, the establishment of an internal market characterised by the removal of obstacles to the free movement of goods, persons, services and capital; secondly, a system ensuring that competition in the internal market is not distorted, and, thirdly, a common commercial policy. P.J.G. Kapteyn, P. Verloren van Themaat. Introduction to the Law of the European Communities. From Maastricht to Amsterdam. L.W. Gormley (ed.) Kluwer Law International London 1998: 122. The internal market differs from the common market since it does not include the element undistorted competition.

7 The principle of equal treatment requires than persons in similar cases should be treated equally. It has been applied as the prohibition of discrimination on reasons of sex or nationality and regulated by secondary Community law.

8 Economic and social cohesion aims to reduce disparities between the levels of development of the various regions and backwardness of the least favoured regions, article 158 of the Treaty. Since the EU Treaty, cohesion has constituted an express objective for the Community and the Union guiding the implementation and co-ordination of Member States' economic

and, until fairly recently, subsidiarity,[9] proportionality[10] and transparency.[11] Since the Treaty of Amsterdam, the European Union explicitly adopted the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the *rule of law* (article 6 EC) as general principles of Community law. Finally, the most recent treaty amendment (Treaty of Nice) introduced a "Charter of Human Rights of the European Union".[12] The Charter enshrines the very essence of the European acquis regarding fundamental human rights around a few major principles: human dignity, fundamental freedoms, equality, solidarity, citizenship and justice.[13] All these matters are of fundamental importance. In view of article

---

policies and the determination and implementation of Community policy. K. Lenaerts, P. van Nuffel R. Bray. Constitutional Law of the European Union. Sweet and Maxwell, London 1999: 240.

9 Under article 5 (ex art. 3b) of the Treaty, Community action is justified where both aspects of the subsidiarity principle are met: the objectives of the proposed action cannot sufficiently achieved by Member States action (the necessity criterion), and the objective can be better achieved by action on the part of the Community (the effectiveness criterion). Before the EU Treaty entered into force, the subsidiarity principle did not constitute a general principle of law by reference to which the legality of Community acts should be reviewed. Case T-29/92 ECR 1995 II-289 *para* 310-311.

10 The principle of proportionality is closely related to the subsidiarity principle and restricts the authorities in their exercise of powers by requiring a balance to be struck between the instruments used and the intended objective. It is a general principle of law which affects the exercise of powers by Member States as well as by the Community. Lenaerts *o.c.*:106 *et seq.*

11 The transparency of decision-making has been entrenched in article 1 para 2 EC. Transparent decision-making reinforces the democratic character of the institutions.

12 The Charter of Human Rights of the European Union OJ C 364/1, 18 december 2000. The Charter reaffirms the rights as they result, in particular, from the constitutional traditions and international obligations codified in European treaty instruments (e.g., the EU Treaties, ECHR, ESC, and the Biomedicine Convention). Apart from the Charter, the core of the Nice Treaty concerns the EC institutional structure reforms, notably the composition of the European Parliament and Commission and Council decision-making.

13 The question on the nature of the Charter is still not clear. During the Cologne European Council, the Heads of States or Government decided to answer this question in two stages: first, the European Parliament, the Commission and the Council should solemnly proclaim the Charter. Then, "it will then have to be considered whether and if so, how the Charter should be integrated into the treaties." Conclusions of the Presidency of the Cologne European Council, 3-4 June 1999, Annex IV. A new Intergovernmental Conference end of 2001 will decide on the Charter's final status. Since the Charter's principles belong to the general principles of Community law it is likely that the Charter will become compulsory through the Court of Justice's interpretation of it. Prior to any rulings from this Court, in the *Max.mobil* case, the Court of First Instance already confirmed the relevance of certain EU-Charter principles, by declaring that "judicial review is one of the general principles that are common to the constitutional traditions of the Member States" (Case T-54/99 *Max.mobil v. Commission*, para. 57). However, it is unclear whether the Court of Justice will follow the Court of First Instance. For the Commission, this incorporation is not a matter of theoretical or doctrinal considerations. It must be addressed in terms of legal effectiveness and common sense. "*It is therefore preferable, for the sake of visibility and certainty as to the law, for the Charter to be made mandatory in its own right and not just through its judicial interpretation.*" COM(2000)644 final, para 11.

7 of the Treaty (persistent violation of human rights and fundamental freedoms), a serious breach of these principles can have serious consequences for (candidate) Member States. Moreover, the Charter may constitute an important set of principles for EU relations to third countries: the protection of human rights is actually part of the central objectives of the Union's foreign and security policy as well as its economic development co-operation policy.[14] As it will appear hereafter, the aforementioned European principles affect – directly and indirectly – European health law, although from a different perspective. Therefore, in terms of the model of law-making, the Community legal principles are reflected by a separate circle of EC principles, following the principles of health care law (figure 8.2).

The constitutional principles guide and control the common market, and set the scene for legal rules. For instance, the harmonious and balanced development of economic activities, a high degree of convergence of economic performance and solidarity (article 158 EC) reflect new tasks of the Community related to economic and social cohesion.[15] The objectives are subsequently transformed in policy regulatory means (e.g., the realisation of the "internal market") and countless obligations. It can therefore be concluded that the principles function as the source of Community law; provide the foundation of *ius commune europaeum* and vesting fundamental rights with rather clear contours. The general principles do not seem to correspond with the functions of health care law as discerned in the previous model.[16] The originally discerned clusters public health, the organisation, financing of the health care, quality control and patients' rights reflect the functions of law in health care, the so-called "law-jobs". The European law-jobs, however, do not entirely cover these discerned clusters. The European legislature excluded most of these functions from its competencies. Apart from the public health article, the EC Treaty does not provide the Community with a direct legal competence in the field of organising and financing health care. This is a direct consequence of the subsidiarity principle. However, as it will appear hereafter, health systems and health care are influenced by measures taken adopting the internal market acquis and alignment of other EU policies. For instance, the organisation, planning and financing of health care (by means of the co-ordination of social security schemes and free movement of persons, goods and services), the quality of health care (by means of

---

14 The EC Charter of Fundamental Rights still under discussion. Editorial comments. *CMLR* 2001, Iss. 1: 5.

15 P.J.G. Kapteyn and P. Verloren van Themaat. Introduction to the Law of the European Communities. From Maastricht to Amsterdam. L.W. Gormley (ed.) third edition Kluwer Law International, London 1998: 113.

16 *Supra* chapter 3, section 4.

regulations dealing with pharmaceutical and other medicinal products, mutual recognition of professional qualifications and diplomas, *et cetera*), and patients' rights (by means of consumer protection law, data protection law, access to cross-border health care, and in the near future, the EU Human Rights Charter). As such, Community law covers the discerned clusters of health law, although with certain restrictions. *Mutatis mutandis* Community health policy, since it reflects and expresses health legal objectives.[17] It is therefore justified to conclude that the legal-theoretical model is also applicable to the EC legal decision-making process and may rationalise the approximation of laws process.

With regard to the sequence of the identified health care clusters, the proposed chronology has already been argued.[18] The primacy of public health has been considered as a fundamental condition for a community to enjoy its health. The subsequent clusters match the free movement principles, the "core content" of the internal market acquis, to be approximated. Nonetheless, the circular character should not be interpreted as a strict consecutive course. It reflects a theoretical-methodological series of considerations, in order to explicate the complexity of the law-making process.

Observed legislative deficiencies and omissions can therefore be explained by the legal-theoretical model (e.g., inadequate problem analysis of current legal problems or an insufficient impact analysis of potential legal problems adopting the acquis in the data analysis stage). Moreover, the model can attempt to rationalise further legislative decision-making in the light of law approximation. In a way this could contribute towards improving the quality of legislative decision-making, both in terms of drafting and substance. For example, In the initial stage the Europe agreements, the White Paper, Agenda 2000, the national strategies and national programmes on adopting the acquis are important attempts to rationalise the legislative activity. They reveal and formulate the impulses ("problem impulse") that imposes the legislature to a normative activity. They define the legislative agenda by what are considered priorities in the legislative alignment process.[19] But there is more required than a list of

---

17 *Supra* chapter 4, section 2.

18 *Supra* chapter 4, section 2, p. 112 *et seq.*

19 *E.g.*, Article 6 prohibits any discrimination on grounds of nationality as between Member States and their nationals; Article 8a establishes the right of citizens to move and reside freely within the territory of the Community; Articles 9-12 require the abolition of customs duties and taxes having equivalent effect on exchanges between the Member States; Articles 30-36 prohibit quantitative restrictions and measures having equivalent effect on trade in goods and establish the conditions for exceptions; Article 37 forbids discrimination by State monopolies; Articles 48-51 establish the principles which ensure the free movement of workers; Articles 52-57 ensure freedom of movement and freedom of establishment for self-employed people and Article 58 for companies; Articles 59-66 provide for the freedom to

formulated priorities and time schedule to rationalise the decision-making. It necessitates for instance an adequately carried out data analysis on all relevant aspects involved. This is particularly the case when it concerns the implementation of EC co-ordination regulations 1408/71 and 574/72, affecting various social security schemes in all the Member States. Both regulations will have far reaching legal, financial and administrative consequences for applicant countries' health care system. The implications have become more complex since the latest European Court rulings increasing the influence of EC law on the organisation and financing of health care systems.[20] Up to now, applicant countries have not made substantial progress on implementing these co-ordination regulations. One of the reasons is the lack of knowledge about the precise impact on their health insurance system. Applicant countries primarily fear the financial implications of consequent cross-border health flows. Comparative (scientific) research examining the possible consequences may contribute to increase understanding in this field. Recently initiated collaboration projects that support the approximation activities enable an exchange of results. Evaluation of the current practise based on recently concluded bilateral social security treaties could further provide information necessary for decision-making on a multilateral level.[21]

The drafting of ultimate legislative norms is mainly an activity carried out by legislative lawyers at the ministries. In almost all countries, as well as within the European Union, the legislature or government have developed guidelines or manuals intended to improve the quality of legislation in terms of drafting and substance and to decrease the number of legislative norms.[22] The European Commission, in particular, has

---

offer services: Article 67, later replaced by Article 73b, provided for the abolition of restrictions on the free movement of capital; Articles 85-86 prohibit anti-competitive behaviour by undertakings which could otherwise negate the effects of the internal market; Article 90 ensures that the competition rules apply to public undertakings and undertakings granted special or exclusive rights; Article 92 establishes strict conditions for aid granted by states to their undertakings to protect the integrity of the internal market; Article 95 concerns the obligation of Member States not to discriminate in fiscal matters.

20 *Cf., e.g.*, Ferlini, Smits/Peerbooms, Vanbraekel, *infra* chapter 8, section 3.

21 For instance, concerning the nature and scope of benefit entitlements, the relevant administrative and financial procedures, *et cetera*. At the moment, Hungary has already concluded such a bilateral agreement with Germany which came into force in May 2000. A similar agreement with Austria will be effective in January 2001. Poland and the Czech Republic have also concluded similar treaties with, *inter alia*, neighbouring member States. According to the Hungarian-Germany agreement, *mutatis mutandis* Hungary-Austria agreement, socially insured of both countries are conditionally entitled to health care services in the host-country (Article 15).

22 *E.g.*, the "blauwe Prüffragen" Checklist of the Federal Government of 20 december 1989, the Dutch Policy Paper "Legislation in Perspective" (1989), the Recommendation of the OECD on improving the quality of government regulation (1995) as well as EU Council

adopted a large number of measures described in its annual "Better Lawmaking" reports that include a drastic reduction in the number of proposals for new legislation as well as guidelines comprising similar criteria for Community law-making to improve the quality of drafting.[23] The European "Checklist" imposes new measures to improve legislative drafting and to incorporate them in the decision-making process.[24] The most conspicuous example is the SLIM initiative (simpler legislation for the internal market).[25] This project has already enabled several simplification proposals to be presented. In order to make it more effective, the Commission has launched an assessment programme in co-operation with the Member States, and recommendations will be made. As the Commission Communication on the strategy for Europe's internal market suggests, the SLIM approach must be applied to Community Directives and to the national transposition measures alike.[26] Legislative drafters in applicant countries facing problems with approximating Community law, for instance implementing social security rules, should consider the application of a concurrent approach in view of the similarities in the legal problems faced.[27] Effective implementation and enforcement of Community law calls for the establishment and the enhancement of the administrative and judicial structures. The applicant countries' efforts to effectively implement and enforce this part of the acquis have also been reported by the Commission to the Council. Its findings in the Regular Reports focus on the main administrative structures which are required to implement the acquis. The Commission reported that the necessary administrative bodies and agencies involved have been established in the field of registration of pharmaceuticals, supervisory authorities on the manufacturing, processing and marketing of pharmaceuticals and medicinal products. Furthermore, the occupational safety inspectorate, a consumer protection officer and data protection ombudsman and have largely started to operate. However, the notion of implementation also includes the control of the application

---

resolutions on the quality of drafting.

23 1995 (CSE(95)580), 1996 (CSE(96)7), 1997 (COM(97)626).

24 COM 1998 715, OJ C 73 of 17.3.1999.

25 Communication from the Commission "Simpler legislation for the internal market (SLIM): a joint project", COM(96) 204 final.

26 COM(1999) 464 final.

27 SLIM phase III reviewed the implementation of regulations 1408/71 and 574/72, recent case law of the Court of Justice in the field of social security and identified specific rules and procedures in order to propose recommendations for their simplification. The series of recommendations presented by the SLIM team (Annex) may be grouped under three broad headings: the scope of co-ordination (personal and material); the determination of applicable legislation, and the co-ordination of the various categories of benefits. SLIM III Report from the Commission to the Council and European Parliament. Report of the third Phase of SLIM and follow-up of the implementation of the recommendations of the first and second Phases.

of Community law and its enforcement. This can be derived from the underlying idea of Article 5 EC. This means that Member States take the appropriate measures necessary to ensure the application of Community law and its supervision and effectiveness.[28] In the case of the applicant countries, the application and its enforcement of Community law have been seriously hampered by insufficient understanding of public administration and the judiciary in the field of European law.[29] This means, therefore, that the staff need to be trained adequately in Community law.

Concern for the quality of approximated legislation further requires an ongoing policy of evaluating (incorporated) legislation. The assessment of legislation should be carried out in the earliest possible stage of the legislative process.[30] At the moment, the only *systematic* review of legislation that takes place are the Commission's Regular Reports. Since applicant countries already have difficulties in complying with the strict law approximation schedule, the absence of (post-) legislative scrutiny of legal norms is understandable. Still, it is not considered superfluous given the volume and complexity of the legal norms to be incorporated. As it will appear hereafter, the latest Commission's Regular Reports identified several major inconsistencies in domestic legal order compared to the Community acquis which hinder the effective realisation of the acquis. In countries with experience of the systematic evaluation of the effectiveness of legislation (e.g., the Netherlands), legislation is scrutinised selectively in order to prevent that the procedure becomes a meaningless ritual.[31] After analysing the practise of evaluation, it was concluded that evaluation rarely results in fundamental adjustments of the scrutinized legal act.[32] This does not necessarily mean that evaluation ex post has no effect. The evaluation provides information that can and is used in the subsequent stages of the legislative process.[33] Apart from the Commission's review reports, the Court of Justice will only be competent to evaluate applicant countries approximated legislation *after* ratification of the accession agreement by all the Member States and subsequent publication (expected in 2003). However, such an assessment will only take place on an *ad hoc* basis. Nonetheless, the

---

28 *E.g.*, Case 30/70 Judgement of 17 december 1970 *Scheer v. Einfuhr- und Vorratsstelle für Getreide und Futtermittel* ECR 1970 p. 1197, at 1206, joined cases C-205-215/82 judgement on 21 september 1983 *Deutsche Milchkontor GmbH.v. Germany* 1983 ECR p. 2633, at 2665-6.

29 *E.g.*, Regular Report Hungary, Chapter Consumer and Health Protection, p. 68, *mutatis mutandis* the Czech Republic and Poland.

30 Recommendation p. XXXII-XXXIII, report of the conference Improving the quality of legislation in Europe (ed.) A.E. Kellerman, Kluwer Law International, The Hague 1998.

31 M. Lokin, Evaluatie van wetgeving: van praktijk naar beleid (Evaluation of Legislation: From Practice to Policy), *Regelmaat* 1997: 131.

32 A. Ringeling, Wetsevaluatie (Evaluation of Legislation), *Regelmaat* 1995: 49-56.

33 Ph. Eijlander and W.J.M. Voerman, Wetgevingsleer (Legislative science), Tjeenk Willink, Deventer 1999: 364.

legal consequences of posterior review can be considerable and can abruptly gain political significance as appeared in Hungary, when a provision concerning European competition law of the Europe agreement (article 62) was challenged by the Hungarian Constitutional Court. The question raised concerned the implementation of article 62 in national law, establishing a special competition co-operation regime.[34] Although the Court did not review the constitutionality of an international treaty directly, in casu the Europe agreement, it ruled that certain Hungarian provisions of the transforming act were unconstitutional since they are part of the Hungarian legal order and as such a legal norm in the sense of posterior review (absence of appropriate transformation).[35] As a temporary measure, Hungarian authorities have solved this problem by suspending the alleged provisions of the implementation rules. It is suggested that the Hungarian authorities should re-negotiate the co-operation regime, which will impose the Hungarian legislature to introduce certain amendments of the Constitution.[36] The subsequent delay has seriously hampered the implementation of article 62 of the Europe agreement.

The Hungarian example made clear that the legal and political implications of (types of) evaluation could necessitate alignment of the law approximation agenda. Evaluating the implications of the internal market acquis to the health care sector will increase in importance. Rules governing the intra-communautaire trade directly affect various health markets (pharmaceuticals, health care goods and persons and insurance), notably due the role of the European Court. Consequently, more than focussing on the public health acquis which will appear rather limited, approximation of health law should emphasize the internal market and its direct concern to the functioning of the health care sector. Graphically, the aforemen-

---

[34] According to article 62 of the Europe agreement, in case of anti-competitive practices, the Hungarian competition authority (the Hungarian Office of Economic will Competition, OEC) collaborates with the European Commission to enforce the competition regime based on the competition provisions articles 85 and 86 EC.

[35] December 4/1997 (I.22) AB, ABH 1997, 41 [49]. It concerned the annulment of articles 1 and 6 of the Annex to Government Decree 230/1996 (Implementation Rules), applying the criteria referred in article 62(2) EA. According to the Court it is a constitutional requirement that Hungarian law enforcement authorities cannot apply directly the application criteria of article 62(2) EA due to the dualism in the Hungarian legal system. "As a result of the unconstitutionality of the proclaiming Hungarian law, the unconstitutional internationally undertaken obligation cannot become effective and cannot be applied in (Hungarian) domestic law... It is the task of the legislator to establish the harmony of domestic law and the obligation undertaken on the international level". Europe Agreement Judgement VI.2 quoted by: J. Volkai. "*The Application of the Europe Agreement and European Law in Hungary: The Judgement of an Activist Constitutional Court on Activist Notions*". Harvard Jean Monet Working Paper 8/99, 2000: 24. Harvard Law School, Cambridge USA.

[36] Volkai, *o.c.*: 34, including an authorization into the Constitution that partially transfers souvereign legislative rights to the European Union.

tioned considerations are reflected by the modified model of law-making (figure 8.2) to rationalise the approximation of law process.

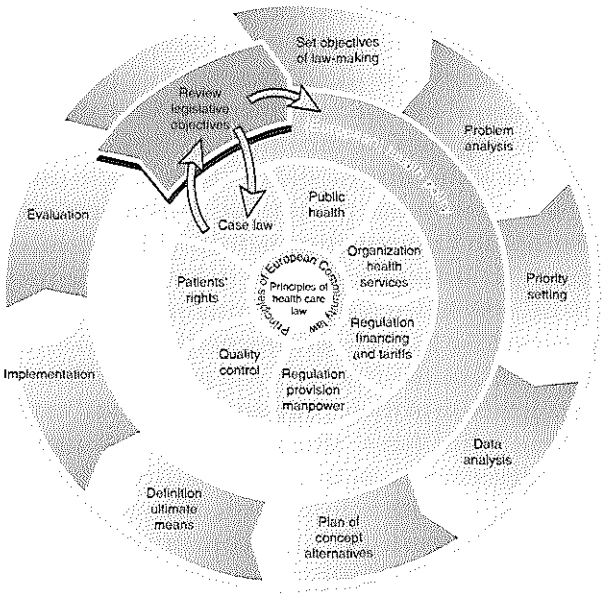


Figure 8.2: A modified model of health care law-making

3 PAVING THE WAY TOWARDS ACCESSION

To rationalise the law approximation process, the theoretical model starts to identify and select priorities of European Community legislation to be incorporated into national law. It goes without saying that the wide range and complexity of emerged obstacles in the law approximation process necessitate acceding countries to select and prioritise the core elements of the European law. To support applicant countries in defining a law-approximation strategy, the European Union concluded several agreements that set the framework for incorporating European Community law. The most important legal document includes the Europe agreements, the first step towards integral accession. Subsequent policy papers such as Agenda 2000, the Accession White Paper and national acquis programmes enable applicant countries to formulate the objectives of legislative harmonisation and the relevant strategy.

The Europe agreements

In the immediate aftermath of communism, the relationship between the European Union and Central and Eastern European countries has changed dramatically. As early as 1990, the EU launched a programme for concluding far-reaching collaboration with Central and Eastern Europe. As a result the first so-called Europe agreements were signed by several signatories in mid-1991.[37] These "first generation" Europe agreements (EA) established an association between the European Communities and their Member States, of the one part, and the individual candidate states on the other part. Characterised as mixed agreements, the Europe agreements were concluded between the European Communities, individual EU Member States and applicant states.[38] To overcome possible delay due the long period of ratification, the EC concluded so-called "Interim agreements" which should overlap the period the Europe agreements came into force. Since the competence of the EC in the field of trade and trade-related provisions is exclusive, the conclusion of these "Interim agreements" could be solved easily and come into force shortly after ratification.[39]

Originally, the Europe agreements were aimed at strengthening economic and political collaboration with individual countries without the intention of enlarging the EU. Member states had grave reservations about negotiating full integration into the EU. Instead, Eastern partners were offered several alternatives to accession, such as membership of the European Free Trade Association (EFTA), or the European Economic Area (EEA). The Eastern counterparts considered this offer as a "waiting room" alternative and insisted on integral accession to the EU. Such a legal integration into the Communities was agreed at the Copenhagen European Council. At that meeting EU Member States withdraw their objections; they

---

[37] Hungary: OJ L 347, 31/12/1993 p. 0002 – 0266; Poland: OJ L 348 , 31/12/1993 p. 0002 – 0180; Due to the dissolution of former Czechoslovakia renegotiations with the separated states was necessary and resulted in separate agreements: the Czech Republic: OJ L 360, 31/12/1994 p. 0002 – 0210 and the Slovak Republic: OJ L 359, 31/12/1994 p. 0002 – 0210. In the same year Europe agreements were concluded with signatories Bulgaria and Romania: OJ L 358, 31/12/1994 p. 0003 – 0222 and OJ L 357, 31/12/1994 p. 0002 – 0189. Finally, the Baltic states and Slovenia signed in 1995, respectively 1996 (OJL 068 , 09/03/1998 p. 0003 – 0198; OJ L 026, 02/02/1998 p. 0003 – 0255; OJ L 051, 20/02/1998 p. 0003 – 0242; OJ L 051, 26/02/1999 p. 0003 – 0206). The Europe agreements follow more or less the same structure and wording, *viz.* general principles (title I); political dialogue (title II); free movement of goods (title III); movement of workers, establishment, supply of services (title IV); payments, capital, competition and other economic provisions, approximation of laws (title V); economic co-operation (title VI); prevention of illegal activities (title VII); cultural co-operation (title VIII); financial co-operation (Title IX), and general and final provisions (Title X).

[38] M. Maresceau, E. Montaguti, The relations between the European Union and Central and Eastern Europe: A legal appraisal. *CMLR* 1995, Iss. 6: 1329.

[39] Maresceau and Montaguti *l.c.*: 1329.

agreed to the possibility of eastern EA partners joining the EU and formulated criteria for membership, which are often referred as the "Copenhagen criteria". According to these criteria, membership requires that the candidate country has achieved: stability of institutions, guaranteeing democracy, the *rule of law*, human rights and respect for the protection of minorities, the existence of a functioning market economy as well as the capacity to cope with competitive pressure and market forces within the Union, and the ability to take on the obligations of membership including adherence to the aims of political, economic and monetary union.[40] These criteria were subsequently incorporated in the concluded Europe agreements.

This new approach of the Europe agreements requires that candidate countries approximate their legislation to that of the European Union, notably in the areas relevant to the internal market. The "approximation of laws" strategy is considered as a crucial condition for future accession. This includes, *inter alia*, applying legislation favouring competition, which is compatible with comparable legislation in the EU.[41] Other crucial conditions on the free movement of workers, services and the establishment for self-employed persons are only partially compatible with EC treaty provisions. Most of the internal market provisions incorporated in the Europe agreements derive from the EEA agreement. However, the separate Europe agreements show some important institutional disparities with the EEA agreement. One of the main differences is the absence of a common judicial institution reviewing EA treaty provisions. There is no equivalent to the EEA Joint Committee, the EFTA court, or the EFTA Surveillance Authority.[42] Instead, the bilateral Europe agreements establish Association

---

[40] Copenhagen European Council (1993). In addition to the Copenhagen Summit, the Essen European Council (1994) refined the pre-accession strategy to prepare the partner countries for EU membership. This strategy is based on three main elements: implementation of the Europe Agreements, the PHARE programme of financial assistance, and the "structured dialogue" bringing all Member States and candidate countries together to discuss issues of common interest. As far as the legal nature of the declaration of general accession criteria is concerned, it is purely a unilateral act of the European Council, without any contractual commitment to accept an associated State as a member if the criteria – which, in any case, are open to interpretation – are not met. P-C Müller-Graff. Legal Framework for EU-CEEC Relations in: Enlarging the European Union. Relations between the EU and Central and Eastern Europe, M. Maresceau (ed.) Longman, London 1997: 32.

[41] *E.g.*, EA Hungary, article 68. Other areas of approximation concern: customs law, company law, banking law, company accounts and taxes, intellectual property, protection of workers at the workplace, financial services, rules on competition, protection of health and life of humans, animals and plants, food legislation, consumer protection including product liability, indirect taxation, technical rules and standards, transport and the environment.

[42] S. Peers. An ever Closer Waiting Room? The Case for Eastern European Accession to the European Economic Area. *CMLR* 1995, Iss. 1: 192, 202-203. The EEA Joint Committee consists of representatives of the Contracting parties and ensure the effective implementation and

Councils. These are bilateral meetings at ministerial level between the European Union and an associated country, at which any major issues arising within the framework of this Agreement, such as the approximation towards the EU can be discussed.[43] Since the Council meets only once a year (Article 104) effective surveillance of the harmonisation process by the Council is questionable. The Council is, however, being assisted by the Association Committee in the performance of its duties (Article 108). These meetings, at senior official level, review in more detail all areas covered by the Europe agreements. They are complemented by a series of sub-committees, which provide for regular in-depth technical discussions on all areas covered by the agreements. None of the Europe agreements, however, establishes an independent court in disputes concerning the interpretation of agreement. The absence of such a single judicial body in the agreements itself, hinders a uniform interpretation of EA provisions.[44] The subsequent diversity in interpretation by national judicial bodies impedes effective implementation of the internal market philosophy. Although it is likely that in the light of accession national courts' reasoning, EA provisions will – informally – be influenced by European Court of Justice's interpretation. Alternatively, extending the direct effect of European Court's rulings upon issues excluded by the Europe agreements would increase the legal importance of these agreements. Furthermore, a harmonised interpretation of these bilateral agreements would strengthen an effective implementation of the internal market provisions, in particular the free movement of workers provisions.

Despite its shortcomings, the bilateral Europe agreements constitute the first binding legal document recently aimed at accessing the European

operation of the agreement (the EFTA Court is mainly competent to deal with infringement actions brought by the EFTA Surveillance Authority against an EFTA State with regard to the implementation, application or interpretation of an EEA rule, whereas the EFTA Surveillance Authority has been given powers corresponding to those of the European Commission in the exercise of its surveillance role.

[43] EA Hungary, article 104, *mutatis mutandis* other Europe Agreements.

[44] However, the European Court of Justice (ECJ) has some alternative competence in disputes concerning the interpretation of EA, derived from article 310 EC Treaty (ex Art. 238). Under article 310 EC, Europe Agreements form part of the Community law. As such they form an integral part of the Community legal order and within the legal framework of the European Court has jurisdiction to give preliminary rulings concerning their interpretation (Case 12/86 *Demirel v Stadt Schwäbisch Gmünd* [1987] ECR 3719. However, with respect to issues excluded by the EA (for example free movement of workers) the Court has no competence since case law on direct effect is only applicable in the Community legal order. Only recently, the Court has taken some steps to extend the direct effect of third-country agreements, but there is considerable uncertainty about the extent of this reasoning (Case 12/86 *Demirel*, paragraph 14, Case C-18/90 *ONEM v Kziber* [1991] ECR I-199, paragraph 15, and Case C-162/96 *Racke v Hauptzollamt Mainz* [1998] ECR I-3655, paragraph 31).

Union by means of a common strategy, *viz*, approximation of current and future legislation.

The White Paper

Preparing their accession to the European Union, a broad pre-accession strategy was proposed which focussed first and foremost on realising an internal market. This was recognised at the Essen European Council of december 1994.[45] The Council identified the preparation of the associated countries for integration into the internal market as "the key element in the strategy to narrow the gap". The Commission was therefore invited to formulate a plan that created the conditions that will allow the internal market to function properly after enlargement. In 1995, the Commission presented the "White Paper on Enlargement", a non-binding legal document, that identifies key measures and approximation scenarios but they are merely indicative.[46] The White Paper does not set any timetable in the legislative programme of approximation. The Commission's reasoning was that applicant countries' diversity in economic, social and political situation requires a "demand-driven" approach, defined and differentiated by each candidate country. Given the preconditions set by the Europe agreement, such an approach implies a certain "margin of discretion" in prioritising legislation for approximation. Although the White Paper is focussed on realising the internal market, it must be distinguished from accessing the EU which will involve the acceptance of the "*acquis communautaire*". This is broader than the internal market conditions. Adoption of the acquis covers the entire field of Community law, including incorporating the European Court of Justice's case law. Still, the White Paper functions as a pivotal instrument in the pre-accession stage. It extensively, describes the fields of law to be approximated by applicant countries. Whereas the Annex describes in extenso, the measures candidate countries should take.[47] The Commission considered that it is appropriate in the pre-accession phase to propose an appropriate sequence in which the associated countries could take over the legislation for each major area. Resources for the approximation exercise are limited in both the Community and the associated countries, whether in terms of legal or

---

45 *Supra* note 40.

46 Officially, "White Paper on the Preparing of the Associated Countries of Central and Eastern Europe for Integration into the Internal market", COM(95)163 final and Annex COM(95)163 final/2 which forms the hard core of the White Paper.

47 The Council recognised that integration involves more than the approximation of legislation and regulatory systems, standards and certification methods compatible with those of the European Union. Beyond the approximation of legislation, the Annex therefore highlights and describes the structures which will be necessary to make the legislation effective.

technical expertise, parliamentary time, or the availability of training.[48] The Commission therefore selected areas and presented the legislation for each area in a way that distinguishes "key measures" from the total number of measures applicable.[49] Subsequently, a further split of key measures into two stages was proposed. The division into Stage I and Stage II measures shows the indicative priorities which emerge from the logic of the legislation itself and provides a guide to the associated countries for the most effective sequencing of their work programmes for the approximation, implementation and enforcement of legislation.[50] In each area, central issues are emphasized as stage I measures, while the rest of the regulations are labelled as stage II measures.[51] As stated before, selected priorities to different sectors depend on the political and economic situation of each associated country. To certain degree, they have already started with national priority-setting before the publication of the White Paper. Subsequently, the applicant countries are at different stages in their approximation programming, which means that the choice has to be made by those countries each rather than by the Union.

Given its systematic approach in aligning internal market legislation, the White Paper is a valuable instrument. Still, it has some important weaknesses that put its value into perspective. A serious defect is the incomplete approach of approximating internal market law. Similar to the Europe agreements, the White Paper is mainly focussed on free movement of goods, capital and services. For obvious reasons, free movement of persons was left out of the Europe agreement and the Commission's recommendations. The embarrassing silence on free movement of persons

---

48 White Paper, chapter 3, section 16.

49 In total there are thirty areas covering, *inter alia*, the free movement principles, agriculture, social policy and employment.

50 Stage I measures have the highest priority and have usually been selected using one or more of the following criteria: (i) the measures concerned provide the overall framework for more detailed legislation, (ii) the measures concerned address fundamental principles or provide for the basic procedures which govern the sector concerned; (iii) the measures are a precondition for the effective functioning of the internal market in that sector (Ch 3.18). Stage II measures, on the contrary, have in the Commission's view a more subordinate or complementary character and can therefore be adopted in a later stage of the approximation process.

51 Sometimes it was impossible for the Commission to define a strict hierarchy of stage I and II measures because the legislation concerned represents a whole and the adoption of any single part of it could yield no benefit without the rest. In such cases suggested measures were not differentiated in stages (*e.g.*, radioactive contamination of foodstuffs). Otherwise, in some cases (*e.g.*, mutual recognition of professional qualifications) an additional third stage has been introduced. This is due to the sensitive character of the topic concerned. The Commission prefers to introduce an additional stage in the approximation process rather than to undermine its chances of success by proposing a quick alignment scheme which could cause serious problems in the associated country. M-A Gaudissart, A. Sinnaeve. The role of the White Paper in the preparation of the Eastern Enlargement in: Maresceau 1997 *o.c.*: 49.

shows the ambivalent attitude of the Commission and Member States towards candidate countries. Although ultimately aimed at full integration in the EU, nullifying legal restrictions on the free movement of persons were not referred as those which *directly* affect the internal market. Instead, it indirectly affects the operation of the single market.[52] Since the White Paper does not cover the entire *acquis communautaire*, other (secondary) legislation is not included. Such a selective approach of the internal market has been criticised in the literature. "In the EU's practise the distinction between measures that would directly affect the operation of the internal market and measures which have indirect implications for the functioning is less pronounced".[53] Referring to the bulk of secondary legislation and relevant Court of Justice's case law, particularly in the field of equal treatment and social security, the indirect effect-argument is difficult to maintain.[54] From the original Europe agreement perspective however ("structured political dialogue and strengthening economic co-operation"), the Commission's reasoning is more plausible; removal of legal impediments on free movement of goods and capital and leaving out the free movement of persons.

Its voluntary, indicative character has already been mentioned. The implied flexible and "programmatic" character of this approach may also threaten a uniform interpretation of internal market provision. Particularly since neither the White Paper nor the Europe agreement mention the role of the Court of Justice in case of interpreting internal market law. Under the EEA agreement, however, courts in the EFTA states are allowed to ask the European Court of Justice's opinion and to decide on the interpretation of EEA provisions,[55] while the EFTA Court delivers judgements and opinions to the EFTA states' obligations. In this respect, the EFTA court functions in parallel with the European Court of Justice. The symmetry in competences and functioning of EU-EFTA institutions is aimed at a uniform interpretation of the provisions of the agreement and those provisions of Community legislation. This aspect is almost absent from the EU relationship with Central and Eastern European countries.[56] Nonetheless, indirectly, the White Paper suggested some improvements compared

---

52 White Paper, chapter 3, section 5.

53 Gaudissart and Sinnaeve *o.c.*: 69.

54 *E.g.*, Regulation 1612/68/EEC on the free movement of workers and Co-ordination Regulation 1408/71 on social security and applicable Court rulings. In the field of health care, with recent cases on cross-border care (Decker and Kohll, Ferlini, Smits/Peerbooms, Vanbraekel and the pending case Müller-Faure) the Commission's reasoning seems untenable. The impact on national health care schemes is substantial and may directly affect the operation and funding mechanisms of these systems (*infra* chapter 8, section 4).

55 Article 107 EEA; Protocol 34.

56 Gaudissart and Sinnaeve *o.c.*: 70.

to the Europe agreement. By referring to court rulings on equal treatment and the mutual recognition of professional qualifications, the White Paper suggested measures to overcome obstacles to the free movement of persons (i.e., professionals) and services. Yet such references are few. They do not cover the entire *acquis communautaire* in the internal market field, and do not impose candidate countries to comply with the Court's rulings.[57] Besides, the mutual recognition will only take place in the third stage of approximation laws. Such an approach emphasises the Community's cautious approach of candidates' integration in the internal market.

Agenda 2000

After the White Paper's recommendations, the Agenda 2000 report suggested a reinforcement of the pre-accession strategy which was defined by the European Council in Essen (1997). The concept of an intensified pre-accession strategy comprised new elements, *inter alia*, a strategy of enlargement of the Union. Two other elements which are strongly related include the so-called cohesion and structural funds, and a Common Agricultural Policy. This so-called "package approach", on which the Commission insisted, was welcomed as a rational means of ensuring coherence between the different elements.[58] In Agenda 2000, the Commission is developing its opinion on the application of EU membership, applying the Copenhagen criteria, looking at the progress being made in transposing measures identified in the White Paper, assessing the national pre-accession plans and institutional restructuring in the light of the obligation embodied in the Europe agreements, and is also looking at the extent to which the applicant countries were implementing non-White Paper legislation. The Commission's analysis was focused on four areas: political criteria, economic criteria, the capacity to take on the obligations of membership (generally considered to be the ability to take on the *acquis communautaire*), and administrative and judicial capacities.[59] This approach has been criticised since it did not include social criteria in applying for EU membership. Considering the problems that might occur in the area of public health in the event of enlargement, it should be one of the issues in on the Enlargement agenda.[60] The analysis was aimed to determine what the prospects for the countries were, taking into account not only the current situation but reforms planned or underway. The outcomes are

---

57 Gaudissart and Sinnaeve *o.c.*: 70.

58 G. Avert. F. Cameron. The Enlargement of the European Union. Sheffield Academic Press, 1998: 101.

59 Agenda 2000 Vol. I. p. 49. DOC/97/6.

60 Dommers, J Agenda 2000 and the Role of Public Health in Applying for EU Membership. Editorial *EJHL* 1997, Iss. 4: 318.

described in two volumes.[61] Volume I, which called for "a stronger and wider union", became the basic document. This documents draws the main conclusions and recommendations from the opinions and presents the Commission's view on issues relating to enlargement. Volume II, on the other hand, describes the general effects on the Union's policies of enlargement to the applicant countries of Central and Eastern Europe.

Probably the most important recommendation made by the Commission is to open negotiations with the following countries: Hungary, Poland, Estonia, the Czech Republic and Slovenia. To reinforce the existing pre-accession strategy (found in the Europe agreements, White Paper and PHARE programme) for all Central and Eastern European applicant countries, a new instrument was developed: the accession partnership.

Accession Partnerships

The dual approach with regard to the obligations under the Europe agreements, as well as actions recommended by the White Paper is still important since it provides applicant countries with a concrete instrument for transposing the core of the Community acquis. However, it is equally important to note that in certain areas no provisions exists in either the Europe agreements or the White Paper, for instance, in the field of education and training and research and technology development. In other areas, such as environment and social security, the White Paper only identifies a fraction of the acquis that exists, while the Europe agreements contain few concrete provisions.[62] The incomplete and unbalanced approach of both documents was hampered by the differentiation of addressed policy areas among candidate countries. In many cases, it was not possible for the Commission to make an adequate analysis of the approximation of legislation process. Therefore, the Luxembourg European Council decided to reinforce the pre-accession process as defined in 1994 at the Essen Summit. The Council adopted a regulation that assists applicant states in the framework of the pre-accession strategy, and in particular on the establishment of Accession Partnerships.[63] In subsequent Council decisions, it decided on the principles, priorities and general conditions of each Accession Partnership.[64] This new instrument of the bilateral Accession Partnerships constitutes the key feature of the

---

61 Agenda 2000 Vol. II, Doc 97/7.

62 M. Soveroski. Agenda 2000: An Appraisal of the Commission's Blueprint for Enlargement. European Institute of Public Administration, Maastricht 1997, 12.

63 Council regulation (EC) No. 622/98. OJC L85 of 20/03/1998, p. 1-2.

64 Council Decision 98/259/EC, OJC No. L 121 of 23/04/1998, p. 1-5 (Hungary); 98/260/EC OJC No L 121 of 23/04/1998 (Poland), p. 6-10; 98/267/EC, OJC No L 121 of 23/04/1998, p. 41-45 Czech Republic. Subsequently, each Accession Partnership was adopted by the Commission and the Council.

enhanced pre-accession strategy. These partnerships should assist each state in preparing for membership and in developing its national programme for taking up the *acquis* as well as a relevant timetable for its implementation. Therefore, each country's Accession Partnership sets out in a single framework the *acquis* priority areas and the financial resources for assisting each applicant state to implement the priorities identified during the pre-accession period and, in particular, those commitments relating the Europe agreements and the adoption of the Copenhagen criteria.[65] The programming of accession priorities and objectives, as set out in the Commission's White Paper, break down into two groups: short-term and medium term priorities and objectives, to be adjusted during subsequent revisions of the partnerships. The progress made in the accomplishment of priorities will be recorded in an annual report to be written by the Commission and submitted to the European Council. These annual reports are based on the country's Europe agreement and National Programme for the Adoption of the Acquis (NPAA). These national programmes are the main policy instrument used to help the candidate countries in their preparations to membership. They complement the Accession Partnerships and give details of each country's commitments with regard to achieving the Copenhagen criteria and adopting the *acquis communautaire*.[66] The implementation of the priorities set out in the national programme is subject to monitoring by the national governments, whereas the subsequent appraisal is carried out by the relevant ministries. The main adjustment priorities to be accomplished in the pre-accession period result from the provisions of the Europe agreements and reflect political criteria (democracy and the *rule of law*), economic criteria (free movement), law adjustment (internal market directives) and administrative capacities to enforce (European) law. Some of these priorities are focussed on the health sector since alignment of public health standards are part of the EU accession preparations. The tasks derived from these priorities concern primarily candidate members' public health policy and relevant legislation. However, to examine the full impact of EU accession to national health legislation, apart from reviewing the public health adjustment priorities, such an analysis should also include the impact of the internal market on national health care systems, notably the organisation and financing legislation of

---

65 Article 1 EC regulation 622/98.

66 *E.g.*, Poland National Programme of Preparation for Membership in the European Union, may 1999. The programme consists of two parts: a synthesis, containing *inter alia*, a short description of the programme's aim, the structure and method of formulating adjustments tasks, etc. the second part contains a detailed description of each priorities/tasks including aspects such as the identification of the necessary legislative and institutional changes and timetable and financing.

health care systems and secondly, to what extent candidate countries comply the Community health acquis.

4 IMPACT OF EU ACCESSION TO NATIONAL HEALTH LEGISLATION

The examined legal documents set, although not extensively, the scene for law-approximation. Consequently, the problem-analysis stage enables the analysis of the priorities of Community law and its consequences for national health legislation. It is argued that EU accession addresses both the public health acquis as well as internal market rules.

Alignment of the community's public health provision

Concluded agreements with applicant countries identify public health law as one of the adjustment priorities of EU accession preparations.[67] According to the EC public health provision (Art. 152 EC), the Community has supranational competence to run policy of diseases prevention and promotion, whereas the entire area of health services remains within the domain of national governments.[68] After the ratification of the Treaty of Amsterdam, special emphasis was placed on certain areas such as measures in the veterinary and phytosanitary fields of public health importance. These are already the basis of a substantial body of Community legislation

---

67 Europe Agreement (EA) Hungary, article 68; EA Czech Republic, article 70, and EA Poland, article 69.

68 Besides article 152, article 3(1)(p) is the second key source relevant to public health. Other important treaty articles relating to health protection are: articles 43-48 (right of establishment, which covers inter alia doctors and other health sector professionals); article 49 and 50 (Services, including medical and other health services); article 71 (Transport safety); article 95 (Approximation of laws, which includes food safety, tobacco, pharmaceuticals, medical devices, chemicals and other dangerous substances, applications of biotechnology); articles 131-133 (Common Commercial Policy, *e.g.* on food and on pharmaceuticals); article 137 (Social security and social protection of workers); article 149 (Education and vocational training, including exchanges in the health field); article 158 and 161 (Economic and Social Cohesion, i.e. the structural funds and the cohesion fund which support health-related projects); articles 163-173 (Research and Technological Development, which includes the area of health); article 177 (Development Co-operation, including in the health field), and article 300 and 302 (Conclusions of agreements with third countries and international organisations, including on health and health-related matters. Hereafter, the key issues penetrating national health policy will be discussed more extensively.

with major health implications.[69,70] The difference now is that such proposals fall within the public health context. Moreover, article 152 includes measures in relation to the quality and safety organs and substances of human origin and blood and blood derivates. The scope and potential of this new provision has not yet been fully explored. However, given the importance for health protection of ensuring a safe blood supply, and the rapidly growing need for human organs and substances of human origin, the potential, taking into account national provision on the donation of medical use of organs and blood, is considerable.[71] Relevant actions should promote the attainment of self-sufficiency in human blood or plasma derived from non-remunerated donations and to develop derived blood products, in line with relevant Community public health measures and activities.[72] Furthermore, the public health provision entitles the Community to take actions with a direct bearing of health protection. These include "incentives measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States".[73] This has served as a basis for the current set of eight public health programmes and for the decision on a network on the epidemiological surveillance and control of communicable diseases.[74] A

---

69 COM(99) 719 final of 12 January 2000 White Paper on Food Safety includes an extensive programme of legislative actions aimed at putting in place high standards of food safety from "farm to table". The actions that are set out intends to close identified loopholes in current legislation and cover animal feed, animal health and welfare, hygiene, contaminants and residues, novel food, additives, flavourings, packaging and irradiation.

70 Still, the revised content has led to a widespread view that the public health article is an *ad hoc* political reaction to the BSE crisis and not addressing the basic needs for institutional reform for integrating health considerations into Community policy-making. E. Mossialos. The influence of EU law on the social character of health care systems in the European Union. Brussels november 2001:35. This view was confirmed by the former Social Affairs Commissioner Flynn stating "I must confess to a certain degree of disappointment on the text [...] Yes, the draft Treaty does confer new Community competencies in the field of public health. However, [...] in my view, the new Treaty provisions do not provide the Commission with an adequate legal basis to address further concerns." Flynn P. Reactions to the Treaty of Amsterdam. *Eurohealth* 1997, Iss. 2: 2-3.

71 Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the regions on the health strategy of the European Community. Brussels 16.5.2000 COM(2000) 285 final.

72 Council Resolution (OJ No. C 374 of 11-12-96, p. 0001) on a strategy towards blood safety and self-sufficiency in the European Union; Council Recommendation 98/463/EC (OJ No. L 203 of 21-07-98, p. 0014-0026) on the suitability of blood and plasma donors and the screening of donated blood in the European Community.

73 Article 152(4)(c).

74 The full lists of programmes and other actions is as follows; Actions under the 1993 Public Health Framework: The programme of Community action on health promotion, information, education and training (Decision No 645/96/EC of the European Parliament and of the Council, OJ L 95, 16.4.1996, p. 1); The action plan to combat cancer (Decision No 646/96/EC of the European Parliament and of the Council, OJ L 95, 16.4.1996, p. 9); The

number of the public health community programmes for applying the acquis are open to candidate countries, for example four programmes for the period 1996-2000: prevention of AIDS and other communicable diseases, combating cancer, drug dependence and health promotion.[75] Although legislative harmonisation at EU level is excluded, participation in European health programmes is likely to produce a certain degree of convergence among national health policies.[76] For accession countries, participation in each programme is considered to be necessary since it will enable them to become more familiar with Community's legislation and

programme of Community action on the prevention of AIDS and certain other communicable diseases (Decision No 647/96/EC of the European Parliament and of the Council, OJ L 95, 16.4.1996, p. 16); The programme of Community action on the prevention of drug dependence (Decision No 102/97/EC of the European Parliament and of the Council, OJ L 19, 22.1.1997, p. 25); The programme of Community action on health monitoring (Decision No 1400/97/EC of the European Parliament and of the Council, OJ L 193, 22.7.1997, p. 1); The programme of Community action on injury prevention (Decision No 372/1999/EC of the European Parliament and of the Council, OJ L 46, 20.2.1999, p. 1); The programme of Community action on rare diseases (Decision No 1295/1999/EC of the European Parliament and of the Council, OJ L 155, 22.6.1999, p. 1), and The programme on pollution-related diseases (Decision No 1296/1999/EC of the European Parliament and of the Council, OJ L 155, 22.6.1999, p. 7).

Other Activities are: A strategy on tobacco consumption (Commission Communication on the present and proposed Community role in combating tobacco consumption, COM(96) 609 final of 18.12.1996); a directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (Directive 98/43/EC of the European Parliament and of the Council, OJ L 213, 20.7.1998, p. 8). Recently, the ECJ annulled this Directive in its entirety in *Germany v. Parliament and Council* (C-376/98); A report on smoking prevention (COM(99) 407 final of 8.9.1999), and a proposal for a directive on tobacco products (COM(99) 594 final of 16.11.1999); A strategy on blood safety and self-sufficiency (COM(94) 652 final of 21.12.1994) and the Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood (OJ L 203, 21.7.1998, p. 14); Commission reports on health status in the Community (COM(95) 357 final of 19.7.1995 and COM(97) 224 final of 22.5.1997) and on the integration of health protection requirements in Community policies (COM(95) 196 final of 29.5.1995, COM(96) 407 final of 4.9.1996, COM(1998) 34 final of 27.1.1998 and COM(1999) 587 final of 16.11.1999); Commission staff working papers on the epidemiology and surveillance of Creutzfeldt-Jakob disease and other transmissible spongiform encephalopathies; A Community network for the epidemiological surveillance and control of communicable diseases in the Community (Decision No 2119/98/EC of the European Parliament and of the Council OJ L 268, 3.10.1998, p. 1), and a Council Recommendation on the limitation of exposure of the general public to electromagnetic fields 0 Hz to 300 GHz (Council Recommendation of 12 July 1999, OJ L 199, 30.7.1999, p. 59).

[75] Several of the existing programmes come to an end in 2000 and two at the end of 2001. Given the importance that there is no interruption or delay in key actions in these programmes that will be sustained under the new programme, the Commission suggests to extend these programmes for a limited time until the new programme comes into effect in order to guarantee the continuity of actions. COM(2000)285 final, p.14; COM(2000) 448 final.

[76] T. Hervey. European Social Law and Policy. Longman, London 1998: 138.

procedures. Moreover, participation will support them in tackling the major health problems they face.[77]

Finally, the EC public health provision excludes the organisation (including the financing) of health services and the provision of medical care from Community policy. As a result of the subsidiarity principle, this field remains the explicit responsibility of Member States (art. 152 section 5). Notwithstanding the exclusive competences of national authorities in this field, both the organisation and delivery of health care services are affected by policy decisions taken at European level and provisions of EC law designed to realise the internal market (e.g., free movement and competition principles). The internal market provisions' impact on the health sector is, however, incomplete and differs by provision.[78] To achieve a more coherent and effective approach to health issues across all different policy areas, the Commission proposed the new public health strategy setting out the Community's broad health strategy.[79] The actions under such a public health framework emphasise a proper link with health-related initiatives in other policy areas such as free movement articles, consumer protection, environment and agriculture. Within these sectors a significant number of legislative norms related to health protection is included, for example directives related to smoking, public health programmes as well as and the legislation on health and safety at work.[80]

Occupational health

The Community policy on *health and safety at work* is of particular relevance to public health in ensuring the attainment of a high level of health protection. The preventive approach towards protection against workplace risks, work accidents and occupational diseases is based on article 137 EC (ex article 118a). Occupational health and safety legislation has been

---

77 Article 6(2) of Decision 645/96/EC opens the possibility for acceding countries to participate in these Community programmes OJ. 1995 L 95/1.

78 *Cf. e.g.*, H.D.C. Roscam Abbing. Volksgezondheid in het Verdrag van Amsterdam. Een beknopte analyse (Public Health and the Treaty of Amsterdam: A short analysis). *Tijdschrift v. Gezondheidskunde* 1998, Iss. 2: 80.

79 COM(2000) 285 final p. 5.

80 *E.g.*, EC legislation on tobacco includes two directives: Council Directive 90/239/EEC concerning the tar content of cigarettes and Council directive 89/622/EEC concerning the labelling of tobacco products, as well as Council resolution 89/01/EC on banning smoking in places open to the public. In a recent judgement, the ECJ annulled another Tobacco Directive (Directive 98/43/EC) relating to the advertising and sponsorship of tobacco products on the grounds that the legislature had no competence for introducing it on the basis of internal market legislation (C-376/98 judgement of 5 October 2000 *Federal Republic of Germany v. the European Parliament and Council of the European Union* EC). The Directive was based on article 95 (ex art. 100a(1) of the Treaty, intended to improve the conditions for the establishment and functioning of the internal market. The Court held that article 100a was not an appropriate legal basis for the Directive and therefore annuled the Directive.

receiving Community attention over the last thirty years. The first series of binding legal acts were based on article 100 of the EEC Treaty and started with Council Directive 77/576/EEC on safety signs at places of work[81] followed by the first framework directive 80/1107/EEC which is designed to protect the health and safety of workers against the risks arising from exposure to chemical, physical and biological agents in the workplace, supplemented by individual directives dealing with specific agents.[82] Following the adoption of the Single European Act, the second series of EU health and safety at work legislation took its present structure with the new legal basis of article 138 (ex article 118a) to regulate health and safety at work matters on a European level. This structure comprises a new framework directive 89/391/EEC which contains basic provisions for health and safety organisation in the workplace. It outlines the responsibilities of employers and workers, and is supplemented by individual directives for specific groups of workers, workplaces or substances. By its wording, article 138 gives only competence to the Community to set minimum requirements and therefore takes account of the principle of subsidiarity.[83] The most recent Community programme in the field of health and safety at work, covering the period from 1996 to 2000, was adopted by the Commission on 12 July 1995[84] following the creation of a comprehensive body of Community legislation adopted under article 118a, aimed at providing assistance in the implementation and application of existing legislation, with greater emphasis also being placed on non-legislative measures.

Consumer protection

Approximation of consumer protection legislation covers a number of directives related to health.[85] In terms of protecting consumers from potentially harmful medical products, the "Directive on Product Liability" (85/374/EEC) gives consumers the right to claim compensation from the producer for defective products.[86] The directive aims, to a large extent, to

---

81 Repealed by directive 92/58/EEC OJ L 245, p. 23.

82 OJ L 327 3/12/80.

83 White Paper *o.c.*: 74.

84 COM(95) 282 final. Official Journal C 262, 07.10.1995.

85 Because of the lack of a specific legal basis prior to the adoption of the Maastricht Treaty, most of the Union's initiatives in the field of consumer protection were based on articles 95 and 308 (ex 100A and 235).

86 OJ 1985 L 210/29, as amended by Directive 99/34/EC including primary agricultural products. Apart from Directive 85/374/EEC, the "General Product Safety Directive" 92/59/EEC OJ 1992 L 228/24 should also be mentioned, imposing a general obligation on economic operators to market only safe products.

harmonise national law on producer liability.[87] Therefore, national measures have to implement the directive's uniform liability rules (e.g., the injured person shall prove the damage, the defect and the causal relationship between defect and damage, and the producer's liability). The directive acknowledges the difficulties in the harmonization process by (candidate) member states where consumers already benefit from advanced protection and have introduced the principle of minimum harmonization. Candidate member states countries may, in the areas covered by the directive, maintain or introduce more stringent consumer protection measures, as long as they are compatible with the Treaty, especially with articles 28 and 30 EC (ex 30 and ex 36 EC). Several applicant countries took this directive as a model to define national product liability legislation. Further lessons can be drawn from the Commission "Green Paper".[88] This report includes an analysis of questions such as: whether the directive ensures adequate protection for victims, whether it helps to discourage the marketing of dangerous (medical) products, whether the insurance sector has managed to cope with the risks addressed in the directive, *et cetera*. The outcomes relating to the functioning of the internal market call for ongoing for protection of health and safety of individuals.

In the safety field, the "Directive on General Product Safety" (92/59/EEC) functions as the "counterpart" of the product liability directive.[89] Together with the product liability directive, the general product safety directive aims to give an incentive to producers, to pay particular attention to the safety aspects of the products they want to market within the European Union. It complements the Community's legal instruments to protect consumers from unsafe products. This directive imposes a general obligation on economic operators to market only safe products. It also imposes on Member States to create an adequate institutional framework empowered to require the compliance of products to the general safety obligation. A major instrument provided by the directive is the so-called RAPEX system, a rapid exchange of information procedure in case of products creating risks for consumers. This system organizes a mandatory Community procedure for notifying emergency measures taken by Member States. When the Commission is informed, it transmits the information to other Member States. Recent crises (dioxin in foodstuff and the BSE crisis) made painfully clear that this directive is far from adequate in protecting consumers. Consequently, the scope of

---

87 The key reason why approximation of national product liability laws is necessary is because the existing divergences may distort competition and affect the movement of goods within the common market.

88 Green Paper Liability for defective products, Annex II. COM(1999)396 final.

89 OJ L No. 228, p. 24. Apart from this general "horizontal" directive prior ("vertical") directives lay down technical standards for specific sectors, *e.g.*, toys, cosmetics, foodstuffs.

the directive was extended to also include primary agricultural products intended for consumers or likely to be used by consumers. Services, however, are excluded from the scope of the directive although Member States are free to regulate this in national legislation.

The "internal market" and health

Besides article 152 and public health related provisions, internal market treaty provisions, may also affect health-related rights.[90] Under certain circumstances, EU citizens may even derive specific rights from EC provisions, notably emanated from the "free movement" provisions. For candidate member states this means that the common market has important consequences for health and their health care system.[91] Hereafter, relevant EC provisions and their impact on acceding countries will be discussed in more detail.

Free movement of persons

As regards the free movement of persons, relevant Treaty provisions include the freedom of movement for "workers" (art. 39-42) and the right of "establishment" (art. 43-48). These provisions have, in turn, been further substantiated by secondary legislation.[92] Free movement for workers shall entail, *inter alia*, the right to stay in a Member State for the purpose of employment in accordance with the provisions governing the employment of nationals of that State laid down by law, regulation or administrative action. As regards the right of establishment, this shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings under the conditions laid down for its own nationals. Interpreted in Community law, this includes a right of access to the territory of the Member States in order to carry out the economic activity in addition to a right to remain on the territory for that purpose.[93] An exception to the free movement of persons is granted in article 39(3) EC, which permits Member States to limit the free movement of persons "on grounds of public policy, public security and public health". The application of the derogation in article 39(3) EC is governed by Directive

---

90 According to article 14(2) EC, the internal market "shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty."

91 A.P. den Exter. Lituvos Stomjimas I Europos Sajunga: Reiksme Nacionalinei Visuomenes Sveikatos strukturai (Lithuania's future accession to the European Union: Relevance to national health policy). *Sveikatos Aplinka* 2000. Iss. 2: 6-10.

92 See, for instance, social security regulation 1408/71 and regulation 1612/68 on the freedom of movement of workers.

93 ECJ Reyners [1974] Case C-74, ECR 631.

64/221/EEC.[94] The only diseases or disabilities that justify a refusal of entry of workers, self-employed and recipients of services are those listed in an annex, article 4 of the Directive. This exemption cannot be used by Member States to restrict access to the medical profession, or branches of the medical profession, as a whole.[95] The free movement of persons provisions are directly relevant for health professionals who wants to enter the employment markets of the European Union. In view of the barriers erected to the mobility of (health) professionals, the Council has issued various Directives regulating the mutual recognition of professional qualifications. The objective of the general system is to promote the free movement of persons within the EU by establishing procedures to ensure that persons wishing to practise a profession in another Member State do not have to repeat their training. The basic principle of this system is that the host Member State cannot refuse access to a regulated profession to a national of a Member State who is fully qualified for that profession in his home Member State. Approximation of EC legislation requires that acceding countries shall have to transpose mutual recognition of qualifications in the health field, applying to doctors, dentists, pharmacists, nurses and midwives.[96] As a consequence of these Directives, national competent authorities giving authorisation to health professionals practising within their territory are obliged to recognise the qualifications obtained in another Member State.

---

[94] OJ 1964 no 56, p. 850. Council Directive 64/221 Council Directive 64/221/EEC of 25 February 1964 on the co-ordination of special measures concerning the movement and residence of foreign nationals which are justified on grounds of public policy, public security or public health.

[95] Case C 131/85 Gül/Regierungspräsident Düsseldorf [1986] ECR, p.1573, no. 17.

[96] Directives 75/362/EEC and 75/363/EEC OJ 1975 L 167/1 and OJ 1975 L 167/14; Directives 78/686/EEC OJ 1978 L 223/1 and 78/678/EEC OJ 1978 L233/10; Directives 85/432/EEC OJ 1985 L 253/34 and 85/433/EEC OJ 1985 L 253/37; Directives 77/452/EEC OJ 1977 L176/1 and 77/453/EEC OJ 1977 L 176/8; Directives 80/154/EEC OJ 1980 L33/1 and 80/155/EEC OJ 1980 L 33/8. The first Directives (75/362/EEC and 75/363/EEC) have now been repealed and consolidated, with various amendments for different specialities in Council Directive 93/16/EEC OJ 1993 L 165/1. Besides establishing minimum training requirements, this directive also aims to establish rules regarding the exchange of information between Member States' licensing/ disciplinary authorities about physicians who have provided substandard treatment due to professional misconduct. In practice, however, there is little evidence that the Directive has been succeeded in promoting mobility among health professionals within the EU. There are numerous differences between the Member States in the area of education, authorisation and disciplinary and compensatory procedures. For instance, Member States face problems in keeping records of problematic health professionals and the issue of liability in cases where competent authorities were unable to enforce aspects of Directive 93/16. Segest, E. Consumer Protection and the free movement of medical practitioners in the European Union. *EJHL* 4:269 At the moment, Directive 93/16 is subject of further amendments.

Besides these specific branch directives, other health professionals may rely on the general "new approach" directives tha facilitate a general system for the recognition of diplomas (Directives 89/48/EEC and 92/51/EEC).[97] Directive 89/48 applies where the diploma requires at least equivalent of three years' full-time study at a university or similar institution. Directive 92/51 applies where the profession requires a post-secondary course at least equivalent to one year's full-time study. Implementing both directives means, *inter alia*, that Member States' competent authorities set up a procedure for examining an applicant to pursue a regulated profession. Failing to transpose the directives may produce a direct impact on citizens experiencing difficulties in gaining access to their profession.

Apart from its relevance to health professionals, the free movement provision is also applicable to consumers. Since the free movement is not restricted to "workers", also relatives, tourists and other categories of EU citizens (such as self-employed persons and pensioners and the members of their family[98] can make an appeal to benefit from this provision. Article 22 of co-ordination regulation 1408/71 in conjunction with article 48 EC, entitles EU citizens, *inter alia*, to pre-authorized care (the so-called E112 procedure).[99, 100] Comparative research on these categories of cross border

---

[97] OJ 1989 L 19/16/EEC; OJ 1992 L 209/25/EEC. Directive 89/48 has now been supplemented by Directive 94/38 OJ 1994 L 217/8/EC. Instead of attempting to harmonise by profession, known as the sectoral or "vertical" approach, the Commission was henceforth to adopt a general or "horizontal" approach, based not on harmonisation but on the mutual recognition of qualifications.

[98] Judgement of 31 May 1979, Case 182/78, Pierik II, ECR 1979, 1977.

[99] The full text of Article 22 (OJ No L028 p. 21-22, 1997/01/30 reads as follows:
1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:
(a) whose condition necessitates immediate benefits during a stay in the territory of another Member State; or
(b) who, having become entitled to benefits chargeable to the competent institution, is authorized by that institution to return to the territory of the Member State where he resides, or to transfer his residence to the territory of another Member State; or
(c) who is authorized by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:
(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;
(ii) to cash benefits provided by the competent institution in accordance with the provisions of the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the provisions of the legislation of the competent State.
2. The authorization required under paragraph 1 (b) may be refused only if it is established that movement of the person concerned would be prejudicial to his state of health or the

care has revealed several important shortcomings and lessons for applicant countries.[101] The main problem for acceding countries confronted with cross border health care, is how to regulate and finance these types of care. More then the current Member States, most candidate countries fear substantial flows of patients due to lacking facilities and/or (possible) divergence in quality. Whether or not justified, this fear has been strengthened by the latest Court of Justice rulings simplifying cross border health care.[102] The necessary legal conditions to regulate patient mobility are set

---

receipt of medical treatment. The authorization required under paragraph 1 (c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

3. The provisions of paragraphs 1 and 2 shall apply by analogy to members of the family of an employed or self-employed person. However, for the purpose of applying paragraph 1 (a) and (c) (i) to the members of the family referred to in Article 19 (2) who reside in the territory of a Member State other than the one in whose territory the employed or self-employed person resides: (a) benefits in kind shall be provided on behalf of the institution of the Member State in whose territory the members of the family are residing by the institution of the place of stay in accordance with the provisions of the legislation which it administers as if the employed or self-employed person were insured there. The period during which benefits are provided shall, however, be that laid down under the legislation of the Member State in whose territory the members of the family are residing; (b) the authorization required under paragraph 1 (c) shall be issued by the institution of the Member State in whose territory the members of the family are residing.

4. The fact that the provisions of paragraph 1 apply to an employed or self-employed person shall not affect the right to benefit of members of his family.

100 Apart from the pre-authorised care (initiated by a so-called E112 or E112+ form), Regulation 1408/71 discerns two other types of cross border care, *viz.* migrant workers, i.e. workers and their family members residing in another member state than that in which they work (Art. 19, Regulation 1408/71). As a special category, frontier workers (defined by Article 1(b) of Regulation 1408/71 as "any employed or self-employed person who pursues his occupation in the territory of another member state to which he returns as a rule of daily or at least once a week") within the EU benefits from a double access to health care, that is both in the state of residence and work at the same time. They have a right to health care covered in the state of residence as though they were insured there, on behalf of the competent state (Article 20, Regulation 1408/71). To initiate this right in a residence state a so-called E106 form is issued. The third category of cross-border care provided access to health care abroad in urgent situations, e.g. applied for tourists and short-term business mobility. To initiate the right to health care in these situations an E111 form is used. Hereafter, the discussion will be focussed on (barriers on) pre-authorised care since the legal and financial implications of this type of cross-border care are expected the most severe.

101 R. Leidl (ed.) Health Care and its Financing in a Single European Market. IOS Press Amsterdam 1999.

102 *E.g.*, cases C-120/5 *Decker* [1998] ECR I-1831 and C-158/96 *Kohll* [1998] ECR I-1931. The European Court of Justice overruled the pertinent Luxembourg regulations, which made reimbursement by the social security system of medical services provided in another Member State – respectively orthodontic treatment and the supply of spectacles – conditional on prior authorisation. However, it cannot be excluded that, for instance, the risk of seriously

by regulation 1408/71, article 22.[103] Although Member States authorities are authorized to define the conditions for entitlements, an over-restricted interpretation of article 22(1) (a) would "cause a significant obstacle to the freedom of movement of persons whose conditions necessitates continuous and regular medical treatment such that they will be likely to require immediate benefits in the event of a stay in the territory of another Member State."[104] Regulating patient mobility also requires an adequate authorization policy adopted by (secondary) law, including relevant procedures used when patients claim health care in a host Member State. If not adopted in national (health) law, acceding Member States can be accused of breaching EC law.[105] Further lessons, drawn from relevant court rulings show the relevance of non-discrimination between (non-)nationals,[106] categories of insured such as "workers" as well as pensioners and self-employed.[107] Since the *Decker* and *Kohll* rulings, on several occasions, the Court has been confronted with the legitimacy of pre-authorization in view of internal market principles.[108] A negative answer, i.e. pre-authorization violates the free movement principles, would threaten Member States' competence to regulate cross border care and consequently may open the borders for increased flows of patients and services. Current data on cross border flows do not seem to confirm this assumption, at least not for all EU countries in the same extent.[109] As regards cross-border care between Member States

---

undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier to the fundamental principle of freedom to provide services (C-120/5, no. 39). These rulings remained several questions unsolved, for instance, whether articles 59 and 60 also prohibits the pre-authorization of hospitalisations abroad. This question has been answered in the "Smits/Peerbooms" case.

103 *Supra* note 99.

104 Administrative Commission, quoted by Leidl o.c.: 329.

105 *Supra* p. 167.

106 ECJ Royer Rec. 1976, no. 48/75, p. 497 and more recently, case C-411/98 *Ferlini v. Centre Hospitalier de Luxembourg*, 3 October 2000. In this case, the Court ruled that the application, on a unilateral basis, by a group of healthcare providers to EC officials of scales of fees for medical and hospital maternity care which are higher than those applicable to residents affiliated to the national social security scheme constitutes discrimination on the ground of nationality prohibited under Article 12(1) EC, in the absence of objective justification.

107 C-215/90, judgement 31 May 1979, *Twomey v. United Kingdom* Rec 1992, p. I-1823.

108 *Infra* Smits/Peerbooms, Vanbraekel and Müller-Fauré/Van Riet.

109 In a recent study that analysed the implications of recent rulings on the coordination of health care protection systems it was concluded that the financial impact of cross border care within the European Union remains very marginal. This is born out year after year by the financial reports drawn up by the Audit Commission for the Administrative Commission. On average, cross-border care within the framework of this coordination system represents only 0.3 – 0.5 percent of total public health spending, or under 2 Euro per inhabitant. J. Hermesse. The opening of frontiers to patients. What economic consequences? in: Health care without frontiers in the European Union? Free movement of goods and services in the health care sector, Proceedings of the International Symposium, Luxembourg 18 November AIM, 1998: 49-58; quoted by W. Palm, J. Nickless, H. Lewalle, A. Coheur. Implications of

and candidate countries, no reliable data have been found. But it is likely that a (partial) withdrawal of the pre-authorization procedure can have considerable financial consequences to candidate Member States facing substantial numbers of migrating citizens to other member states,[110] or patients requesting health care abroad due to differences in quality. Apart from the "fear" of numbers of patients flowing abroad, the rulings may have even greater implications on the organisation, operation and management of the (candidate) Member States' health care system. One of the greatest concerns is that it would no longer be possible to exclude (private) providers from the system of social protection. In countries where, in the context of social protection, care is provided by a limited number of contracted providers, private providers have expressed particular interest in the *Decker* and *Kohll* rulings. They might refer to the decisions of the ECJ to claim reimbursement for their services provided to patients who are covered under the social health protection system.

The Court confirmed the *Decker* and *Kohll*-reasoning in a more recent ruling the "*Smits/Peerbooms*" case.[111] In this mixed case, the European Court

---

recent jurisprudence on the coordination of health care protection systems. General report produced for the Directorate-General for Employment and Social Affairs of the European Commission. Association Internationale de la Mutualité (AIM), Brussels, May 2000: 36-37.

[110] In 1998, there are around 3 million Central and Eastern Europeans legally resident in the EU. J. Nickless. Kohll and Decker: a new hope for third-country nationals. *Eurohealth* 1999, Iss. 1: 20.

[111] *Geraerts-Smits/Peerbooms v. Stichting CZ Groep Zorgverzekeringen* (C-157/99), European Court of Justice, 12 July 2001. The mixed Smits/Peerbooms judgement concerned the refusal of a Dutch Health Insurance Fund to reimburse the costs of hospitalisation in another EU Member State. Mrs Smits, suffering from Parkinson's disease, was treated in a German private hospital without the prior approval of the Dutch Health Insurance Fund and Mr Peerbooms, a patient in a coma, who did not satisfy the conditions for admission to two Dutch hospitals, was given intensive treatment in an Austrian private hospital. Dutch legislation stipulates that patients must obtain prior authorization before receiving medical treatment, either in The Netherlands or abroad, in hospitals that are not part of the national health system, and the authorities considered that in these two cases, the treatment received abroad had no advantage compared with the treatment available in the Netherlands. In his Opinion, the Advocate-General of the ECJ, Ruiz-Jabaro did not consider that health care is a service as defined in the Treaty (para 49). The prior authorization procedure therefore does not violate the Treaty. In case the Court would not accept this argument, which appeared the case, the A-G concluded that the Court should consider prior authorization as a necessary and proportionate instrument to maintain the financial balance of an equitable accessible system of health care services to the entire population (para 72). At the same day (12 July 2001), the Court ruled in another "prior authorization" case, although the question primarily focused on the applicable reimbursement tariff, *Vanbraekel v. Alliance nationale des mutualités chrétiennes* (C-368/98). In this case, the Belgian mutual health fund had incorrectly refused prior authorization for an orthopedic treatment in France. The transferring court, having already ruled that it was illegitimate to refuse authorization, made a preliminary ruling to the ECJ concerning the applicable reimbursement tariffs (higher Belgian or lower French tariffs), explicitly referring to the Kohll judgement. Here, the Court ruled that in case of unfounded refusal of the competent institution, the person concerned is entitled to be

concluded that Community law does not, in principle, preclude a system of prior authorization (para. 82). The approval of such authorization must be justified with regard to the overriding considerations examined (guaranteeing a rationalised, stable, balanced and accessible supply of hospital services) and satisfy the proportionality requirement. In casu, the possible risk of seriously undermining a social security system's financial balance, may constitute a justified barrier to the free movement of hospital services.[112] Different from *Decker* and *Kohll*, the Court accepted such a justification in case of non-contracted hospital services. Despite the acceptance of the prior administrative authorisation procedure, the domestic authorisation conditions must, however, be based on "objective non-discriminatory criteria, which are known in advance" (para. 90). In the disputed Dutch situation, this was not the case.[113]

Although the Court upheld the Dutch contracting system, the pre-authorization as applied by the Dutch authorities was criticised by its (potential) discriminative effect.[114] Therefore, the Court set rules that Member States should respect when using their discretionary competences determining the conditions governing entitlements to benefits. Member States should apply the pre-authorization procedure consistently and that

---

reimbursed directly by the competent institution, in casu the Belgian mutualité, by an amount equivalent to that which would have been borne by the institution if authorization had been properly granted in the first place (para 53). Otherwise, if a patient would be guaranteed a lower reimbursement than in his home state, this would deter, if not prevent him from looking to health care abroad. For – the heirs of – Mrs Vanbraekel this meant a profit of the difference between the Belgian and French tariffs.

112 Conform the Kohll ruling, the possible risk of seriously undermining a social security system's financial balance may justify barriers to freedom to provide medical services. In the context of hospital services, according to the Court, it is well known that the number of hospitals, their geographical distribution, the mode of their organisation and the equipment with which they are provided are all matter for which planning must be possible (para. 76). The aim of ensuring sufficient and permanent access to wide range of hospitals and the need for cost containment in the social security system, justify prior authorization' (para. 80).

113 The actual Dutch system of sickness fund insurance enacted a general legal rule under which the costs of medical treatment will be assumed provided that the treatment is "normal in the professional circles concerned". This expression is however open to a number of interpretations, depending, in particular, on whether it is considered normal only in Dutch medical circles, which seems to be favoured by the national court. The Court decided that to allow only treatment habitually carried out on national territory and scientific views prevailing in national medical circles to determine what is or is not normal, will not offer those guarantees (objective, non-discriminatory criteria, known in advance and not used arbitrarily) and will make it likely that Dutch providers will always be preferred in practice (para. 96).

114 In the case where treatment is sufficiently tried and tested by international medical science, refusal of the prior authorization cannot be justified. Further, to satisfy the normal-criterion it must take into consideration all the relevant available information, including, existing scientific literature and studies, authorised opinions of specialists and the fact that the proposed treatment is (not) covered by the sickness insurance system of the Member State in which the treatment is provided (para. 98).

patients cannot be denied health care abroad arbitrarily (i.e. non-discriminatory, transparent procedure, that is subject to appeal); the criteria should be "Euro-speak".[115] For patients entitled to benefit-in-kind services, the ruling means that it should be just as easy to receive medical treatment from a foreign non-contracted provider as it is to obtain from a non-contracted provider in the country of insurance. As such, the Court's interpretation of communal pre-authorization conditions created new opportunities for an extended access to health care abroad.[116] Nonetheless, the fear of increased flows of patients seems rather unfounded since the Court argued that authorization can be refused on the ground of lack of medical necessity "only if the same or equally effective treatment can be obtained without *undue delay* at an establishment having a contractual arrangement with the insured person's sickness insurance fund" (para 108). It means that in case of sufficiently contracted hospital services, the insured's request for authorizing trans-border care will be unsuccessful.[117]

Apart from a future right to access to cross-border care based on ECJ rulings, respectively the EC Treaty, it is questionable whether the applicable Europe agreements may already invoke such a right since the Europe agreements are part of Community law.[118] The Europe agreement makes provisions for workers, the self-employed and service providers. In this respect, it is modelled on the EC Treaty, dividing into the same categories types of economic activity carried out by, *inter alia,* natural persons. With regard to the cross-border care discussion, the inclusion of provisions on movement of natural persons is relevant, in particular the co-ordination

---

115 Nickless, J. Smits/Peerbooms: Clarification of Decker and Kohll? *Eurohealth* 2001, Iss. 4: 9.

116 Temmink, H.A.G. Kroniek van het Europees recht (in Dutch). *Nederlands Juristenblad* 2001, Iss. 31: 1502.

117 At this moment, two more or less identical Dutch cases are pending for the Court, *Müller-Fauré/Van Riet v. OZ Zorgverzekeringen and Onderlinge Waarborgmaatschappij ZAO* (C-385/99). Given the similarities with the "Smits/Peerbooms" case, it is not unlikely that the Court will consolidate its previous reasoning. Both in Müller-Fauré and Van Riet, the Central Administrative Appeal Court (CRvB) requests a preliminary ruling on prior authorization of hospital care in view of article 49 and 50 EC. In these case, the national court explicitly questions whether a hospital admission and treatment abroad without prior authorization can justify a restriction of the freedom of movement of services (in view of the risk of seriously undermining the financial balance of a social security scheme). The case of Müller-Fauré, in which the patient deliberately requested dental care during her holiday in Germany, could reveal whether the priority given to contracted providers would also be upheld for ambulatory medical services. This case is important because of an increasing perception that provisions for emergency care (certified by E111) are actually being used to by-pass the restrictive policies with respect to non-emergency health care. Mountford, L. Health care without frontiers? The development of a European market in health services? London, Office for Economics, 2000, quoted by Mossialos, *supra* note 70, chapter 3.

118 Art. 310 EC, ex Art. 238 in conformity with the procedure set out in Article 300 EC, ex Article 228.

of social security systems. Article 38 EA states that workers of the Polish nationality, legally employed in the territory of a Member State, and the members of their family, legally resident there, are (conditionally) entitled to benefit medical care in that concerned Member State.[119] In accordance with the Europe agreement, by analogy of regulation 1408/71, the Association Council, shall adopt the appropriate provisions to implement the co-ordination of social security systems (Article 39). Different from regulation 1408/71, however, the Europe agreement restricts the entitlement to cross-border health care for Polish workers by subjecting it to "*the conditions and modalities applicable in each Member State*".[120] Such impediments can also be found in Europe agreements with Hungary and the Czech Republic. In contrast, agreements with third countries, such as Morocco, Tunisia and Algeria do not include similar workers' freedom of movement obstacles.[121] Can Polish workers, by analogy of regulation 1408/71, claim access to cross-border care by virtue of Article 38 irrespective national conditions set by Member State? In the *Polydor* case, the European Court of Justice ruled that it would not necessarily apply the same interpretation to a trade agreement that it would to an identical provision of the EC Treaty, which depends on "the purpose and nature of the agreement".[122] Although the scope of this restriction is highly undefined, the ultimate purpose of the Europe agreement is full integration in the European Community (Article 1). Realisation of the internal market, *ergo* removing free movement barriers, is a *conditio sine qua non* of full integration. In the light of this "purpose" test, a similar interpretation of the Europe agreement, at least concerning freedom of movement of workers seems likely. In consequence, discriminatory obstacles by nationality, such as the "conditions and modalities" in the context of social security may create an illicit restriction, prohibited by European law. The consequences of such

---

119 *Mutatis mutandis* Europe agreement Hungary and the Czech Republic.

120 Article 38 Europe agreement Poland.

121 EEC-Morocco Co-operation Agreement Council Regulation (EEC) No 2211/78, 26 september 1978 OJ L264/1. Such a provisio was not inserted because of the far reaching consequences of such provision arising from the *Kziber* judgement (C-18/90 ECJ *Office National de L'Emploi v Kziber* 1991 Rec p. I-199). Bahia Kziber, a national of Morocco, lived in Belgium. After finishing her studies, Kziber applied for unemployment benefits which were denied her. According to the Belgian Office of Employment, the basis for the denial was her Moroccan nationality. Kziber appealed the denial citing Article 41 of the Co-operation Agreement between the EC and Morocco. The ECJ gives direct effect to dispositions of international agreements if the contain a clear, precise and unconditional obligation and if the objectives of the agreement sustain that interpretation. The Court then examined the possibility of direct effect of article 41(1), looking at the terms, nature and object of the agreement and found a clear, precise and unconditional obligation in article 41(1).

122 C-270/80 Judgement of 09/02/1982, *Polydor* vs *Harlequin*. European Court Reports 1982, no. 16, p. 329.

an interpretation is that workers from candidate countries have an enforceable right to cross border care analogous to regulation 1408/71. In the European law literature, several commentators argued a uniform and consistent interpretation of the European agreements with the EC Treaty.[123] The addition of the "conditions and modalities" provisio relating to national law raises serious questions as to whether the non-discrimination right can be directly effective. Until the Court of Justice clarifies the meaning of the provisio it may be premature to suggest a *mutatis mutandis* application of the jurisprudence relating to the Maghreb agreements.[124]

The Court gave that clarification in three recent judgements by denying a Maghreb conform interpretation, although the right invoked concerned the right of *establishment* of non-EU nationals within a Member State.[125] In this particular case, the Court was asked essentially whether the right to establishment (article 44, section 3 EA) is directly applicable and whether restrictions imposed on the right of establishment by the UK's immigration legislation are compatible with the conditions set out in article 58(1) of the agreement (para 28).[126] With respect to article 44(3), the Court applied

---

123 E. Guild (ed.) The Europe Agreements: The Rights to Establishment in the Central and Eastern European Agreements in: The Legal Framework and Social Consequences of Free Movement of Persons in the European Union. Kluwer Law International, The Hague 1999: 128. S. Peers. An ever Closer Waiting Room? The Case for Eastern European Accession to the European Economic Area. *CMLR* 1995, Iss. 1: 210.

124 Guild, *o.c.*: 130 referring to the non-discrimination provision without the limitation of national discretion contained in the Morocco Agreement Babahenini C-113/97 judgement of 15 January 1998 *Babahenini v. the Belgian State*. EC 1998, p. I-183.

125 Judgements of the Court in Cases C-63/99, *The Queen and Secretary of State for the Home Department v W. Gloszczuk and E. Gloszczuk, mutatis mutandis* C-257/99, *The Queen and Secretary of State for the Home Department v. Barkoci and Malik*, and C-235/99, *The Queen and Secretary of State for the Home Department v Kondova*, 27 september 2001 on the interpretation of Articles 45 and 59 of the Czech Europe agreement. The questions have arisen in a dispute between Czech nationals, and the UK Secretary of State for the Home Department in respect of two decisions by which the latter refused to grant them leave to enter the United Kingdom. According to the Court, article 45 EA lays down a precise and unconditional principle which is sufficiently operational to be applied by a national court (ergo, direct effect). Nonetheless, the authorities of the State concerned remain conditionally competent to apply to those nationals their own national laws and regulations regarding entry, stay and establishment, in accordance with Article 59(1) of that Agreement (*para* 39). This interpretation was confirmed in C-268/99 *Malgorzata Jany and others v. Staatssecretaris van Justitie*, of 20 november 2001 in which Polish and Czech nationals contested the dismissal of the Dutch Secretary of State on the merits of their objections to his earlier decisions refusing them residence permits to enable them to work as self-employed prostitutes (para 28-31). See also Van Ooik, who subscribes the direct effect of the EA freedom of establishment. R.H. van Ooik. Case law. The Jany ruling and prostitution as economic activity (in Dutch). *NTER* 2002, Iss. 1-2 , pp. 2-3 and R. van Ooik and H. Staples. Direct appeal on Europe Agreements by East-European self-employed (in Dutch). *NTER* 2001: 313-319.

126 Article 44(3) of the Association Agreement provides: "Each Member State shall grant, from entry into force of this Agreement, a treatment no less favourable than that accorded to its own companies and nationals for the establishment of Polish companies and nationals as

the "wording, nature and purpose" test and ruled that "within the scope of application of that Agreement, article 44(3) establishes a precise and unconditional principle which is sufficiently operational to be applied by a national court which is therefore capable of governing the legal position of individuals" (direct effect thus). But "notwithstanding the fact that the authorities of that State remain competent to apply to those nationals their own national laws and regulations regarding entry, stay, and establishment, in accordance with article 58(1) of that Agreement" (para 38). The Court therefore did not follow a Maghreb conform interpretation given the difference in purpose between the EC Treaty and Association agreement.[127] "A mere similarity in the wording of a provision of one of the Treaties establishing the Communities and of an international agreement between the Community and a non-member country is not sufficient to give to the wording of that agreement the same meaning as it has in the Treaties" (para 48).[128] It follows from the wording of article 58(1) that the rights of entry and residence are not absolute privileges, inasmuch as their exercise may, where appropriate, be limited by the rules of the host Member State concerning entry, stay and establishment of Polish nationals (para 51).

The Court further examines whether the restrictions imposed on the right of establishment by the host Member State's immigration legislation are compatible with the condition set out in article 58(1), i.e. not restricting these rights in any unreasonable or excessive way. In casu, the Court answered this question by determining whether the immigration rules applied by the competent national authorities are appropriate for achieving the objective in view or whether they constitute measures which would strike at the very substance of rights which article 44(3) grants, by making exercise of those rights impossible or excessively difficult (para 56).

Although the concerned cases involved the right to establishment, a similar interpretation concerning free movement of workers is very likely since article 58 refers to title IV, including conditions limiting both the

---

defined in Article 48 and shall grant in the operation of Polish companies and nationals established in its territory a treatment no less favourable than that accorded to its own companies and nationals", whereas article 58(1) reads: "For the purpose of Title IV of this Agreement, nothing in the Agreement shall prevent the Parties from applying their laws and regulations regarding entry and stay, work, labour conditions and establishment of natural persons, and supply of services, provided that, in so doing, they do not apply them in a manner as to nullify or impair the benefits accruing to any Party under the terms of a specific provision of this Agreement [...]".

127 The Association Agreement is designed simply to create an appropriate framework for the Republic of Poland's gradual integration into the Community, with a view to its possible accession, whereas the purpose of the Treaty is to create an internal market, establishment of which involves the abolition, as between Member States, of obstacles to the free movement of goods, persons, services, and capital (para 50).

128 Conform *Polydor and RSO Records*, para 14-21.

freedom of movement of workers and services. Therefore, in case Member States' social insurance legislation do not restrict cross-border care in "any unreasonable or excessive manner", residents from applicant countries cannot claim such a right by virtue of the Europe agreements.

Free movement of services

The second freedom applicable to the health sector is the right to provide services within the Community.[129] The principle of freedom of movement of services is regarded as a fundamental principle, designed as a fundamental Community right. In the Smits/Peerbooms case it was already decided that the provisions of freedom to provide services are applicable to medical, notably hospital services.[130] In this respect, it did not follow the opinion of the Advocate-General arguing the payment element. According to the Court, this argument cannot be upheld. It is settled case law that medical activities fall within the scope of Article 50 (ex Article 60) of the Treaty, there being no need to distinguish in that regard between in and outpatient health care (para 53).[131] Moreover, the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement (para 54). Neither the fact that hospital treatment is financed directly by the sickness fund on the basis of agreements and pre-set scales of fees (para 56). This being said, it can be concluded that the *Decker* and *Kohll* judgements cannot be considered as an rare incident.

In addition to the competition principles, they affect recent market reforms of health care systems. The introduction of market forces in health care raises the question of whether EC competition principles are applicable in traditional public law activities, such as social health insurance. Two of the most important provisions covering competition in the EC Treaty are articles 81 and 82 of the Treaty (ex articles 85 and 86 EC). These provisions forbid "all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market", article 81 (1). Whereas "any abuse ... of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market insofar as it may affect trade between Member States." Assessing the impact of health system reform,

---

129 Articles 49-55 EC Treaty.

130 In other contexts this is already standing procedure (*Grogan* C-159/90 [1991] ECR I-4685, para 18: *Bond van Adverteerders and others* Case 352/85 [1988] ECR 2085, para. 16 and Jointed Cases C-51/96 and C-191/97 *Deliuige* [2000] ECR I-2549, para. 56).

131 *Supra* note 111.

EU Member States have introduced greater competition into the public field of health care, through the creation of so-called quasi-markets.[132] Such markets are characterised by increasingly (collective) contractual relationships between payers and providers and an increase of various "managed competition" elements (free choice of provider/insurer). It is however not unlikely that the EC anti-cartel provisions are also applicable to the health care sector, irrespective the legal status of the entity and the way in which it has been financed. The central issue here is whether the concept "undertaking" is applicable to social health insurance funds such as Sickness Funds.[133] According to the ECJ case law, the basic principle underlying this case was the use of the concept of solidarity to perform a social objective under supervision of the state without making any profit. But increasing reliance on the market and privately financed health care services may make social health insurance funds subject to EC competition rules. "When solidarity elements are replaced by an equivalent principle by which premia are fixed in relation to the degree of risk, the social insurance becomes increasingly blurred and even can take the feature of private insurance. Too sharp an increase in, for example, the non-income related part of the premium (the nominal premium) could cause social health insurance to lose its original character".[134, 135]

---

[132] The Impact of Market Forces on Health Systems. A Review of Evidence in the 15 European Union Member States. European Health Management Association, Dublin, March 2000: 51.

[133] C-159/91 and C-160/91 Judgement of 17 February 1993. *Poucet and Pistre v. Assurance générales de France and Caisse mutuelle* 1993 p. I-637. From this case, a number of criteria has been distilled allowing the fulfilment of a social objective: the insurance is legally valid; the insured person has a legal claim to health care; premia are levied on the basis of solidarity; open enrolment for everyone, and the system is directed towards a social objective. In case of a positive answer, the principle of solidarity is applicable and thus the activity was not economic and the entity could not be considered as an undertaking. Ergo, the system of social health insurance can, for a large part, be withdrawn from the scope of the EC Treaty. H. Hermans, I Tiems. Convergence in the Dutch Health insurance: Possibilities and Obstacles in a European Perspective *Eur. J. of Law and Economics* 1997, Iss. 4: 378-379. See also, A. Winterstein. Nailing the Jellyfish: Social security and Competition Law. *ECLR* 1999, Iss. 6: 329-331.

[134] Hermans and Tiems *o.c.*: 379. Such a development can be observed for instance in the Netherlands. The Dutch Anti-Cartel Authority (NMa) concluded that sickness funds purchasing health care services based on the Sickness Fund Act can be considered as "undertaking" in the sense of the Anti-Cartel Act since they purchase a good or service at a market, i.e. an "economic activity" (NMa Decision no. 1165, ANOZ Verzekeringen 29 december 1998, RZA 2000, 132). Whereas providing health insurance, they are exposed to financial risk due to freedom of contracting providers and restricted discretion in premium setting. In that case, sickness funds can also be considered as "undertaking" despite their social character.

[135] In more recent rulings, the ECJ held that a non-profit making organisation which managed a pension scheme intended to supplement a basic compulsory scheme, established by law as an optional scheme and operating according to the principle of capitalisation, was an undertaking within the meaning of article 61 (ex 85) et seq. of the Treaty. This is clearly contrast to *Poucet* and *Pistre*. Optional affiliation, application of the principle of capitalisation

Since the introduction of social health insurance early 1990s, accession countries have evolved new types of purchasing mechanisms including quasi-markets.[136] A serious threat however, is the absence of stable relations between well-established payers and providers. The dominant role of certain market actors and absence of effective anti-cartel legislation may hinder the entrance of new market actors. In the light of future accession, these countries should be aware of the potential consequences of EC competition law on their social security system, in particular the impact of introducing market elements in newly established social health insurance funds.[137] Of further relevance is the impact of the "Third Insurance Directives", in particular the "third non-life insurance Directive"

(financial risk) and the fact that benefits depended solely on the amount of the contributions paid by the beneficiaries and the financial results of the investments made by the managing organisation implied that that organisation carried out an economic activity in competition with life insurance companies. Neither the social objective pursued, nor the fact that it was a non-profit making, nor the requirement of solidarity, nor other rules concerning, in particular, the restriction to which the managing organisation was subject in making investments altered that fact that the managing organisation was carrying on an economic activity. *Féderation* Française *des Sociétés d'Assurance* Case T-106/95 Judgement of 27 February 1997 EC 1997, p. II-229, quoted in: *Albany International v. Stchting Bedrijspensioenfonds Textielindustrie* C-67/96 Judgement 21 september 1999 EC I-5751 para. 79; *Brentjens' Handelsonderneming v. Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen.* Jointed cases C-115/97 and C-116/97 and C-117/97 judgement on 21 september 1999 EC 1999 p. I-6025; *Drijvende Bokken v. Stichting Pensioenfonds voor de Vervoer- en Havenbedrijven* C-219/97 Judgement on 21 september 1999 EC 1999 p. 6121, para 68-69; Pavlov v. Stichting Pensioenfonds Medische Specialisten C-180/98 to C-184/98 Judgement on 12 september 2000 para 74-76.

136 After the ancient regime, virtually all applicant countries introduced social health insurance legislation based on, at least officially, a purchaser-provided split. The latest amendments introduced free choice of provider/insurer, including the right to switch insurer and the concept of selective contracting providers. However, free choice of insurer is absent in Hungary (national health insurance, *OEP*).

137 In a different setting the Court ruled that competition provisions are applicable to ambulance services but that national (or local) authorities can refuse authorisation to new operators from running ambulance transport services in a geographically limited area. The case concerned Ambulanz Glöckner who obtained in 1990 authorization to provide a patient transport service in Germany. In July 1994, it applied for the renewal of its authorization to the competent territorial authorities (Landkreis). Under the German 1991 law, those authorities may refuse to grant such authorization if its use might have an adverse effect on the functioning and profitability of the public ambulance service the operation of which has been entrusted, as allowed under the law, to medical aid organisations. The Landkreis refused authorization since the existing emergency facilities provided by two other organisations were not fully used. The German national court asked the Court of Justice whether the grant of a monopoly over the transport of patients in a limited geographical area was compatible with the Community rules on competition. The Court ruled that, although existing ambulance services (providing both emergency and non-emergency transportation) may have a quasi-monopoly over the transport of patients, the general economic interest task of transporting patients entrusted to these organisations by law may justify a restriction or exclusion of competition if that is necessary for the particular task concerned in order to achieve an overall economic balance (para 65). Judgement in Case C-475/99 *Ambulanz Glöckner v Landkreis Südwestpfalz.* 25 October 2001.

(92/49/EEC).[138] The "Third Insurance Directives" introduced a single system for the authorization and financial supervision of an insurance undertaking by the Member State in which it has its head office (article 4, "home country control"). Such authorization issued by the home Member State enables the insurance undertaking to carry out its insurance business anywhere in the European Union. The directives also required Member States to abolish controls on premium prices and prior notification of policy conditions ("single licence system"). The main impact of the single licence regime laid down by the "Third Directives" has been an increase of competition within different national markets. The abolition of prior approval of policy conditions and tariffs by supervisory authorities, which was the rule in many Member States before the adoption of the "Third Directives", has encouraged insurers to enter new markets, and so increased competition.[139] The "Third Directives" allow individuals and businesses to buy insurance in another Member State. As such, the directives had a liberalizing influence on the insurance market. In practice, insurance undertakings may be unwilling, for commercial reasons, to enter into a private insurance contract with a policyholder living in another Member State. In the case of private health insurance, the third directive on non-life insurance retained Member States special powers to regulate private health insurance which can substitute the statutory system "wholly or in part".[140] The Member State may also require prior notification of policy conditions before such policies are marketed. The Irish Health Insurance Act and the Dutch Health Insurance Access Act were based on this exception. For acceding countries, this exception will be of relevance particularly in case of restricting the scope of social health insurance entitlements and the introduction of mutual health funds. Given the need for cost containment, compulsory health insurance funds consider the exclusion of non-necessary and non-effective health care services from the social insurance scheme.[141] These services could then be covered by private complementary health insurance (reinsurance). The introduction of such a private complementary health insurance scheme within the social insurance scheme may partly

---

138 Officially Council directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions related to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC.

139 Commission Interpretative Communication Freedom to Provide Services and the General Good in the Insurance sector. European Commission Brussels, 2/2/2000 C(1999) 5046: 1.

140 Article 54 directive 92/49/EC.

141 The introduction of private insurance into the social insurance scheme is being considered in the Czech Republic, whereas the Polish General Health Insurance Act (1999) already anticipates on such a development (article 9 General Health Insurance Act). In the Czech case, this raised the question whether or not the third non-life directive allows compulsory health insurance funds to market such a private insurance policy. Correspondence R. Kares (*VZP*) – A. den Exter (EUR), January 2000.

replace the statutory system and therefore falls within the scope of the exception made in the non-life insurance Directive. In that case, the legislator can impede restrictions for the "reason of general good" to the freedom of providing insurance services, for instance imposition of standard clauses or minimum insurance conditions and clauses imposing minimum levels of excess in insurance policies.[142] Failure of setting these conditions may encourage risk selection by private insurance companies, consequently threaten access to certain health care services.[143] Finally, to encourage free movement of services the rules of public procurement of services should be mentioned. Public procurement, or the rules of public purchasing of services has been regulated by the "Public Services Directive" 92/50/EC.[144] As a result of this directive contracting authorities are obliged to award the listed services according to awarding (tender) procedures (Article 10). The Directive means with contracting authorities: the State, regional or local authorities, bodies regulated by public law, associations formed by one or more of such authorities or bodies governed by public

---

142 The concept of the general good is based on the Court's case law. It was developed first in the context of the free movement of services and goods and was subsequently applied to the right of establishment. The Court requires that a national provision must satisfy the following cumulative requirements if it is validly to obstruct or limit exercise of the right of establishment and the freedom to provide services: it must come within the field which has not been harmonised; it must pursue an objective of the general good; it must be not discriminatory; it must be objectively necessary; it must be proportionate to the objective pursued, and it is also necessary for the general good objective not to be safeguarded by rules to which the provider of services is already subject in the Member State where he is established. In its interpretative communication, the Commission has applied these principles to the insurance sector. Commission Interpretative Communication. Freedom to Provide Services and the General Good in the Insurance Sector. C(1999) 5046 Brussels, 2.2.2000, pp. 22 and 27-28.

143 In the light of market developments in social health insurance, it has been questioned whether article 54 provides a sufficient legal basis to regulate complementary (private) insurance (and mutual health funds). Given the solidarity problems, purchasing both basic and supplementary insurance (France), a new generation insurance directives has been suggested, a "fourth insurance directives". In particular, the "fourth non-life insurance directive" should simplify and increase the minimum guarantee funds for reinsurance purchased by primary insurers, creating a wider regulatory framework for human and social risk insurance, binding on all insurers, in order to prohibit any selection of risks, to offer permanent health insurance and to rule out the possibility of any cancellation of contracts due to age or stage of health. G.J.A. Hamilton, Towards a fourth generation of European insurance directives. Association Internationale de la Mutualité (AIMS), Brussels, March 1999: 1-3. An alternative is the recognition for private not-for-profit social services, possibly by introducing a general exception for such services on the basis of general interest in Article 16 of the EC Treaty. Opinion of the Economic and Social Committee on private not-for-profit social services in the context of services of general interest in Europe, CES 1120/2001, 12 september 2001.

144 EC/92/50, OJ L 209 of 24.7.92, p. 1 regulating the coordination of procedures for the award of public service contracts. Lately amended by Directive 97/52/EC of 13 October 1997, OJ L 328, p.1.

law.[145] In the field of purchasing health care services, this directive has also consequences for statutory health insurance funds since they are generally considered as bodies "governed by public law". According to the directive, such a body can be understood as "*established for the specific purpose of meeting needs in the general interest not having an industrial or commercial character, having a legal personality, and financed for the most part by the State, or regional or local authorities, or other bodies governed by public law, or subject to management supervision by those bodies, or having an administrative, managerial or supervisory board, more than half of whole members are appointed by the State, regional or local authorities or other bodies governed by public law.*"[146] Social health insurance funds will comply these conditions, and thus fall within the scope of this directive.[147] Consequently, social health insurance funds will have to make public their purchasing requirement as soon as possible after the beginning of their budgetary year in the *Official Journal* of the European Communities. The obligation to publish an indicative notice does not apply to contracts that are excluded by the Directive.[148] Since the contracting authority must use the open or restricted procedure for the purpose of seeking offers, this will mean that other (EU) service providers that offer a proposed service contract can be invited to tender. Persons being harmed by an infringement of the award procedure may eventually award damages.

In the *Tögel* judgement, it became clear that this Directive is of direct relevance to (candidate) Member States' social health insurance funds.[149] Since the Directive falls under judicial review of the European Court of Justice, individuals can directly complain at the Court about Member States' violations. Mr Tögel, who had a licence to carry on a hire-car business limited to the transportation of injured and sick persons, had been repeatedly requested the regional sickness fund ("Niederösterreichische Gebietskrankenkasse") for a contract, without success. The sickness fund turned down the applicant's request for a direct-charging contract on the ground that that type of transport was adequately provided for under existing agreements. Mr Tögel complained that the contract at issue concerned a service covered by Directive 92/50/EC (Annex I A) and that, consequently, a public tender procedure should be carried out. The applicable Austrian court requested the Court for a preliminary ruling,

---

145 Article 1 (b) EC/92/50.

146 Article 1 (b) EC/92/50.

147 Whether or not social health insurance funds are "financed for the most part by the state can be questioned but they are supervised by public law bodies and therefore fulfil the third condition.

148 Articles 4-7, *e.g.*, public services contracts in the field of defence, or below an estimated threshold of 200.000 ECU.

149 C-76/97 judgement 24 september 1998. *Tögel v. Niederösterreichische Gebietskrankenkasse* EC 1998 p. I-5357.

questioning whether the services as mentioned in the case had to be classified as services under the directive (Annex I A) and contracts for such services thus be awarded in accordance with the provisions of the Directive.[150] The Court answered this question positively, ruling that "services consisting in the transportation of injured and sick persons with a nurse in attendance come within Annex I A (Land transport services) and I B (health services), of the Directive, so that a contract is covered by article 10 of Directive 92/50/EC."[151] Moreover, since the provisions of the Directive are unconditional and sufficiently precise, individuals may directly rely on those provisions against a State where that it fails to implement the directive in national law correctly.[152] The Directive, however, does not apply retroactively to existing public service contracts. Since the contracts were concluded before the Directive came into force, Mr Tögel could not claim termination or another intervention from the awarding authority based on Community law.[153]

The implications for acceding countries are, first and foremost, the obligation to transpose the "Services Directive" in national law. In general, this entails the establishment of procurement procedures for certain types of public services contracts (article 10 categories). These procedures should regulate the award of public services contracts as well as providing the extension to the field of services of the review procedures set out in the "Review Directive".[154] This means the establishment of a review body, empowered to review the procedures. Candidate Member States should furthermore ensure that decisions taken by the bodies responsible for review procedures could be effectively enforced. The consequences for the contracting authorities, i.e. social health insurance funds, can be to carry out a public tender procedure for services listed in article 10 (Annexes A and B) including, among others, "ambulance services" (reference number 93192). Secondly, this reference number must be read in its context.[155] The general category "Human health service" (Annex I B category 931) includes "Hospital services" (9311), "Medical and dental services" (9312), and "Other human health services" (9319), which is further subdivided into "Deliveries and related services, nursing services, physiotherapeutic and paramedical services" (93191), "Ambulance services" (93192), "Residential health facilities services other than hospital services" (93193) and "Other

150 *O.c.*: para 20.
151 *O.c.*: para 40.
152 *O.c.*: para 47.
153 *O.c.* para 54.
154 Officially, Council Directive 89/665/EEC of 21 december 1989 OJ 1989 L 395 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts.
155 Opinion Advocate General, para 36.

human health services" (93199). These services are, *prima facie,* classifiable under public tenders. In case social health insurance funds fail to carry out such a public tender, discriminated services providers may directly rely on the directives provisions before national courts.

Free movement of goods

Besides liberalising the trans-national product market, the right to free movement of goods (arts. 23-31 EC) has also a clear health dimension, *viz,* protecting consumers from harmful medical goods. The free circulation of products, notably certain pharmaceuticals and blood products and medical devices, has been regulated by a very large body of existing Community regulation on quality, safety and efficacy. Directive 65/65/EEC is the principle directive with the aim of harmonising safety and efficacy standards for medical products.[156] It imposed on Member States to enact laws to ensure that new medical products may not be marketed on their territories without the approval of a competent regulatory body. More detailed harmonisation provisions for the criteria and procedures according to which approval may be given by national regulatory bodies for new medical products followed.[157] A large number of directives extended the scope of Directive 65/65/EEC covering all industrially produced medicines, including vaccines, blood products and radio pharmaceuticals.[158] Two landmark directives, 75/381/EEC and 75/319/EEC introduced a procedure for the mutual recognition by Member States, of their respective national marketing authorisations. To facilitate mutual recognition, Directive 75/319/EEC set up a Committee for Proprietary Medicinal Products (CPMP) which assessed whether candidate products complied with Directive 65/65/EEC. The specified standards and protocols for the performance of tests and trails on medical products are an effective means to control these products, hence to protect the health of consumers. In addition to the quality, safety and efficacy criteria, further rules that were harmonised promote the appropriate use of medicines including procedures for labelling (packaging to include information relating to dose, ingredients, side effects),[159] and advertising of medical products (advertisement to the general public of prescription drugs is prohibited).[160] To control expenditures on medicinal products, Member States have adopted measures including direct and indirect controls on the prices, limitations

---

156 Directive 65/65/EEC OJ 1965 L 22/369.

157 F. Sauer. The European Community's Pharmaceutical Policy in: Health Care in Europe after 1992. H.E.G.M. Hermans, A.F. Casparie, J.H.P. Paelinck eds Dartmouth Aldershot 1992: 133.

158 Directive 89/342/EEC, OJ 1989 L 142/14; Directive 89/343/EEC, OJ 1989 L 142/16; Directive 89/381/EEC OJ 181/44.

159 Directive 92/27 OJ 1992 L113/13.

160 Directive 92/28 OJ 1992 L 113/13.

on the range of products covered by national health insurance systems. Unmistakably, such arrangements, related to financing and organisation, are among the Member States' competences. However, disparities in price fixing measures may hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the single market for pharmaceuticals. Moreover, in the public health context the promotion and protection of public health requires that patients and consumers have wide access to pharmaceuticals at affordable cost. To achieve this, the "Transparency Directive" 89/105/EEC contains requirements that intend to remove pricing disparities of medicinal products between Member States.[161] Convergence of price setting legislation – and the subsequent solving of price distortions – is however difficult to achieve. It will become even more difficult with the forthcoming enlargement. Enlargement brings with it the prospect of a considerably larger market for pharmaceuticals. Otherwise, the average per capita income in applicant countries is considerably lower than the average in the current Member States and raises therefore the question of how patients are to have access to affordable pharmaceuticals at prices that are realistic in the internal market context.[162]

Free movement of capital

The final free movement provision, the free movement of capital does not directly affect health or national health care systems. Indirectly, however, applicant member states may face substantial cross border flows of capital for instance in case of investments (e.g., by multinational pharmaceutical or health insurance companies). As in other sectors, (legal) obstacles need to be removed to enable cross border capital flows, consequently to attract foreign capital investors. Approximation of legislation will first and foremost address the incorporation of relevant directives.[163]

Data protection

The establishment and functioning of the internal market, in particular the free movement principles, require that personal data should be able to flow freely from one Member State to another, but also that the fundamental rights of individuals should be safeguard, notably the right to privacy with respect to the processing of personal data. This area has already been regulated by a package of Community legal measures.

---

161 Directive 89/105/EEC OJ 1989 L 40/8.

162 COM(98)588 final Commission Communication on the Single Market in Pharmaceuticals. p.8.

163 *E.g.*, the first Council Directive of 11 May 1960, OJ No. 43 of 12 July 1960, Directive 63/21/EEC, OJ No. 8 of 22 January 1963, Council Directive 86/566/EEC, OJ No. L 332/22 of 26 november 1986, White Paper *o.c.*: 4.

Technical progress in the field of information and the increasingly frequent processing of personal (e.g., medical) data for diverse reasons have highlighted the need to protect the private life of individuals and more generally, their fundamental freedoms and rights. As a direct consequence of the common market, there is a market increase in flows of personal data within the European Union. These flows include data exchanges between firms, national administrations to provide mutual assistance, epidemiological research institutions, *et cetera*. In view of these cross-border flows, there is a need for convergence of protective national standards since divergence in legislation may create obstacles to the free movement of personal data in the Community. Because of the lower degree in protection in the Member State of origin or destination of this data, a Member State could invoke the general interest and oppose the free movement of data from its territory. In the health care setting, the processing of "sensitive" medical/epidemiological data and the subsequent cross border exchange of these data (e.g., in the field of clinical trial records, telemedicine, telematics) directly influence individual's privacy and therefore require strict safeguards. Since the difference in the level of protection in the Community hinders the free movement of personal data, the "Directive on Data Protection" (Directive 95/46/EC) was developed.[164] This directive is considered an essential measure requiring approximation in national legislation.[165] The obligations and rights set down in the Directive build upon those set down in the European Convention for the Protection of Human Rights and Fundamental Freedoms (article 8) the Council of Europe Convention No. 108 (article 1) which, in turn, are not dissimilar from those included in the OECD guidelines (1980).[166] The purpose of this directive is to protect the fundamental rights of individuals, notably the right to privacy and, simultaneously, to abolish the obstacles to the free movement of personal data and distortions of competition by creating equivalent and high level of protection throughout the Community. The Directive applies to all processing of personal data in the private and public sectors, with some exceptions falling outside the scope of the directive (e.g., defence, national security). The directive spells out the obligations on the controller of data-processing operations, *inter alia*, with regard to data quality, technical security, notification of processing to the supervisory authority, and the circumstances in which data processing may lawfully be carried out. Furthermore, it specifies the rights of the data subject to be

---

164 Directive 95/46/EEC OJ 1995 L 281/31.

165 White Paper, *o.c.*, 306-307; COM(95) 163/2 def.

166 Council of Europe Convention for the Protection of individuals with regards to Automatic Processing of Personal Data No. 108, 1981 and OECD Recommendation of the Council concerning Guidelines governing the Protection of Privacy and Transborder flows of Personal Data (23 september 1980).

informed about processing, to have access to the data, to request corrections, and even to object to processing in the circumstances.

The level of protection guaranteed to the citizens in the accession countries may not be uniform (some are even in the process of passing data protection laws). Potential obstacles to the free flow of information need therefore to be removed while guaranteeing the protection of the right to privacy.

For accession countries it is important to recognize that the internal market legislation, more specifically the free movement provisions, are of particular relevance to domestic health legislation and may *a fortiori* influence the administration, organisation and financing of national health care systems. Instead of defining barriers to prevent or minimise these effect, it seems to be more effective in anticipating the increasing influence of EC law on traditionally national policy issues such as the health sector. Review of the current legal framework, and subsequently its revision or the incorporation of new European standards, are the main steps in this approach. One of the problems observed here is the lack of an integrated and consistent approach of the health acquis. Approximation of EC health and health related legislation is still incomplete and spread over various treaty provisions. Whereas the new public health provision attempts to realize an integrated health approach, this has still not crystallised. Ultimately, such an integrated approach requires a uniform legal framework that is consistent with European law and, simultaneously, covers the underlying values of European health care systems. However, "in the absence of a clear statement of principles on which health care policy in Europe should be based, the European Court of Justice is bound to base its decisions primarily on the imperative to promote the single market".[167] Although it acknowledges the specific circumstances, and despite its positive influence on individuals' rights, its piecemeal approach of judgements on health care also created uncertainties and major difficulties to health care policy-making in the Member States. To minimise the conflicts and, still more, the ambiguities between health policy and the promotion of the internal market, a European health policy is suggested based on a common position, at least at the level of principles, embedded in the future treaty.[168] These fundamental principles of general interest should enshrine the objectives of European health systems (e.g., to preserve solidarity and promote equitable, effective and efficient treatment) and the internal

[167] Mossialos *o.c.*: 9.
[168] Mossialos *o.c.*: 115.

market. To implement the internal market for health care systems, a system of open co-ordination has been suggested.[169]

This approach, however, will take time, and for acceding countries it is apparent that there seems no alternative than a step by step integral assessment of their current legal framework starting with a number of priorities defined in the Europe agreements, White Paper, Agenda 2000 and National Programmes for Adopting the Acquis. These documents can be characterised as important guidelines for accession countries, determining the approximation agendas and providing a timetable to complete legislative approximation. Since accession countries are already aligning their legal framework towards EC law, the subsequent question concerns the outcomes of that process so far, notably its impact on national health legislation. Observed differences with Community law can give rise to further regulatory amendments.

5 LAW APPROXIMATION EXPERIENCES

From the previous analysis it became clear that accession to the European Union undoubtedly has serious consequences for the national health sector of candidate countries and its legal framework. As the first Central and Eastern European countries that will access the European Union, the Czech Republic, Hungary and Poland have already made considerable "progress" in bringing their health care legislative framework in line with European law. At the time of writing this thesis, the aforementioned countries are in the middle of the law approximation process. Therefore, conclusions cannot be drawn before actual accession, the moment at which the adoption of the acquis will be completed. Based on the available information, however, several interesting findings have been found in this stage of the pre-accession. At this stage, the approximation of laws process has been partly realised. The outcomes correspond with the stage "definition of ultimate means", as identified in the analytical model and consequently enables a first examination of its conformity with EC law, and if necessary, suggests recommendations for necessary changes. In other words, the demonstration of the relevance of the analytical model to adopting the health acquis.

Analysis of the progress in transposing EU law in national health legislation is largely based on the national reports called the "National

[169] Mossialos *a.c.*: 116. What is known as the "open co-ordination method" (OCM) is one such new form of collective action to strengthen mutual coherence between Member States' public policies. Covering a variety of arrangements, it combines pure legislative integration with straightforward coorperation. Presidency Conclusions. Lisbon European Council, 23 and 24 March 2000, item 37.

Programme Adopting the Acquis" (NPAA) formulated by the candidate Member States. These NPAAs largely follow the approach set by the White Paper (structure and priorities). The NPAAs describe the annual progress and the major steps in the law approximation process. Public health, as part of the acquis, has been included in the Chapter "Social policy and Employment". The progress that has been made by each of the candidate countries in preparation for membership will be subsequently assessed by the Commission. The Commission's reports (titled "Regular Reports") screen the governments' efforts in aligning and implementing the Union *acquis* on an annual basis. These reports function therefore as the second main source examining the stage of legislative reforms made so far. Since 1998, several NPAAs and Regular Reports have been published by the Commission and are publicly available.[170] The Commission's reports will provide the basis for decision-making about future accession. Apart from assessing the political criteria set by the 1993 Copenhagen European Counsel (democracy, *rule of law*, human rights, protection of minorities), the review of the law approximation process and the respective implementation and enforcement capacities are the "core content" of these reports. Apart from the published reports, additional information has been derived from the previous country analysis.[171]

Public health law

Analysis of public health legislation in the countries examined already made clear that public health law was not a priority in the legislative reform programme. Since the late 1990s, governments in the Czech Republic, Hungary and Poland have introduced significant changes in health care legislation, excluding public health law. Major changes were primarily focussed on the introduction of (social) health insurance legislation, mostly excluding public health. Consequently, the public health concept was mainly based on obsolete legislation emphasizing the previous notion of public health i.e. including health protection and prevention. The previous names of relevant public health institutions are illustrative to the nature of its activities.[172] Public health, respectively public health law in the EU's perception is, however, much broader particularly since the ratification of the Amsterdam Treaty (article 152 EC). Nowadays it also includes the promotion of community care, whereas its subject has also widened

---

170 Most recently SEC(2001) 1746 Czech Republic; SEC(2001) 1748 Hungary, and SEC(2001) 1852 Poland.

171 *Supra* part two.

172 *E.g.*, the Institute of Hygiene (Czech Republic) that was transformed in the National Institute of Public Health. Its current tasks, however, remained primarily focused on defining and monitoring hygienic norms.

(mental health, elderly care). Such a notion of public health also emphasizes respect for individual rights of patients.

The necessity to adopt the EU's public health acquis has therefore resulted in several legal changes in public health legislation, notably in Hungary with the establishment of the National Public Health and Medical Officers' Service (*ÁNTSZ*). The ÁNTSZ oversees public health and disease prevention activities based on a more modern public health concept.[173] The situation in the Czech Republic as well as in Poland is, however, quite different. Major legal changes in the field of public health remained largely absent. Czech legislative reforms were mainly concentrated on individual health care, *i.e.* the introduction of a compulsory health insurance system.[174] The main legal basis for public health was the 1966 Health Care Act of 1966, which has been concluded as obsolete in view of the new public health concept.[175] Apart from some specific tobacco and alcohol regulations, Czech legal attempts to introduce a new general public health law conform the EC public health acquis have not been successful. The latest proposal, however, the draft Law on Public Health Protection subscribes a broad notion including *e.g.*, health protection at work, prevention of outbreak of infectious diseases, vaccination programmes, and promoting quality assurance (certificates).[176] In Poland, public health has not been regulated by a separate general law. Apart from mental health, public health is characterised by a fragmented and incoherent approach due to the lack of an overall strategy. Recent developments, however, such as adopting the Commission document on "Health and Enlargement of the European Union", indicate that this is going to change. Future efforts are aimed at incorporating a comprehensive public health regulatory framework, starting with the Act on Prevention, Detection, Treatment and Control of Communicable Diseases that came into force in september 2001.[177] Since article 152 EC opens the possibility for candidate countries to participate in Community action programmes, all of them have started

---

173 Act XI of 1991 on National Public Health and Medical Officers' Service, Act CLIV of 1997 on Health and their implementing Decrees.

174 *Supra* chapter 6, section 2.5.

175 Act No. 20/1966 on the Health of the Population as amended, *supra* chapter 6, section 3.

176 The Act on Public Health Protection entered into force in January 2001 (Act No. 258/2000 Coll.), which ensures the alignment of public health protection legislation with the acquis (e.g. the powers and authority of state healthcare supervisory bodies). Commission of the European Communities. SEC(2001) 1746. Regular Report on the Czech Republic's Progress towards Accession 2001: 42, 67.

177 Commission of the European Communities. SEC(2001) 1752. Regular Report on Poland's Progress towards Accession 2001: 65.

to collaborate in specific programmes.[178] The participation of these programmes imposed legal changes on existing public health legislation and/or derived legal norms in order to implement these programmes.[179] Another direct implication of the adoption of the public health acquis is the incorporation of Community legislation relating to the protection of health, *e.g.*, the tobacco directives. Council Directive 90/239/EEC stipulates that the maximum tar level shall not exceed a certain amount per cigarette. Due to some economic problems in realizing this level by its tobacco industry before accession, Hungary has therefore requested a transitional period.[180] The Czech Republic and Poland, on the other hand did not ask for a transition period since they already have implemented the respective directive into national law.

Major legal reforms closely related to public health concern the revision of pharmaceutical legislation. A wide range of European directives applicable in this field (notably defining technical conditions) have been or will be incorporated in the very near future. For instance, the Czech Act 79/1997 Coll. on Pharmaceuticals has largely transposed the pharmaceutical acquis, whereas the derived regulations will implement the directives on good production, laboratory, and clinical practise criteria, and the registration of medicinal products. The harmonization of Polish pharmaceutical legislation is also being considered. The current Act on Pharmaceuticals, Medical Products, Pharmacies, Wholesalers and Pharmaceutical Supervision (October 1991) will be revised substantially. For instance, in the very near future, a new independent Office for Registration of Pharmaceuticals will be established. In parallel, a new Law on Prices will introduce a uniform price system under the competence of the Ministry of Health based on the Transparency Directive 89/105/EEC.[181] Finally, a Pharmaceutical Inspectorate has been separated from the Ministry of Health as an independent government office responsible for supervising and controlling the quality and manufacture of medicinal products conform Directive 65/65/EEC.[182] Such measures reflect key elements of incorporating the pharmaceutical acquis.

Occupational health and safety directives, already implemented in Hungary are still not fully incorporated in the Czech regulatory system. For instance Directive 89/391/EEC and Directive 80/1107/EEC have been

---

178 *E.g.*, Hungary: health promotion, combating cancer, prevention of AIDS and other communicable diseases and Drug dependence. Decision No. 1/98 of the Association Council, *mutatis mutandis* the Czech Republic, Decision No. 2/1999.

179 Decision No 645/96/EC, art 6(2); Decision No.646/96/EC, article 6(2); Decision no 647/96/EC, article 6(2); Decision No 102/97/Ec, article 6(2).

180 Hungary NPAA 2000 Social Policy and Employment, p. 89.

181 Adopted in July 2001. Poland Regular Report 2001, *o.c.*: 39.

182 Poland NPPM 2000, p. 23.

identified as acquis short-term priorities that require the development of a new model of the public health supervision in the workplace to encourage improvements in the safety and health of workers while working.[183] The revised Czech Labour Code (Act No 65/1965 Coll.) foresees incorporating the framework Directive 89/391/EEC in 2001.[184] More or less similar protective measures have already been incorporated in the Polish Labour Code (Part X) as amended in 1996 including newly introduced rights and duties of employees and employers as well as obligations of the government. In the following years, derived regulations have regulated safety signs at work, minimum safety and health requirements for the use of work equipment by workers at work and minimum safety and health requirements for the use of personal protective equipment. Consequently, both the Czech and Polish occupational health system have been prepared on the basis of Directive 89/391/EEC and the so-called specific directives.[185]

Consumer protection

The adoption of the acquis on consumer protection and health imposed the introduction of various consumer protection rules. The two most important directives in this field, the Product Liability Directive and the General Safety Directive resulted in a number of new laws in the field of consumer protection, both in Hungary as well as in Poland.[186] In Poland, the recent General Product Safety Act provided the legal basis for numerous derived regulations ("Ordinances") approximating health related Community directives on, *inter alia*, the safety of toys and labelling of products. Already having a functioning general consumer protection system, the Hungarian competent authority subsequently started to establish a transitional early warning system between candidate countries to prevent, restrict or impose conditions on the marketing or use of

---

183 Czech NPAA 2000: Social Cohesion – Health and Safety at work, p. 247.

184 Chapter 5 of the Labour Code as amended, NPAA 2000: 3.6 Economic and Social Cohesion, Safety and Health Protection at work, p. 237.

185 The Council Directives issued hitherto contain minimum standards concerning the workplace (Council Directive 89/654/EEC; work equipment (89/655/EEC); personal protective equipment (89/656/EEC); manual handling on heavy loads (90/269/EEC); work with display screen monitors (90/270/EEC); safety of temporary and mobile construction sites (92/57/EEC); safety and/or health signs (92/58/EEC); work involving exposure to carcinogens (90/394/EEC); work involving exposure to biological agents (90/679/EEC, with amending directives); work safety in extraction industry (92/91/EEC, 92/104/EEC), and work conditions in sea fishing (93/103/EEC).

186 Hungary: Act CLV of 1997 on Consumer Protection, Act XXV of 1998 on Medicinal Products for Human Use, Act X of 1993 on Product Liability; Poland has very recently adopted a Law on General Product Safety, Journal of Laws 2000, No 15 Item 179 and the Law on the Protection of certain Consumer Rights and on the Liability for Damage caused by Dangerous Products, Journal of Laws 2000, No 22, Item 271.

products posing a "serious and immediate risk" (TRAPEX).[187] This system will be the basis for future integration with the European Union's RAPEX system. The Czech Republic on the other hand, still has to incorporate these consumer directives in national legislation. Of particular importance is the introduction of a supervisory authority with the necessary powers to take appropriate measures (including imposing penalties in the event of failure to comply with the obligations derived from the Directive). According to the Czech NPAA, the government will therefore submit a series of consumer protective laws that should provide the necessary legal and organisational measures, including a RAPEX system.[188]

Free movement provisions

The introduction of health insurance schemes combined with the privatisation of primary care services have introduced new actors in the health care field such as statutory health insurance funds and individual providers (GPs, dentists and pharmacists working as entrepreneurs). New phenomena such as freedom of contracting, (the prevention of) risk selection, co-payments, *et cetera.* mean that the health care sector is not immune for European law aimed at abolishing market impediments. Landmark rulings such as *Dassonville, Duphar, Poucet and Piste, Decker and Kohll, Tögel* confirm this thesis although the European Court also takes into account the specific nature of the health care sector. By adopting the *acquis communautaire* and facing similar tendencies and developments in the health care systems as current Member States, candidate countries will have to consider how European law, notably the internal market rules will affect their health care legal system. The following results that are derived from the annual screening reports make clear that candidate countries have recognised the relevance of the internal market provisions to the health care sector, given the numerous legislative and/or regulatory amendments related to the health professions, organisation and financing of the health system and patients' rights. For instance, in order to realise free movement of persons the mutual recognition of professional qualifications and diplomas of health professionals is considered a precondition. It appeared that Hungary is already largely in line with the acquis criteria such as a supervisory authority ensuring compliance with the rules governing the profession (Ministry of Health and the Chamber of Physicians), registration and licensing for practising a medical profession, and a disciplinary code imposed disciplinary sanctions. Government decree No 47/1995 (IV.27)

---

187 Hungary Regular Report 2000, p. 68.

188 Czech NPAA 2000, p.318. In the meantime, the Czech Republic is already participating in the transitional RAPEX system aiming to assist preparations for the full RAPEX system. Czech Regular Report 2001 *o.c.*: 87.

on the recognition of degrees, diplomas and certificates has been prepared taking into account Council Directive 89/48/EEC and Council Directive 92/51/EEC and provide for a procedure consistent with the acquis. Apart from these general systems for the recognition of qualifications, the sectoral directives, particularly those concerning the medical professions, have been recently aligned by the new Act on Public Health that came into force in January 2000. Outstanding issues relate in particular to alignment with EC legislation on pharmacists.[189] The situation is comparable in the Czech Republic. The latest proposal of the Czech Health Professions Act, the Act on Ability for Health Care Provision and further Education in Health Care will incorporate the recognition of (foreign) qualifications in health care. National requirements will also be repealed in Poland. The implementation of the professions directives will be done by the adoption of a horizontal law concerning all professions, with the exception of those regulated by sectoral directives.[190] To guarantee equal treatment of EU nationals the formal requirement of a language test needs to be abolished since this can – de facto – lead to discrimination and is therefore incompatible with European law.[191]

The system of free movement of persons will also require the participation in a system of social security co-ordination.[192] Apart from the regulatory adaptations, participation will be subject of several conditions, such as conformity of social security benefits, a properly organised social security administration, existence of databases needed for obtaining information on all those insured and for the exchange of this information between these individual countries. As far as the social health insurance scheme is concerned, all three countries have a relatively new compulsory health insurance scheme[193] that includes the main conditions set by the main social security treaties (ILO treaties on social security minimum standards, medical care and sickness benefits, and the European Social Code of Social

---

189 SEC(2001) 1748 Commission of the European Union. 2001 Regular Report on Hungary's Progress towards Accession 2001: 43.

190 In February 2001, the Law on the Professions of Nurses and Midwives were amended introducing a system that allows the mutual recognition of the professional qualifications of nurses and midwives. Other amendments concern the Law on the Profession of Medical Doctors and the Chambers of Physicians Act granting EU nationals the right to take up and pursue the profession of medical doctor in Poland, as well as the registration and membership in professional organisations. Outstanding issues concern, *inter alia*, the alignment of legislation on pharmacists. Poland Regular Report 2001 *o.c.*: 42-43.

191 The directives, however, do not exclude other means of testing the language.

192 Based on Co-ordination Regulation 1408/71 and 574/72.

193 *I.e.*, Act No 1997 on Health Insurance (Hungary): Act on Public Health Insurance 48/1997 (Czech Republic), and the Act on General Health Insurance 1997 in Poland. These laws have in common that they provide (a majority of) the population a statutory right to access to basic health care services covered by social health insurance and primarily financed by premiums.

Security). Up to now, these countries do not have much experience with the co-ordination of health insurance schemes. The social security provisions on free movement of migrant workers, their relatives and tourists have been mostly regulated by bilateral treaties concluded with several Member States, notably with Germany and Austria.[194] These treaties on medical care of nationals staying on a temporary basis in the territory of the other contracting party provide experience for the application of regulations 1408/71 and 574. Apart from these bilateral treaties, further institutionalisation of bilateral co-operation by means of, for instance, the so-called Euregions has not been established. As a consequence of the co-ordination regulation, the Czech government drafted a new Act on Public Health Insurance that will replace the current Act No 48/1997 Coll.[195] This new act will cover the health care services provided abroad to migrant workers and the reimbursement of the costs. In accordance with the regulations, the act will, *inter alia*, specify the scope of entitlements covered by social health insurance, the conditions as well as the classification of non-reimbursable benefits. The co-ordination of social insurance entitlements will be fully operational at the time of accession, including the application of the so-called E-forms (covering cross-border workers, emergency care and pre-authorized care). Consequently, from that moment, socially insured in the accession countries will be formally entitled to (conditional) health care services abroad based on both co-ordination regulations.[196]

Poland's readiness to participate in the co-ordination of social security systems at the time of accession is, however, rather unsure. Although the General Health Insurance Act introduces the possibility of receiving health care abroad the Act only recently came into force (January 1999). Therefore, Poland has little experience with the functioning of the newly established system and its financial consequences. The application of regulation 1408/71 and the subsequent expanding of the current health insurance benefits with health care provided to migrants in the European Union and reimbursement of these costs may threaten the system's financial soundness. The Polish government has therefore requested some flexibility concerning the date of full co-ordination of the social security system.[197]

---

194 *E.g.*, the Hungarian-German and Hungarian-Austrian bilateral agreements on social security (2001).

195 In combination with a new Act on Insurance Premium for Public Health Insurance and a new Act on Health Insurance Companies.

196 *Mutatis mutandis* current Member States.

197 Poland NPPM 2000, p. 43.

Public procurement rules

Another key issue in the internal market acquis that has been approximated are the public procurement rules. Hungary and the Czech Republic have already adopted general public procurement legislation, which is predominantly in line with the European rules.[198] Important pre-conditions such as the elimination of national preferential provisions for domestic applicants for public contracts, fine tuning value thresholds, the obligation of publishing announcements of tenders for public contracts in the European Community's Official Bulletin, and enforcement and remedies still needs to be transposed. As a consequence of the new Act, in Hungary, the number of public procurement procedures increased rapidly.[199] According to this Law, both local governments' (the owner of most health care facilities) as well as the National Health Insurance Fund's financed purchases above a certain threshold have to be announced including tender invitations for medical equipment and services.[200] The tendering parties are primarily domestic suppliers which can be explained by the national preference clause. The Act established a Public Procurement Arbitration Committee monitoring and reviewing the procurement procedures. This law-enforcement body can be considered as a quasi-judicial institution as required by the acquis.[201] A comparable institution has been found in the Czech Republic. The Office for the Protection of Economic Competition is the competent body involved with supervising public procurement in the Czech Republic. Whereas in Poland a draft Law on Public Procurement has been submitted to the Parliament.[202] The (draft) Law will cover all the stipulated procedures of all the EC procurement directives at the time of accession.

---

198 Respectively Act XL of 1995 on Public Procurements, and Act No 199/1994 Coll. on Public Procurement (including subsequent amendments).

199 In 1999, the total number was 3,829. Chapter 1, free movement of goods Regular Report 2000.

200 The threshold is for products exceeding HUF 10 million and for services over HUF 5 million (18,000 Euro).

201 As an indication, the Committee received 283 complaints in the first half of 2000. Infringements were found in 180 cases and 150 contracts were annulled. The decisions of the Committee are challenged in court in a quarter of the cases. Regular Report 2000.

202 Law of June 22, 2001 amending the Law on Public Procurements (*Dz.U.* 2001, No. 76, item 813) entered into force on October 25, 2001. The Law harmonizes the acquis requirements pertaining to public procurement. Poland Addendum to the information for the European Commission's Regular Report on Poland's Progress towards Accession to the EU 2000-2001: 34.

Data protection

In the field of data protection, the countries vary substantially in incorporating the acquis. Hungary already had a Data Protection Act in 1992,[203] whereas Poland has adopted an Act on Personal Data Protection in 1997.[204] Both countries have established a fully independent Commissioner (Inspector) appointed by Parliament and responsible for the protection of personal data. The Polish Data Protection Act has been largely inspired by the European data protection directive 95/46/EC determining the conditions under which the processing of personal data is lawful, safeguarding the data subject's access to information and providing judicial remedies with regard to the processing of personal data. Personal information cannot generally be transferred to "third countries" unless the country ensures the same level of data protection. Areas where the Polish legislation is still inconsistent refer, *inter alia*, to the definition of the notion of personal data (article 2a of Directive 95/46/EC), and preliminary control of personal data processing (article 20 of the Directive).[205] In addition to Act on the Personal Data Protection, Poland ratified the European Convention on the Protection of Personal Data in 1999. Accordingly, both Hungary and Poland have made considerable progress adopting the data protection acquis.

In the Czech Republic, however, adopting the data protection acquis has still remained unsatisfactory. Apart from the current legislation on data protection already in force,[206] provisions remaining to be transposed concern the transfer of personal data to third countries, the registration of operators handling personal data and the absence of sanctions for unauthorised data processors. Neither does the act foresee in an independent monitoring authority.[207] It is foreseen that a newly defined draft Law on Data Protection, already submitted to the Czech Parliament, will comply with these requirements.[208]

---

203 Act No LXIII of 1992 on the Protection of Personal Data and Disclosure of Public Interest (lex generalis) and Act No. XLII of 1997 on Processing and Protection of Medical Data and Related Personal Data (lex specialis).

204 Act on Protection of Personal Data, no.133, Item 833, 29 October 1997, which came into force on April 30th 1998. The Act established the institution "Inspector General for the Protection of Personal Data" as supervisory authority (article 8) who is appointed by Parliament. His main task is to supervise the compliance of data processing with the provisions on the protection of personal data (article 12).

205 Poland's Position Papers for the Accession Negotiations with the European Union. Chancellery of the Prime Minister of the Republic of Poland, Warsaw 2000: 64.

206 Act No. 256/1992 on the Protection of Personal Data in Information Systems.

207 Czech Regular Report 1999 conclusions.

208 Resolution 70 of 27 January 1999. The 2001 Regular Report mentioned that an independent supervisory authority – the Office for Personal Data Protection (OPDP) – was established in June 2000 on the basis of Act No. 101/2000 Coll. (Data Protection Law). The office carries out the standard activities of an independent supervisor (registration, promotion of data

Considerations law approximation process

Since the ratification of the Europe agreements, it appeared that the accession countries have made considerable progress in terms of approximating the European Union's health acquis. Both the national reports (NPAAs) as well as the Commission's regular reports describe in a general manner the current stage of the health (related) acquis since 1998. In a way, they enabled the review of the impact of EU law on national health legislation. Subsequently, the outcomes of the analyses enable redefinition of the acquis strategy in the next national reports.

With regards to the public health acquis, up to now, the most obvious alignment can be found in participation in Community's public health action programmes. The subsequent underlying notion of public health imposed various changes in the existing public health legislation, notably to regulate and facilitate the implementation of strategies combating cancer, drug, *et cetera*. Besides the Community public health programmes, alignment of European health and safety regulations have been observed. Unlike public health action programmes, these (occupational) health safety regulations have a more "technical" character. They necessitate the incorporation of common technical standards in, for example, the field of tobacco (tar maximums, labelling conditions), pharmaceuticals, including vaccines and blood-derived medicals (production, processing and marketing criteria) as well as imposing administrative requirements (authorization and supervision procedures of medicinal products). Progress in this field shows a divergent picture. Whereas Hungary have already largely implemented the pharmaceutical acquis, Poland, and to less extent the Czech Republic, are still in the in the stage of drafting and submitting legislative proposals conform the acquis. Consequently, institutional structures supervising the manufacturing, processing and marketing of pharmaceuticals and medicinal products in Hungary have the advantage of already experiencing European practise. Regarding tobacco directives, the opposite is the case. The Czech Republic and Poland have already implemented relevant directives whereas Hungary has requested an extension of the transition period to adopt the acquis. The reasoning was based more on the financial or economical than on legal considerations. What these countries have in common are the occupational health and safety measures that are already largely harmonized.

---

protection awareness, control, issuing permissions for data transfers abroad, et cetera) and is empowered to impose financial sanctions. According to the Commission, the new Law is largely in line with the personal data protection acquis, notably with Directive 95/46/EC. Although some fine-tuning will be required for full compliance. Regular Report Czech Republic 2001 *o.c.*: 50.

In general, the legal implications of public health and (occupational) health safety acquis are not that spectacular. Although the range of legal modifications in these fields is significant, the technicality did not impose complex legislative revisions. This is different from the internal market rules that affect the health systems. The requirement of approximating law in the field of free movement of persons, social security, public procurement and data protection impose accession countries to introduce new legislation (or amendments of existing legislation), introducing unknown concepts such as equal treatment of non-nationals in the labour market (health professions), access to health care services abroad (patients), the notion of European public procurement (health products and services) and the processing of (medical) data. However, it appeared that the legal implications of these notions are not always fully understood (and differ from country to country). For instance, access to cross-border care and the reimbursement of the costs require, first and foremost, a clear definition of the entitlements under the social health insurance scheme. Furthermore, the establishment of an (administrative) legal complaint procedure to enforce patients' entitlements, and transposing the criteria set by the co-ordination regulation, i.e. the "immediate necessity" of the treatment abroad and the reciprocity of coverage. Absence of such provisions (in Hungary and Poland) may seriously hinder the free movement of patients. In this respect, analysis of court rulings on cross-border health care as examined in existing Member States could provide valuable experiences to candidate countries. Secondly, as far as concern public procurement of health products or services, the national preferential provisions for domestic applicants for public contracts still needs to be abolished in all the examined candidate countries. This would open, *de iure*, the health care public procurement market for providers from EU Member States. Furthermore, in order to review decisions of contracting authorities infringing Community law as rapidly as possible, candidate countries should comply with the conditions set in the "Review" Directive (e.g., law enforcement and judicial remedies).

Finally, the outcomes of data protection legislation revealed certain omissions in legal protection of processing data, notably in the Czech Republic. However, the latest report of the Commission described major developments in alignment of the data protection acquis, in particular the directive's requirements concerning the transfer of data to third countries and the establishment of an independent monitoring authority. Further less drastic legal changes require some fine-tuning for full compliance.

Grosso modo, approximation of laws in the field of health seems to be the most successful in Hungary, whereas review of the outcomes revealed considerable delays and shortcomings particularly in Poland and the Czech Republic.

6 CONCLUSIONS

The previous analysis made clear that with the concluded Europe agreements, the influence of EC law on applicant countries' domestic health legislation has increased. Transposing the *acquis communautaire* is, however, not restricted to public health and health related issues only. The internal market rules in particular made health care systems and health care sectors vulnerable to Community law. Apart from the more traditional fields such as pharmaceuticals and medical professions, increasingly European law intervenes with the organisation, planning and financing of health care systems. This can be derived from recent Court of Justice rulings concluding that the health care sector is a market, not excluded from Community law. Emanated from the general anti-discrimination principle, free movement and competition rules, European law impose (future) Member States to reconsider national health law conflicting with communautaire values. For the social health insurance market, for instance, this can have considerable consequences, notably due the increasing need for cost containment while maintaining the solidarity principle. This dilemma forced Member States to introduce market elements in a field traditionally dominated by social values. By doing so, the social insurance market and its underlying legal norms will be increasingly subject to EC law. Additionally, purchasing health services, anti-cartel provisions and public procurement rules affect contracting and tariff arrangements. Most recently, the equal treatment principle has (potentially) major consequences concerning trans-border flows of persons and services. In the near future, extended human rights competences can be expected with the ratification of the EU Human Rights Charter. It is without doubt that these developments will also have a major impact on applicant country's health care systems.

First analysis of the observed legal problems make clear that most of the legal shortcomings concern inconsistencies with European law; lacking knowledge of the impact of European Court rulings; inadequate legal guarantees, and finally, unforeseen implications of drafted legislation as well as existing rules. As was concluded in part two, the observed deficiencies and omissions in approximating legislation can, to a large extent, be reduced to the drafting stage since most of these problems had been caused due to insufficient considerations in the initial stages in the law-making process. It was argued that the agreements and subsequent policy papers set the first steps in implementing the *acquis communautaire*. Analysis of the identified and missing priorities should enable applicant countries to formulate the approximation of health laws strategy. A systematic approach, reviewing the interim stages of harmonization and subsequent modification of the law-approximation strategy made clear most of the applicant countries have already or largely succeeded in incorporating Community

public health legislation. As mentioned earlier, the harmonisation of internal market rules is more problematic.

To support applicant countries in the harmonisation process, the underlying assumption of discerned clusters of health care law enable the formulation of a more structural approach to the internal market law approximation process, annually monitored by the European Commission in its Regular Reports and, if necessary, adapted according to the accession criteria. The clusters of health law function as substantial parameters of law approximation. Therefore, adopting the internal market acquis starts with aligning legislation addressing the organisation and financing of health care, and patients' rights. Simultaneously, impact analyses function as normative guidelines to be considered in that activity. Given this approach, and considering the current stage of law approximation in Hungary, for instance, it would mean that the alignment of organisational and financial regulatory norms needs to be prioritised. Hungary already incorporated a system of recognition of diplomas and qualifications of health professions (Directives 89/48/EEC and 92/51/EEC). Alignment should therefore focus on the free movement principles affecting the domestic organisational and financial order. More specifically, the incorporation of social security co-ordination regulations 1408/71 and 574/72. It appeared that bilateral agreements already anticipate the implementation of these regulations. However, these agreements do not entirely correspond with EU social security regulations (e.g., a restrictive personal scope concerning cross-border health care). Current experiences and future accession further urge the national legislator to specify the scope of social insurance entitlements and non-reimbursable benefits. Moreover, it will impose national insurance authorities to set procedures for the reimbursement of member states' social security authorities in case of health care provided abroad. Simultaneously, Hungary, as other (applicant) countries, has to consider the consequences of the latest Court rulings, extending the possibilities of cross-border care. It will necessitate, *inter alia*, to reconsider the conformity of national pre-authorization criteria with communautaire principles and adapt (potential) discriminatory provisions. Other internal market rules, such as the public procurement provisions also need to be completed in national law (non-preferential clause, transposition of enforcement and remedies mechanism, *et cetera*). Finally, the *acquis communautaire* includes respect for human rights. Hungary already incorporated the notion of human rights in health care in its 1997 Health Care Act, whereas prior legal norms focussed on data protection, which are largely conform EC data protection rules. Nonetheless, the EU "Human Rights Charter", will pressurize Hungary to review its "compatibility" with existing patients" rights legislation.

For the Czech Republic and Poland, however, the situation is slightly different. Although the general tendencies are similar, there are several important differences that require modification of the national acquis programmes. For instance, observed delay in adapting the public health (related) acquis include occupational health and safety directives (minimum safety requirements), consumer protection rules (the RAPEX supervisory authority) and the parts of the pharmaceutical acquis (registration system, supervision and control medicinal products). In terms of the analytical model, prior to internal market measures, the national authorities have to bring in line the observed omissions with existing European rules. But apart from public health, the similarity in adaptation problems with regard to the internal market and human rights rules (free movement, public procurement, data protection) do not give reason for a different approximation strategy.

These findings confirm the relevance of the suggested approach. Whereas concluded agreements provide the general legal framework for accession, setting the agenda and adapting the health acquis, applicant countries still face major problems. By structuring the law approximation process according to the discerned clusters of health law, problematise the path of accession, and the subsequent transposition into national law, it has been argued that the theoretical model of law-making could provide a valuable instrument that encourages a more rational approach of "approximation of health laws" process, which subsequently, could contribute towards improvement of the quality of legislation.

CHAPTER 9: FINAL CONCLUSIONS

This study examined the relevance of a theoretical model of health care law-making in three selected countries in Central and Eastern Europe. Confronted with the legacy of the ancient regime, these countries initiated major health reforms. Inspired by pre-war "Bismarckian" experiences, these countries shifted away from a "socialist" model towards a more "market-oriented" health care system. From a legal perspective, this change of system imposed on government the need for drastic reforms of their national legal framework. The most prominent example has been the introduction of health insurance legislation establishing a compulsory health insurance scheme based on the notion of solidarity. In addition to, or prior to, these health insurance reforms, the legislature introduced massive privatisation of health care services.

It goes without saying that these changes were highly problematic. The system change required a revision of the role of law and the legislature in the field of health care. However, defining and realising the exact role of law and the legislature appeared to be one of the major problems these countries had to face, particularly since either a conceptual legal framework of health care law was absent, or simply not in tune with altered circumstances. Such a normative framework should guide and monitor the role of the legislature in health care. Facing these problems, legal reforms in health care have been characterised by a rather incoherent and even inconsistent approach that not always recognised the legal consequences of important changes. Frequently, the legislature has been criticised for this approach. In an attempt to strengthen decision-making in reforming health care legislation in Central and Eastern Europe, this study examined the following hypothesis: "whether, and if so, by what means, a legal-theoretical model of law-making can contribute towards a review of the process and content of legislative reforms in Central and Eastern European health care systems?" Such a theoretical model should structure the law-making activity and provide a normative framework to guide and review changes in the field of health care legislation. To verify this thesis, this study examined three central questions. Firstly, the ability to develop a legal-theoretical model of health care law-making (part one). Secondly, whether such an analytical model is applicable to Central and Eastern European legislative practice. The relevance of this theoretical model to legislative practice has been examined, by means of empirical review in three selected countries (part two). Finally, a more thorough search of its relevance for the alignment of European Community law; to review the EC "approximation of laws" process (part three). The outcomes of research enabled several conclusions to be drawn as well as recommendations on strengthen-

ing the process and content of legislative reforms in Central and Eastern European health care systems. Furthermore, it will become apparent that the importance of this legal-theoretical model is not restricted only to the three selected countries but may also be applicable to other countries in transition in the region.

A legal-theoretical model of health care law-making

Drafting legislation can be interpreted as a desirable rational and controllable activity, reflected by a dynamic iterative process (Noll, 1973). Since full rationality is unlikely, it should be considered more as an *attempt* to rationalise the legislative process. The rationality concept enables the characterisation of the legislative activity according to the theoretically discerned stages of law-making. This method of well-ordered activity allows the formulation of normative statements with regard to the content of the legislative activity, aimed at optimising rational law-making. Such a theoretical method of law-making has been subscribed by authoritative commentators in both "Western" and "Eastern" Europe, and can be demonstrated graphically by means of a simplified model. It represents an analytical series of considerations to facilitate explication of the complexity of law-making. The scientific-rationality concept is based on underlying normative and instrumental functions of law-making. Although the implied objective-determined approach of law-making cannot be considered as a panacea to rationalise law-making, it does, however, have certain advantages. This is particularly true of the Central-Eastern European setting, where the priorities set and the far-reaching nature of the reforms require a clear strategy on legislative policy to guide and direct these changes.

The analytical model of law-making can be applied to the field of health care law. This raises the question of the basic values of health care law, since these norms define and guide legislative activity. Identified primordial values of health care law are the right to health care and individual self-determination (patient autonomy). Both principles have been recognised in national and international human rights law. These basic values reflect the dichotomy between social and individual rights. In modern international human rights law, however, this dichotomy seems to have perished. This was demonstrated when the United Nations World Conference on Human Rights (1983) declared that "it is now undisputed that all human rights are indivisible, interdependent, interrelated and of equal importance for human dignity. Therefore, States are responsible for violations of social rights, as they are for violations of civil and political rights." This means that social rights, including the right to health care, may impose immediate obligations on national governments. A viewpoint that has been supported by both legal doctrine and the ICESCR Committee. The direct effect of the Covenant's health care right must be differentiated according to the

type of obligation involved. The obligation to respect, protect and ensure (*e.g.*, to refrain from interfering with the enjoyment of health care, to protect equal access, and to ensure basic prevention and primary health care facilities to those in need) impose an obligation of result and have immediate effect. Whereas the obligation to promote (*e.g.*, public health) implies an obligation of conduct and enable governments a certain margin of discretion in implementing necessary policy measures.

This typology of obligations provide an important instrument in specifying the content and scope of the right to health care in national law. Functioning as (non)binding standards, normative intervention include both the organisation, finance, quality, and provision of health care services as well as patients' rights. Non-compliance with the obligations can be considered as a violation of the Covenant. Although national governments are not obliged to actual intervention in, for instance, the provision or finance of basic health care services, market deficiencies in providing basic health care requirements impose governments to ensure and maintain a certain minimum of health care services. In the national judicial practise, however, violation of the obligations under the Covenant's right to health (article 12) rarely imposes legal consequences to States parties to ensure the highest attainable standard of physical and mental health. To comply with their international obligations in relation to article 12, States parties should enhance the direct effect of (elements of) the right to health care, notably by incorporating the (core) obligations into their national legal order. Secondly, the national judiciary should adjudicate violations of the right to health care, or at least its core obligations, by direct reference to the Covenant.

The second dominant legal value is individual self-determination or patient autonomy. It appeared that since the endorsement of the Universal Declaration, this principle has acquired a prominent place in the human rights discussion, *i.e.* the individual basic principle of health care law. It functions as the cornerstone of a newly derived category of rights, *viz*, individual patients' rights. These rights have been primarily formulated as refraining from (government) intervention in the private sphere. However, this is now changing. This can be concluded from international treaty law confirming the unity of individual and social rights by identical preambles being included in both the International Convention on Civil and Political Rights and the International Convention on Economic, Social and Cultural Rights, *mutatis mutandis*. Secondly, newly emerged conventions and declarations (Biomedicine Convention, Declaration on the Promotion of Human Rights in Europe and the Ljubljana Charter) that explicitly recognised the right to the highest attainable level of health and/or equitable access to necessary health care as a *precondition* to enjoying personal, individual rights. Such a formulation emphasizes that individual

and social rights in health care are interrelated. What is more, since its recognition in international human rights law, patient autonomy and corollary rights such as the right to individual dignity, integrity and the prohibition of ill-treatment have been developed including positive obligations, notably the promotion of effective safeguarding of these rights, *de iure* and *de facto*. Simultaneously, the social right to health care has been interpreted as embracing negative obligations, *inter alia*, refraining from denying equal access and abstaining from discriminatory practises. The varying nature of State party obligations strengthen the interdependency and complementarity of social and individual rights. A development that has been supported by human rights doctrine and authoritative international forums. More progressive, although still in an embryonic stage, it may even indicate that the strict dichotomy between individual and social rights is becoming blurred.

Both unique principles of health care law, embedded and elaborated in various international legal documents, constitute a major source of the normative framework. They entail understanding the essential concepts, instruments and strategies of health care rights in State parties concerned and means these rights can be realised, notably by adopting legislation. The definition of legislation has been considered in terms of the functions of health care law, classified by normative and instrumental values of law. The formulated functions identified encompass a broad scope of health care law: public health, the organisation and financing of health care services, quality control and patients' rights. Interpreted as "law-jobs", these functions of health care law hand over a conceptual frame of instruments that, imbedded in international law, substantiate the legislative activity. Since they are structured to the subject of intervention they intent to restructure and rationalise the legislative activity, notably the legislative reform process.

The final stage to develop a legal-theoretical model of health care law-making includes the correlation between law and policy. One of the lessons learned from the early 1990s is that radical system changes did not appear very successful (e.g., Czech Republic). Since virtually all the transition countries opted for a health system based on the principles of social health insurance, and characterised by a purchaser-provider split, there is a need for an incremental and systematic approach aimed at dismantling the "socialist" legal order towards a market-oriented system based on fundamental principles of parliamentary democracy, the *rule of law*, and respect for human rights. The theoretical model of law-making, integrating the functional qualities of health care law, was developed to support this approach. It provides a coherent model of the concepts, definitions, assumptions and other analytical instruments to develop and review a normative frame of legislation by its primordial values. Since the legislative

process is influenced by health policy, the analytical model integrates the policy dimension. Ideally, health care legislation balances between expressing (autonomous) axiological values and legitimising instrumental policy objectives. The continuous interaction between law and policy-making has been integrated through the dynamic iterative approach of the analytical model.

Its relevance to transition countries concerns the interaction between (conflicting) legal and policy values, in conjunction with the suggested model. The approach of incremental changes, systematically introduced, reveal the classical dilemma between guaranteeing patients' rights (e.g., access to health care) versus cost containment policy measures (e.g., introducing market elements). To solve this dilemma, the conceptual framework of health care law functions as guiding normative standard, whereas the consecutive stages of law-making structure and systematize the diffuse process of decision-making. As such, it provides the legislature an intellectual instrument aimed at rationalizing the legislative reform activity and process.

Relevance Central and Eastern Europe: Country experiences

Case studies enabled the review of the rationality concept in Central and Eastern Europe. Therefore, this research examined the relevance of the theoretical model of health care law-making to the legislative practice in three transition countries, *viz*, Hungary, the Czech Republic and Poland. It started with describing the legal structure of the health care systems in three selected countries.

The analysis made clear that since the collapse of socialist supremacy, these countries have experienced profound legal changes. The nature and the scope of these reforms justify the conclusion that a "legislative revolution" has taken place. First and foremost because newly defined constitutions enshrine basic principles such as parliamentary democracy, the *rule of law* and respect for human rights. These basic principles underlie the following process of legal reformation. In that process, the countries have embarked on re-designing and re-building the legal framework of their health care system. Analysis of the main features of health legislation (public health, the organisation and financing of health services, and patients' rights) revealed several general developments such as the increased focus on health promotion and disease prevention regulation, the shift away from a centralised to a more decentralised and privatised health care delivery system, the establishment of (semi-) independent health insurance funds purchasing (individual) health care providers, and, due to the ratification of international (European) human rights treaties and conventions, the recognition of fundamental rights of patients. Unmistakably, aforementioned "western" legal values underlie these developments

although other factors should not be excluded (demographic, financial, economic, and technological concerns). From a legal perspective, however, these health system reforms are based on revising or re-formulating the constitutional right to health care. Simultaneously, newly enshrined constitutional property rights entitle individual health professionals to start a private (or group) practise and insurance companies to initiate health insurance activities. This constitutional right to launch independent professional organisations was previously forbidden by law. The vested rights revolution has appeared in most transition countries and can be considered as a "return to Europe", a romantic phrase reflecting the euphoria of the collapse of state-socialism and reinstating and safeguarding internationally-accepted human rights.

Despite the general commonalties in development, the countries differ in starting point, stages of reform and modalities of legislation. Comparison of these differences enabled the classification of the countries, in terms of matching the discerned stages and clusters of the model. However, as this research was not planned as a comparative legal study, the "comparative" dimension should be interpreted moderately. Studying foreign legal orders and their institutions should not be confused with comparative law. This requires more than a few descriptive country studies, so-called "Auslandrechtskunde". Comparative law presupposes such studies and knowledge in order to compare legal systems or institutions. As such, Auslandrechtskunde and comparative law differ in both objective and methodology.[209] his means that the subsequent outcomes need to be put in perspective. Having said that, the "comparison" led to the following outcomes.

One of the most striking results is the relative absence of public health legislation in modernising the legislative framework, except for in Hungary. Just after the collapse of the previous regime, legislative reforms were focused on public health and the transferral of responsibilities in the delivery of health care. The 1991 Public Health Act re-organised public health services, followed by occupational health legislation and organisational changes in the health care structure. Health insurance reforms were also less drastic. Initially started in 1992, crucial insurance reforms came into force in 1997. The Czech legislator, however, took a different approach. Here, two main themes were prioritised, *viz*, the introduction of a compulsory health insurance scheme and the privatisation of health care services. Consequently, public health, quality of care and patients' rights have been characterised by relatively minor legal changes although the need for major reforms became evident. Public health law was still

[209] L-J Constantinesco. Traité de Droit Comparé. II. La Méthode comparative. Paris Librairie generale de Droit et de Jurisprudence, Pichon et Durand-Auzias 1974: 126-128.

based on the "socialist" notion of public health, as defined in the Health Care Act and derived regulatory norms. However, alarming figures on the deteriorating health status of the population, the WHO "Health for All 2000" strategy, and the ratification of the Europe agreement meant a gradual shift in public health policy and law. The new understanding of the public health concept (prevention, protection, and promotion of community health) forced the revision of existing public health law (e.g., the Health Care Act, anti-tobacco legislation). Compared to the Polish reform process, transforming public health law is less clear in terms of the model. Originally, health care system reforms were focussed on organisational changes (decentralisation and privatisation of health services). Legal reforms on public health were only fragmentally introduced and mainly focused on mental and occupational health. Encouraged by local WHO programmes and EU accession, alignment of public health law became more urgent in the dawn of the twentieth century. As in other transitional countries, introducing a social health insurance system dominated the legislative reforms. The enactment of the Health Insurance Act was, however, occasionally postponed. Only in January 2000 did the new law came into force.

Where health financing is concerned, after the collapse of the ancient regime, each of the selected countries had prioritised the enactment of a Bismarckian-based social health insurance system. This was considered one of the main priorities. Hence, issuing social health insurance law was the dominant legal issue on the legislative agenda, particularly in the initial stage of transition. The Czech 1991 Health Insurance Act is the most prominent example of this approach by introducing a competitive social health insurance scheme while disregarding existing problems related to other fields of health care law, such as public health and patients' rights. The (imbalanced) approach of the Czech legislator seems to conflict with the suggested theoretical approach and may raise the question of whether that approach is of any relevance to the Czech situation. These experiences, however, do not necessarily refute the hypothesis of structuring reforms according to the subsequent clusters of health care law. Due to the major financial consequences, the emphasis on the funding and organisation of health care is understandable. Apart from the dominant instrumental function of law-making it is, at the same time, evident that since the Czech reforms have started, the guarantee function of the law has played a subordinate role. This is not without problems. For instance, by introducing a Health Insurance Act and legal impediments to social insurance rights, one of the issues that raised concerns is whether the judiciary is willing to accept the notion of individual enforceable entitlements under the new health insurance scheme. It will be no surprise that, in the short term, issues such as patients' rights, the protection and promotion of public

health and strengthening and monitoring the quality of care imposes on the legislature to reconsider its future legal strategy and find equilibrium between both the instrumental and normative function of the law. In this respect, the Czech legislature could start with implementing the National Health Programme (1995) which is still not realised by law. As such, conceptualising the guarantee function includes, for instance, access to public health services and facilities. Furthermore, since such protective, promotional and preventive tasks have a considerable impact on individual rights (e.g., privacy, human integrity), enhancing legal norms that ensure these rights are necessary. The Polish situation is not much different from what has earlier been concluded. So far, the emphasis has been on revising the organisation and financing of health care services. As in the Czech Republic, public health law was not considered a priority. At least, in the initial stage of the health care reform process. Dramatic outcomes of population health status reports forced the modernisation of public health legislation in order to change lifestyle and improve living and working conditions. Initial health care reforms, however, were focussed on the modernisation of the health care organisation through decentralisation and privatisation tendencies. Examining the relevant legal norms, it appeared, however, that the government partly failed to effectuate these norms, which seriously hindered the reforms. In a latter stage of reform, the 1997 General Health Insurance Law dramatically revised the health care financing scene. Instead of the Ministry of Finance, newly emerged actors, such as statutory Health Insurance Funds became legally and financially responsible for both collecting health insurance premiums and purchasing health care providers.

In the field of quality control (quality assurance and improvement), modern legislation has remained largely absent. In Hungary, a possible explanation for this absence of separate cluster quality legislation could be the structure of its legal system. Quality provisions in the Public Health Act, Health Care Act and Hungarian Medical Chamber Act subordinate quality regulation to public health but do not cover the full range of quality norms. What is more likely is that the Hungarian legislature did not prioritise quality control in the legislative reform process. This assumption was confirmed by Gulácsi. Such omissions and latent problems on quality control call for adequate legal measures. The absence of modern quality control norms have also been observed in the Czech Republic and Poland. In the first stage of reforms, legal reforms were dominated by the establishment of (independent) professional organisations such as the Medical Chambers, whose competences include, *inter alia*, monitoring and enhancing the quality of professional care. For instance, by formulating professional and ethical standards, disciplinary rules and developing training programmes for health professionals. But the reasoning to

establish professional organisations was primarily based on privatisation motives (primary care services) and not on quality of care motives. This may explain the relative absence of legislation on quality control. Apart from several provisions in the archaic Health Care Act, Czech quality control is mainly regulated by the professions self-regulative mechanisms. In both the Czech Republic and Poland, this situation raises several questions, notably concerning obscure supervisory procedures and the role of the Medical Chamber. Strengthening the Chambers' supervisory role, the legislature should reconsider the notion of quality control regulated by means of self-regulation. Simultaneously, it should consider the role of newly emerging actors such as (competitive) purchasers, purchasing high quality care and stimulate consumer and patient participation assessing quality of care on various levels. Particularly the role of individual consumers has been underexposed. Ensuring that consumers will participate in quality decision-making issues, the legislature should create the necessary (legal) conditions as adopted in the latest Council of Europe resolution on citizen's participation in health care.[210] Establishing such participatory structures or mechanisms in the field concerned should be one of the legal challenges in the near future.

With reference to patients' rights, it appeared that, for a long period, in each of the country's legislation these were largely missing. Apart from ethical codes, general constitutional rights and freedoms applicable to health care (the right to life, privacy, prohibition of torture), and certain rights for mentally ill (Poland), the notion of patients' rights as fundamental human rights evolved only gradually. Hungary is the only country that introduced a full range of general patients' rights by means of the 1998 Health Care Act, following public health, organisational and financing reforms. The Czech legislature, as well as in Poland, did not opt for such a general legal framework of patients' rights. Instead, patients' rights in the Czech Republic are characterised by a fragmented approach and the absence of effective (judicial) enforcement mechanisms. Incidentally, the legislature endorsed basic patients' rights by separate law, for instance the Health Care Act and, more recently, the Law on Data Protection, *mutatis mutandis* Poland. The legislature has been frequently criticised by this fragmented approach and incomplete range of endorsed rights. There are, however, indications that this is going to change due to the Czech ratification of the Biomedicine Convention. Since the Convention came into force (October 2001), the Czech legislature has committed itself to incorporate the Convention's principles in its internal law including a

[210] Recommendation No. R(2000)5 of the Committee of Ministers to Member States on the development of structures for citizen and patient participation in the decision-making process affecting health care, 24 February 2000.

catalogue of (newly defined) rights and procedural guarantees. Consequently, a wide range of internationally accepted patients' rights constitute part of the Czech legal order either by directly applying the Convention's provisions in domestic law or by enacting the necessary legislation to give effect to them. At the moment, the Ministry of Health is preparing legal drafts on the protection of human genomes, to regulate medical scientific research and transplantation issues. In Poland, however, a Patients' Rights Charter is still "in statu nascendi". These outcomes show that each country, apart from urgent reforms in the field of mental health and data protection, introduced patients' rights legislation in a second stage of transition. Initial legal reforms were primarily focused on health insurance legislation and modernising the health care delivery structure by means of revising the Health Care Act. Apart from the Czech Republic, the modernisation of the organisational structure of the health care system through the Health Care Act preceded the enactment of health insurance legislation. This could explain the serious nature of the problems observed in establishing a social health insurance system in the Czech Republic. With the purchaser-provider split and the subsequent shift towards contractual relationships between purchasers, providers and patients, traditional organisational structures and planning mechanisms became rather obsolete. By focusing on health insurance, the Czech legislature underestimated the necessary coherence between financing and other organisational and planning reforms.

Furthermore, it appeared that, except in Hungary, public health law was not included in the initial stage of reform. From what has been discussed so far, it seems that the Hungarian legislative practise in particular matches the iterative approach of the discerned clusters of health law. The examined features of the Hungarian legislative structure and the sequence of legislative reforms since the early 1990s, confirmed most prominently the pattern of a gradually introduced transition, starting with reorganizing public health legislation. Even more importantly, the described method identified existing and potential obstacles. Accordingly, this enabled the evaluation of legislative reforms in a more systematic manner that is open to reasoning and to formulate priorities in the legislative reform process, which need to be regulated. In facing the addressed problems, in Hungary this means primarily the reconsideration of the quality control system and the improvement of the effectiveness of legal norms in social health insurance and patients' rights (e.g., enhancement of enforcement mechanisms).

In terms of the legislative process, it should not come as a surprise that in the country analysis significant differences emerged between the theoretical model and the legislative practise, *nominatim* in the pre- and post-legislative stages. Despite these differences, by studying the patterns

and deficiencies in law-making, the analytical approach enabled the diagnosis of the pathological features of legal norms to at least a certain extent, since the deficiencies in law-making cannot be explained only by legal reasoning. These arguments, however, are outside the scope of this legal research. What these countries have in common is the poor quality of the legislation. This concerns both the drafting process as well as the outcomes. As in most countries in transition, the legislative activity suffers from major shortcomings. The "pathology of law-making" became manifest by the various symptoms of "legislative malnutrition". Major problems with existing legal norms can be derived from the absence or inadequacies in legislative planning or agenda setting. Where a strategic plan is absent, the legislative activity is prone to personal interests (Czech Republic). That planning activity has been further hampered by the frequent changes of Ministers of Health has been manifested in all the selected countries. Generally, it can be concluded that the consequent *ad hoc* approach of drafting legal norms did not contribute to the quality of legislation in terms of guaranteeing fundamental rights or realising and legitimising socio-economic objectives, for instance the previous Czech Health Insurance Act (1991). What is more, the lack of understanding in emerging concepts such as constitutionalism, contracting health care, regulated competition and, patients' rights. Consequently, often overloaded legislative branches of ministries draft legal norms within relatively short periods of time, lacking specific experiences on e.g., alleviating negative (side) effects of (excessive) privatisation of health services, health insurance and most recently, alignment of domestic legal norms to European Community law. This explains in part, although not exclusively, the poor quality of often rashly developed legal norms. The theoretical approach, emphasizing both the pre- and post-legislative stages of law-making, promotes a more rational notion of law-making. It became evident that where fundamental legal changes in particular are concerned, explicit consideration of newly introduced legal concepts in decision-making is crucial. In view of commonalties in development, comparative studies of different legal systems could be beneficial in preventing unforeseen (side) effects and to improve the quality of legal norms (e.g. contracting mechanisms, price regulation, patients' rights legislation). What is more, the dynamical approach of law-making enabled the assessment of legal norms according to the normative concept of health care law, setting the scene for further legal and/or policy changes.

Of further importance is the "plethora of laws", or "legislative inflation" that occurred in the early stage of transition due to the impetus for radical reforms. The magnitude and complexity of reforms simply overloaded the legislature. Parliaments could not afford to go through all the stages of the time-consuming legislative process. This observation justifies even more

the need of priority-setting in law-making. Where extensive problem and data analysis was absent or lacking, unclear and vaguely defined norms appeared difficult to implement and enforce.

In the preparatory stage, as well as in latter stages, all three countries faced a lack of responsiveness, i.e. participation of relevant actors in the legislative process. The monopolistic approach of the Ministry of Health in drafting legislation often confronted health providers and patients/consumers retrospectively with newly defined norms. Conversely, in case of a weak Ministry, complex major revision of social health insurance norms were "delegated" to the dominant health insurance fund (e.g., the *VZP* in the Czech Republic). A major exception however, is the drafting process of the Hungarian Health Care Act 1997. Prior to enactment, the ministry consulted representatives of several (professional) interest groups and established working groups in which these interest groups participated, to discuss and suggest possible solutions, notably on ethical questions.

After enactment, quasi-judicial institutions in Hungary and Poland occasionally criticised the deficiencies or failure to define adequate by-laws necessary to effect statutory norms. Predominantly, such concerns have been raised by the Parliamentary Ombudsmen, generally recognised as an authoritative institution. Quite often, the legislature followed the Ombudsman's recommendations. Reviewing and curbing the arbitrary use of administrative power, the Ombudsman institution functions as a major mechanism that evaluates legal and administrative norms, although on an individual level. The same goes, *mutatis mutandis*, for ordinary courts. Review by the judiciary revealed several interesting issues, such as the conflict of jurisdiction and the justiciability of constitutional and international law. Since the collapse of the ancient regimes, the countries have established a Constitutional Court following the German and/or American notion on constitutional law. Nonetheless, ordinary courts, notably in the Czech Republic and Poland, questioned and sometimes even refused to accept constitutional law as a source of law. International law is even less accepted as a source of law. On the constitutional right to health care, the courts' positivist approach hampered the justiciability of this right. Emerging international developments such as the rapprochement of individual and social rights and the direct effect of international, particularly EC law, give further reason for concern. Ordinary courts cannot ignore such developments without causing constitutional problems. In a way, a narrow positivist perception hinders the review and evaluative function of the judiciary.

Finally, what the countries additionally have in common is the absence of systematic evaluation. During the research no examples have been found in which the legislature examined or requested to examine existing legal

norms, for instance on the effects of a legal norm as well as certain legal provisions. In a period of transition and due to the lack of resources, this aspect, though necessary and valuable, was generally considered as highly academic. Alternatively, Constitutional Courts introduced a kind of evaluation by the judiciary. Referring to both domestic and international sources of law, such court rulings imposed on the legislature to reconsider its reform plans (e.g., cost containment measures, implementation of the Europe agreement).

In conclusion, in part one, it was argued that one of the reasons to develop such a theoretical model was to rationalise the law-making activity, which is lacking in the current practise. The country analysis in part two made clear that by following the iterative stages of the analytical model, the legal decision-making process is structured and systematised. This enabled the examination and review of the arguments for legal decision-making with the outcomes described. Simultaneously, the classification in clusters of health care law enabled the identification of the main regulatory changes and relevant problems. What is more, it allowed the analysis of these results within the conceptual framework of health care law and, based on this, to make suggestions for improvement. The (relative) success of this approach, in terms of comprehensiveness and effectiveness, confirmed the relevance of the analytical model to the legislative practice, i.e. to rationalise the legislative activity.

Relevance to the approximation of laws process

To prepare accession countries for EU membership, the analytical model of health care law-making can, *mutatis mutandis,* contribute towards rationalizing the EC law approximation process. Bilateral Europe agreements and additional policy documents constitute the conditions for future accession, but fail to define the health acquis in extenso. More than defining the health acquis agenda, the conceptual model of health care law problematises the alignment of EC (health) law. For this reason, the original model incorporated the principles of Community law as far as relevant to the health acquis. Impact analysis made clear that paving the way for enlargement, acceding countries will have to consider both public health problems as well as health related issues. Adoption of the Community health acquis require first, substantial efforts to adopt the public health "flanking" policy measures based on article 152 and the EC internal market provisions. In the field of public health, it can be concluded that the harmonizing effect of Community imposed regulatory reforms is limited, due to the subsidiarity principle. Consequently, approximation of EC public health legislation will therefore be rather moderate. Instead, the coordinating and non-legal measures based on alignment of article 152 EC could realize a certain extent of convergence. In particular the participation of

the (extended) Community public health programmes imply some convergence of supportive (regulatory) actions. The common approach set out in these programmes encourage participating countries to set up a framework of epidemiological surveillance and control of communicable diseases based on common indicators, to exchange information, and define corresponding regulatory procedures. At the same time, candidate countries can familiarise themselves with the Community approach in the management of health risks. All of these actions will contribute to a certain degree of harmonization. Alternatively, article 152 increased the Community's legal competence in public health. Up to now, however, it has remained unclear what legal measures the Community can take in areas such as veterinary and phytosanitary, health blood and blood supplies. This uncertainty means that the EC treaty does not require further alignment of this part of public health legislation. More significant are the possible effects of legislation governing the intra-Communitary trade on national health care legislation. On various occasions (Agenda 2000, the proposal for a new public health framework as well as in the document "Health and Enlargement"), the Commission emphasized the relevance between (public) health and the internal market provisions. Incorporating internal market law, although primarily aimed at realizing a common European market, has considerable effects – directly or indirectly – on human health and health systems.

Transposing EC internal market provisions appeared a main force behind the health acquis imposing regulatory convergence of health care systems. Developments such as the introduction of competition among social health insurance funds, deregulation, increased patients mobility and health professionals border crossing strengthen the role of EC law on candidate countries' health care systems. The most relevant topics relevant to health and health systems appeared to be the free movement of persons and services, competition, consumer protection, pharmaceuticals and medical devices, social security, and health and safety at work. The impact of relevant treaty provisions and secondary legislation vary substantially and is often not recognised as such. Generally recognised are the harmonizing consequences of the wide range of EC pharmaceutical legislation and the transposition of other consumer protective measures on food and tobacco. Less known is the impact of free movement of persons (both professionals and consumers) and services on the health care sector by means of co-ordination regulations 1408/71 and 574/72. Although denied for a long time, latest Court rulings and pending cases on increased patients' mobility and professional border crossing strengthened the role of EC law on the organisation and finance of (candidate) Member States' health care systems. It further appeared that EC competition rules could influence social insurance reforms when considering the introduction of market

elements in the social health insurance scheme. Some accession countries (Czech Republic, Poland) already introduced or are considering the introduction of additional private health insurance or competition among social health insurance funds. Apart from EC competition rules, it means that a wide range of Court rulings interpreting these provisions may become applicable. The widespread privatisation of certain health care services will further increase the impact of EC competition law. In this respect, the public procurement rules for applicable health services will impose contracting authorities (such as health insurance funds) to revise their contract award procedures without discriminating between EU services providers.

In view of these future developments, the analytical model imposes on the legislature to explicate and substantiate such considerations in the law-approximation process. Evaluation of (preliminary) outcomes learned that the accession countries, Hungary in particular, made considerable progress in adopting the acquis. Adopting the public health acquis caused relatively minor problems, although analysis show certain problems with regard to public health related issues such as pharmaceutical and consumer protection law (e.g., authorization and supervision procedures). Manifested problems concentrate on incorporating internal market provisions, in terms of both setting legal norms and adequate implementation mechanisms. Newly emerging concepts such as non-discrimination of non-nationals, the free movement principles, public procurement and data protection rules influence various health care sectors, as well as the health system itself. The exact consequences, however, are still matter of lively debate, and have been complicated by the latest Court rulings extending the scope of Community law to the organisation and financing of health systems. For candidate member states, the observed omissions in law approximation and the complexity of law reforms mean a continuous process aligning their domestic legal framework. To support that process, the theoretical approach enabled the identification and analysis of relevant communautaire concepts. Subsequently, initiate legal decision-making, ideally in accordance with such considerations. As such, the analytical model has confirmed its practical value as explanatory, guiding and steering instrument of both the process and content of transposing Community law, promoting rational decision-making in the approximation of laws process.

So far, the analysis of the central questions and the results were primarily based on three selected countries, *viz*, Hungary, the Czech Republic and Poland. The hypothesis, however, was not restricted to these countries but questioned its relevance to Central and Eastern Europe in general. Therefore, the relevance of this model of law-making can be criticised by

its restrictive scope of research and therefore limited value. Nonetheless, it could be argued that the questioned model can be applied in a broader legal setting than those examined in this study.

First of all, the selected health care systems were intended as illustrative cases to explain the relevance of the analytical model as developed in part one. This choice was explained by the fact that these countries in particular appeared to have a leading role in health care system reforms, by emphasizing the introduction of market elements in health care, both in terms of providing health services as well as purchasing health care. The manifested legal problems are therefore more urgent than in less developed health care systems in this region. For instance, countries such as Bulgaria, Romania and the Ukraine have only recently introduced the concept of social health insurance or are still considering similar reforms (e.g., Romanian Health Insurance Law 1997, Bulgarian Health Insurance Act 1998), and the privatisation of outpatient health services (Bulgaria 2000). In these countries the emphasis of future reforms will be, *inter alia*, on strengthening the purchaser-provider split (selective contracting) and safeguarding patients' rights. In this respect, these countries could benefit from the described experiences with identical developments. In the field of patients' rights, it will mean the ratification of relevant treaties (e.g., the Biomedicine Convention and protocols) and its implementation in national law, whether or not by means of a Charter on Patients' Rights. Moreover, it foresees adequate legal protection to prevent or stop infringements of the Convention's rights. Lessons could be drawn from the Hungarian Health Care Act 1997, for instance in the preparatory stage of drafting with respect to the role of health professions and consumers, as well as in the post-legislative stage, concerning the judiciability of the rights of patients and the role of the (Patients') Ombudsman.

Secondly, the described normative framework of health care law (chapter three) was based on primordial values of health care law. In the health legal doctrine, these principles were transformed into so-called universal "law-jobs", that cover a wide range of activities in the field of health care law, as confirmed by authoritative institutions such as the World Health Organization. The essence of such a notion of health care law is that it conceptualises and guides the regulatory functions of the legislature in health care. Furthermore, the principles and functions have been recognised and elaborated in international human rights treaties and conventions. Since the examined documents were ratified by most of the Central and Eastern European countries, these countries are bound by the treaty obligations. This means, for instance, that party states have to take steps to a maximum of its available resources to progressively achieve the full realisation of the rights recognised (ICESCR).

What is questionable is the sequence of identified clusters. However, the suggested approach of initiating health care reforms was based on previous negative experiences with health care financing reforms in Central and Eastern Europe. A main lesson learned from the Czech experience in the early 1990s is the need for an adequate legal framework that regulates the organisation and financing of a social health insurance scheme. Although primarily focussed on regulating individual health care, such a legal framework should correlate with the public health concept, planning instruments and fundamental rights, such as access to basic health care and quality of care. The absence of such an integrated legislative strategy is one of the reasons that explain the difficulties in the initial stage of health care reforms. The complexity of these reforms and its social consequences therefore require a series a correlated incremental changes, as suggested in the scenarios described in chapter four. Moreover, the suggested approach emphasized the focus on public health in the initial stage of reform. Although the sequence of suggested clusters of health care law (public health, organising and financing health care, quality control and patients' rights) does not exclude a different approach, disregarding public health when initiating legislative reforms could have major consequences for the health status of the population. WHO health status reports in Centreal and Eastern Europe and the EU Commmission's papers on public health confirmed their concerns about the poor health status of the population and need for public health regulatory reforms. However, there is also a more pragmatic reason for Central and Eastern European countries to subscribe to the suggested sequence and to first prioritise public health. In view of future EU membership, accession countries have to implement Community law, including the public health acquis. According to the White Paper on Enlargement, public health is identified as a stage I priority within the approximation of laws process before, for instance, the mutual recognition of professional qualifications (stage III). In addition, all bilateral Europe agreements have confirmed this approach by formulating public health as a precondition to accession. It is therefore evident that both "first wave" and "second wave" accession countries will be "inspired" to incorporate EU health standards.

Finally, the relevance of the formal stages of law-making to other countries is assumed, notably the rationality concept and the iterative, dynamic process of law-making. In part one, it was already noticed that the legislative problems were not unique to particular countries. The problem of so-called "legisflation" or "legisferitis" is known in most countries, as well as at supranational level (European Commission "Better lawmaking" reports). On several occasions, theorists from various countries have confirmed the manifested difficulties with (drafting) legislation, such as rapid social changes, the *ad hoc* approach in legislative planning, unrealistic

time schedules for drafting legal norms, omissions and inconsistencies in legislation, and hampered implementation of the law; symptoms that suggest poor quality of legislation (Karpen 1996, Lafitski 1996, Luarasi 1996, Stalev 1996, Kellermann 1998). In Bulgaria, efforts to improve the legislative activity concern the Law on Normative Acts (LNA 1973), regulating the production of laws and a Decree for its implementation (DNLA 1974). This law was strongly influenced by Noll's rationality concept emphasizing the need for legislative planning, preceding studies problematising normative issues, the "Planspiel" option, external consultation, writing and adopting the law, and post-legislative review (article 53 DNLA). However, evaluative studies on the effectiveness of legislation are exceptional. One of the reasons for this is the lack of knowledge and expertise in the science of legislation, more specifically the methodology of law-making (Stalev 1996). Since the theory of legislation is not part of the Bulgarian curriculum of legal studies, scientific knowledge on drafting legislation is scarce. There are however, exceptions such as in Poland where post-graduate courses in legislation were launched and teaching the basic principles and methods for drafting legislation (Gwizdz 1996).

In a way, these findings confirm that there is a common need to increase the rationality of law-making, to structure and systematise the law-making activity according to the underlying normative and legitimatising concept of law. This concept of law has been acknowledged by all newly established parliamentary democracies in Central and Eastern Europe, ruled by the *rule of law*. Since the model of law-making was intended to strengthen the rationality of law-making it could – despite its limitations and assumptions such as the restricted rationality concept, law-making as a political process, a single actor model – be considered as a valuable instrument for other countries in the Central and Eastern region confronted with major health care system reforms.

REFERENCES AND BIBLIOGRAPHY

Adam, J. Reform of the Pension and the Health Care Systems in the Czech Republic. *Osteuropa Wirtschaft* (1998) Iss. 3, pp. 280-294

Ágh, Attila. *The First Steps* (ed.) Hungarian Centre of Democracy Studies Foundation, Budapest. 1994

– Parliaments as Policy Making Bodies in East Central Europe: The Case of Hungary. *International Political Science Review* (1997) Iss. 4, pp. 417-432

– *Emerging Democracies in East Central Europe and the Balkans.* Elgar Cheltenham 1998

Albert, A, Bennett, C and M. Bojar. Health Care in the Czech Republic. A System in Transition. *J. American Medical Association* (JAMA) 1992; 267, pp. 2461-2466

Annas, G.J. *The rights of patients.* Southern Illinois University Press, 1989

Alston, P and G. Quinn. The Nature and Scope of States Parties' Obligations under the International Covenant on Economic, Social and Cultural Rights, *Human Rights Quarterly* (1987) Iss. 2, pp. 157-223

Arato, A. Constitution and Continuity in the East European Transitions. The Hungarian Case. *Tilburg Law Review* (1994), pp. 65-89

Arato, A. The constitution-making endgame in Hungary. *East European Constitutional Review*, Fall 1996, pp. 31-39

Aristotle, L. *Ethica Nicomachea* (the Nicomachean ethics), translated by H.G. Apostle. Reidel Publishing, Dordrecht 1975

– *The Politics*, S. Everson ed. Cambridge University Press, Cambridge 1988

Attila, Á. *The Politics of Central Europe.* Sage Publications London 1998

Avert, G and F. Cameron. *The Enlargement of the European Union.* Sheffield Academic Press 1998

Baginska, E and M. Nesterowicz. The Polish Solution to the Problem of Realising the Right to Health Care in View of the Changes in the Political and Social System, in: *The Right to Health Care in several European Countries.* A.P. den Exter and H.E.G.M. Hermans (eds). Kluwer Law International, The Hague 1999, pp. 115-126

Banaszak, B. Die Konzeption der Rechte des Individuums in Polen. *Osteuroparecht* (2001) Iss. 6, pp. 487-491

Beauchamp, T.M and J.F. Childress. *Principles of Biomedical Ethics.* Oxford University Press, New York 1989

Beddard, R and D. Hill (eds). *Economic, Social and Cultural rights: Progress and Achievement.* London MacMillan 1992

Bernhardt, R. Europäische Grundrechts in der Zweiten Hälfte des 20. Jahrhunderts in: *Das Künftige Mitteleuropa. Tradition und Perspektiven.* Karolinum univerzity Praha 1998, pp. 43-61

Blasszauer B. The Old Medical Ethics meets the new. *Hastings Center Report*, June 1986, pp. 25-27

Both, J, Czeczot, J. and A.P. den Exter. The Certificate of Need Development: Elaboration of a licensing system according to needs and its Implementation, in: *Standards of Health Services Purchased in the National Health Insurance System.* TNO Prevention and Public Health, Leiden 2001

Bovens, M.A.P., W. Derksen and W.J. Witteveen (eds). *Rechtsstaat en sturing* (Rechtsstaat and steering, in Dutch). Tjeenk Willink, Zwolle 1987

Braybrooke, D and C.E. Lindblom. *A strategy of decision: Policy Evaluation as a Social Process.* New York 1963, pp. 66-69

Cesen, M and V. Mocnik Drnovsek. The process of health legislation reform in the Republic of Slovenia. *European J. Health Law* (2000) No. 1, pp. 73-84

Ciecierska A, D Gajdus. *Information on the results of an audit by the Supreme Chamber of Control on the implementation of the Mental Health Protection Act.* Department of Health and Physical Culture. Supreme Chamber of Control, Poland 1997

Commissioner for Civil Rights protection. *Annual Information* 1992 (in Polish), Warsaw 1993

Commissioner for Civil Rights protection. *Annual Information* 1993 (in Polish) Warsaw 1994

Commissioner for Civil Rights protection. *Annual Information* 1998 Warsaw 1999

Commissioner for Civil Rights protection. *Annual Report* 1999 (in Polish), Warsaw 2000

Constantinesco, L-J. *Traité de Droit Comparé, II, La Méthode comparative.* Paris Librairie generale de Droit et de Jurisprudence, Pichon et Durand-Auzias, 1974

Cornelissen, R. 25 years of regulation (EEC) No 1408/71, its achievements and its limits, in: *European and International Social Security Law*, Institute of Social Law, Catholic University Louvain 1999

Curtin, D.M. and R.H. van Ooik. *Revamping the European Union's Enforcement systems with a view to Eastern Enlargement.* Scientific Council for Government Policy (WRR), The Hague, October 2000

Czech Helsinki Committee. *Report on the State of Human Rights in the Czech Republic* 1995 Prague 1995

Czech Helsinki Committee. *Report on the State of Human Rights in the Czech Republic* 1998 Prague 1998

Czech Helsinki Committee. *Report on the State of Human Rights in the Czech Republic* 1999 Prague 1999

Czúcz, O. Das System sozialer Sicherheit in Ungarn in: *Soziale Sicherheit in Mitteleuropa.* T. Tomandl and W. Mazal (eds.), Orac Verlag Wien 2000, pp. 241-275

Deutsch, E. *Arztrecht und Arzneimittelrecht.* Springer Verlag, Berlin 1983

Diemer-Benedict, T. Die Geschäftsordnung des polnischen Verfassungsgerichts – das Verfassungsgericht in neuem Gewand. *Osteuroparecht* (1997), Iss. 2/3, pp. 303-320

Diemer-Benedict, T. Die Grundrechte in der neuen polnischen Verfassung. *Zeitschrift für ausländisches öffentliches Recht und Völkerrecht.* (1998) Iss. 1, pp. 205-238

Dommers, J. Agenda 2000 and the Role of Public Health in Applying for EU Membership. *European J. Health Law* (1997) Iss. 4, pp. 315-319

Donaldson, R.J. and L.J. Donaldson. *Essential Public Health Medicine,* Dordrecht, 1993

Dósa, Á. New legislation on civil commitment in Hungary. *Medicine and Law* (1995), Iss. 3, pp. 581-588

– Legal aspects of Combating AIDS in Hungary. *Acta Juridica Hungarica* (1997) Iss. 3-4, pp. 139-157

– New Legislation on Health Care in Hungary. *Acta Juridica Hungarica* (1998), Iss. 1-2, pp. 131-136

Dunning, A.J. *Report of the Government Committee on Choices in Health Care.* Ministry of Welfare, Health and Cultural Affairs, Rijswijk, the Netherlands 1992

Dupré, C. Importing German law: The interpretation of the right to human dignity by the Hungarian constitutional court. *Osteuroparecht* (2000), Iss. 2, pp.144-157

Dworkin G. *The theory and practice of autonomy.* Cambridge University Press 1991

Dzialocha, K. Bezposrednie stosowanie Konstytucij PRL przez sady (Direct applicability of the Constitution in the People's Republic of Poland by the Judiciary), *Studia Prawicze* (1988), No. 4

Editorial comments. The EC Charter of Fundamental Rights still under discussion. *Common Market Law Review* (2001), No. 1, pp. 1-6

Eide, A., C. Krause and A. Rosas (eds). *Economic, Social and Cultural rights: A Universal Challenge in: Economic, Social and Cultural Rights.* Martinus Nijhoff Publishers. Dordrecht 1995

Enthoven, A.C. Consumer Choice Health Plan, *New England J. Medicine* (1978) 298, pp. 650-709

– *Theory and Practice of Managed Competition in Health Care Finance.* North-Holland, Amsterdam 1988

Etzioni, A. Mixed scanning. A "third" approach in decision-making. *Public Adm. Review* (1967) pp. 385-397

Exter, A.P. den and H.E.G.M. Hermans. International developments concerning the right to health care in the context of the ICESCR in: *Health, Migration and Return. A handbook for a multidisciplinary approach.* P.J. van Krieken (ed.) T.M.C. Asser Press, The Hague 2001, pp. 10-17

- and H.E.G.M. Hermans. Constitutional Rights to Health Care: The consequences of placing limits on the right to health care in several western and eastern European countries. *European J. Health Law* (1998) Iss. 3, pp. 261-290
- and H.E.G.M. Hermans. *The Right to Health Care in Several European Countries.* Kluwer Law International, The Hague 1999
- Hermans, H.E.G.M. and E.H. Hulst. Health Care Legislation in Central and Eastern Europe. A Problem-Oriented Method of Legal Analysis of Health Care Systems in Central and Eastern Europe: The Albanian Example. *Review of Central and East European Law* (1997), Iss. 2, pp. 117-132
- Health care legislative reforms in Armenia: preparations for a purchaser-provider split. *Medicine and Law* (2000) Iss. 4, pp. 655-661
- Conceptualising a Model of Health Care Law-making: Relevance to Central and Eastern Europe by Exploring Hungarian Reforms. *Acta Juridica Hungarica* 1999, Iss. 1-2, pp. 55-76
- H.E.G.M. Hermans and E.H. Hulst. A Conceptual Model of Health Care Law-making in Central and Eastern Europe. *Medicine and Law* (2000) Iss. 2, pp. 165-180
- Health Legal Reforms in the Czech Republic and Hungary in: *Health Care Reforms in Central and Eastern Europe: Outcomes and Challenges.* E. Krizova and J. Simek (eds). Charles University Press 2000, pp. 27-42
- H.E.G.M. Hermans and E.H. Hulst. Rationalising Health Care Law-making in Central and Eastern Europe: A Legal-theoretical Concept and its Relevance to High Technology Care in: *Medizinethik 1.* Studien zur Ethik in Ostmitteleuropa. J.C. Joerden and J.N. Neumann (eds). Peter Lang Verlag, Frankfurt am Main, 2000, pp. 29-58
- Lituvos Stomjimas I Europos Sajunga: Reiksme Nacionalinei Visuomenes Sveikatos strukturai (Lithuania's future accession to the European Union: Relevance to national health policy). *Sveikatos Aplinka* (2000) Iss. 2, pp. 6-10
- Legal reforms of the Polish health care system in view of accessing the European Union *European J. Health Law* (2001) Iss. 1, pp. 5-25
- Health Care Reforms in the Czech Republic and Hungary: A Reappraisal of the Right to Health Care in: *Medizinethik 2.* Studien zur Ethik in Ostmitteleuropa. J.C. Joerden and J.N. Neumann (eds). Peter Lang Verlag, Frankfurt am Main, 2001, pp. 95-120
- and L. Prudil. The Czech Republic in: *International Encyclopaedia of Medical Law.* H. Nys (ed.) Kluwer Law International, The Hague 2001
- The legal consequences of EU accession to central-eastern European health care systems in: *European Law Journal* (2002) Iss. 4, pp. xxx
- M. Nesterowicz and E. Baginska. Poland in: *International Encyclopaedia of Medical Law.* H. Nys (ed.) Kluwer Law International, The Hague 2002

- and J. Sándor (eds) *Health care studies: A multidisciplinary approach.* Central European University Press, Budapest (in press)
- The Right to Health Care in International Law in: *Health care studies: A multidisciplinairy approach.* A.P. den Exter and J. Sándor (eds) Central European University Press, Budapest (in press)
- Purchasers as the Public's agent: Consumer participation and accountability in: Effective Purchasing for Health Gain. J. Figueras, R. Robinson, E. Jakubowski (eds) Open University Press (in press)

European Observatory on Health Care Systems. *Health Care Systems in Transition: Hungary.* WHO Regional office for Europe, Copenhagen 1999
- *Health Care Systems in Transition: Czech Republic.* WHO Regional office for Europe, Copenhagen 1999
- *Health Care Systems in Transition: Poland.* WHO Regional Office for Europe, Copenhagen 1999

European Health Management Association (EHMA). *The Impact of Market Forces on Health Systems. A Review of Evidence in the 15 European Union Member States.* EHMA, Dublin 2000

Eijlander, Ph. *De wet stellen. Beschouwingen over onderwerpen van wetgeving* (To position the law, in Dutch). W.E.J. Tjeenk Willink Zwolle 1993
- and W.J.M. Voerman. Outlooks for Legislation: Introduction. *Regelmaat* (1999), Iss. 3, pp. 120-125
- and W.J.M. Voerman. Wetgevingsleer (legislative science, in Dutch) W.E.J. Tjeenk Willink, Deventer 1999

Fattore, G. Cost Containment and Health Care Reforms in the British NHS in: *Health Care and Cost Containment in the European Union.* E. Mossialos and J. Le Grand (eds). Ashgate Aldershot 1999, pp. 513-546

Fawcett, J.E.S. *The Application of the European Convention on Human Rights* Oxford University Press 1969

Feachem, R.G.A. and A. Preker. Health and Health Care in: *Labor Markets and Social Policy in Central and Eastern Europe.* The Transition and Beyond. N. Barr (ed) Oxford University Press 1994, pp. 288-321

Flood, C.M. International Health Care Reform. A legal, economic, and political analysis. Routledge, London 2000

Flynn, P. Reactions to the Treaty of Amsterdam. *Eurohealth* 1997 No 3, pp. 2-3

Foltz, A-M. The policy process in: *Health policy and systems development. An agenda for research,* J. Janovsky (ed.). WHO Geneva 1996

Forder, C.J. Positieve verplichtingen in het kader van het Europees Verdrag tot Bescherming van de Rechten van de Mens en de Fundamentele Vrijheden (Positive commitments as part of the ECHR, in Dutch) in: *NJCM-bulletin* (1992), Iss. 6, pp. 611-637

France, G. and H.E.G.M. Hermans. Choices in health care in Italy and the Netherlands: I. Economic and financial dimensions in: Leidl, R. (ed.) *Health care and its financing in the single European market.* Amsterdam, IOS Press 1998, pp. 254-264

Frankowski, S. and P.B. Stephan. *Legal reforms in post-communist Europe: The view from within.* Martinus Nijhoff, Dordrecht 1995

Fridli, J., Tóth, G.A. and V. Ujvári (eds). Data Protection and Freedom of Information. Workshop on Data Protection and Freedom and information. Budapest, May 22-25, 1997

Frowein, J.A. and T. Marauhn (eds). *Grundfragen der Verfassungsgerichtsbarkeit in Mittel- und Osteuropa.* Springer, Berlin 1998

Furrow, B.R., S.H. Johnson, T.S. Jost and R.L. Schwartz. *Health Law: Cases, Materials and Problems.* West Publishing, St. Paul 1991

Gadzhiev, G. The Interdependence of Economic and Social Rights. *Acta Juridica Hungarica* (1998), Iss. 3-4, pp. 213-223

Gajdus, D. The state of observance of patients' rights in Poland – A report on the audit by the Supreme Chamber of Control. Supreme Chamber of Control, Warsaw, 1996

Galligan, D.J. and D.M. Smilov. *Administrative Law in Central and Eastern Europe.* Central European Press, Budapest 1999

Garlicki, L. Soziale Rechte in der Rechtsprechung des Verfassungsgerechtes, in: *Grundrecht im Umbruch: Das Beispiel von Polen und Deutschland.* G. Manssen, B. Banaszak (eds). Berlin Verlag, Berlin 1997, pp. 87-110

Gaudissart, M-A. and A. Sinnaeve. The Role of the White Paper in: *Enlarging the European Union. Relations between the EU and Central and Eastern Europe.* M. Maresceau (ed.) Longman, London 1997, pp. 41-71

Genugten, W.J.M. van. *Mensenrechten in ontwikking: het "goede doel" voorbij.* (Human rights in development, in Dutch) Inaugural lecture, Catholic University of Nijmegen, the Netherlands 1992

Gessner, V., A. Hoeland and C. Varga (eds). Introduction: Complexity of the Challenge Facing Central and Eastern Europe in: *European Legal Cultures.* Dartmouth, University Press, Cambridge 1996, pp. 415-429

Gillis, M. The Relationship of Ordinary Courts to the Constitutional Court in: *The Czech Legal System in European Contexts* SOCRATES/ERASMUS Programme 1998/99, The Czech Constitutional Court, Charles University Prague, Prague 1998

Goldstein, E., A.S. Preker, O. Adeyi and G. Chellaraj (eds). *Trends in Health Status, Services, and Finance. The Transition in Central and Eastern Europe.* World Bank Washington, Technical Paper (1996) No. 341, Vol 1

Gomien, D., D. Harris and L. Zwaak. *Law and practice of the European Convention on Human Rights and the European Social Charter.* Council of Europe 1996

Gostin, L.O. and Z. Lazzarini. *Human Rights and Public Health in the AIDS Pandemic.* Oxford University Press, New York 1997

Görlitz, A. *Die politische Funktionen des Rechtes.* Wiesbaden 1976

Gögl, Á. Minister of Health of the Republic of Hungary. Health and Enlargement of the EU: Views of a candidate Country. *Eurohealth* (1998) Iss. 4, pp. 17-18

Grad, F.P. Public health law: its form, function, future, and ethical parameters in: *Health Legislation at the Dawn of the XXI^st Century. International Digest of Health Legislation.* World Health Organization. (1998) Special Issue. Iss. 1, pp. 19-40

Grubb, A. Treatment decisions: Keeping it in the family in: Choices and Decisions in Health Care by A. Grubb, John Wiley Chichester 1993, pp. 37-96

Guild, E. (ed.) The Europe Agreements: The Rights to Establishment in the Central and Eastern European Agreements, in: *The Legal Framework and Social Consequences of Free Movement of Persons in the European Union.* Kluwer Law International, The Hague 1999, pp. 127-138

Gulácsi, L. and A. Kovacs. *Health Care System and the Health Status of the Population.* Hungary (1995), pp. 11-23

– *Hungarian health care in transition. Studies on the improvement of the effectiveness of health care in Hungary by implementing quality assurance.* University of Amsterdam (Diss.) 2001

Gunsteren, van H.R. Rechtsstaat of juridische traditie? (The "Rechtsstaat" or legal tradition, in Dutch) in: *Rechtsstaat en Sturing.* M.A.P. Bovens, W. Derksen and W.J. Witteveen (eds). Zwolle, W.E.J. Tjeenk Willink 1987, pp. 171-188

Gwizdz, A. Organization of the Post-Graduate Course in Legislation at the University of Warsaw in: *Contributions to the Methodology of the Creation of Written Law.* U. Karpen and P. Delnoy (eds) Nomos Verlagsgesellschaft Baden-Baden 1996, pp. 106-110

Hamilton, G.J.A. *Towards a fourth generation of European insurance directives. Association Internationale de la Mutualité* (AIMS), Brussels March 1999, pp. 1-3

– Competition and solidarity in European health care systems. *European J. Health Law* (1996) Iss. 3, pp. 323-329

Harris, D.J., M. O'Boyle and C. Warwick. *Law of the European Convention on Human Rights.* Buttersworths 1995

Hayes, J.A. Health Care as a Natural Right *Medicine and Law* (1992) Iss. 5, pp. 405-416.

Hellman, J. Constitutions and economic reform in the Post-communist transitions, *East European Constitutional Review* (1996), pp. 46-56

Hermans, H.E.G.M. and A.P. den Exter, Priorities and Priority-Setting in Health care in the Netherlands. *Croatian Medical J.* (1998) Iss. 3, pp. 346-355
- and J. Nooren. Contracting and the Purchaser-Provider Split in Western Europe: A Legal-Organizational Analysis. *Medicine and Law* (1998) Iss. 2, pp. 167-188
- and I. Tiems. Convergence in the Dutch Health Insurance: Possibilities and Obstacles in a European Perspective. *European J. Law and Economics* (1997) Iss. 4, pp. 371-388
- A.F. Casparie and J.H.P. Paelinck (eds). *Health Care in Europe after 1992* Dartmouth Aldershot 1992
- and G. France. Choices in Health care in Italy and the Netherlands: II. Legal dimensions in: Leidl R, (ed.) *Health care and its financing in the single European market.* IOS Press Amsterdam 1998, pp. 265-284
- and A.P. den Exter. Cross Border-Alliances in Health Care: International Co-operation between Health Insurers and Providers in the Euregio Meuse-Rhine. *Croatian Medical Journal* (1999) Iss. 2, pp. 266-272

Hermesse J., H. Lewalle and W. Palm. Patient mobility within the European Union. *European J. Public Health* (1997) Iss. 3 supplement, pp. 4-10

Hervey, T. *European Social Law and Policy*. Longman, London 1998

Herweijer, M. De dynamiek van doeltreffend gedrag: een struikenblok bij evaluatie (The dynamics of effective behaviour: an obstacle at evaluation) in: *Bestuurswetenschappen* (1981) Iss. 5, pp. 348-366

Hill, H. *Einführung in die Gesetzgebungslehre.* Heidelberg 1982

Hoeland, A. The Evolution of Law in Central and Eastern Europe: Are we Witnessing a Renaissance of Law and Development? in: *European Legal Cultures.* V. Gessner, A. Hoeland and C. Varga (eds). Dartmouth, University Press, Cambridge 1996, pp. 482- 484

Hofmanski, P. Menschenrechtenschutz in Polen. Neue Dimensionen nach 1989 in: *Demokratie Gestern und Heute.* 1995, pp. 261-277

Hogwood, B.W. and B.G. Peters (eds). *The Pathology of Public Policy.* Oxford Claridon Press 1985

Holländer, P. The Role of the Constitutional Court for the Application of the Constitution in Case Decisions of Ordinary Courts. *Archiv für Rechts- und Sozialphilosophie* (2000) Iss. 4, pp. 537-552

Hollo, I, M. Long and A. Papp. Health Care Financing in Hungary. Background paper for the Health Reform Conference Hungary, October 1998, pp. 1-34

Holmes, S.H. and C.R. Sunstein. The Cost of Rights. Norton, New York 1999

Huber, M. Health Care Financing in European Union Member States. An Initial Perspective Based on Recent OECD Work on Overall Social

Trends in: *Health Care and its Financing in the Single European Market.* R. Leidl (ed) IOS Press Amsterdam 1998, pp. 59-71

Hugger, W. *Gesetze, ihre Vorbereitung, Abfassung und Prüfung: ein Handbuch für Praxis und Studium.* Nomos, Baden-Baden 1983

International Law Association (ILA). Report on the Status of the Universal Declaration of Human Rights in National and International Law, ILA, Rep. Of the 66th Conference, 1994 *Georgia Journal of International and Comparative Law.* (1995-6) Iss. 1/2 , pp. 525-563

Jarós, J. and K. Kalina (eds). *The Czech Health Care System. Delivery and Finance.* Czech Association for Health Services Research, OECD Study. December 1998

Jilek, D. Human Rights Treaties and the New Constitution in: *Survey of Lectures on Czech Law.* Masarykova univerzita Brno, 1995, pp. 107-116

Johnson, T., G. Larkin and M. Saks (eds). *Health Professions and the State in Europe.* London, Routledge 1995

Jorens, Y and B. Schulte (eds) Coordination of Social Security Schemes in Connection with the Accession of Central and Eastern European States. The Riga Conference. Die Keure 1999

Kant, I. *Fundamental Principles of the Metaphysic of Ethics,* transl. by T. Kingsmill Abbott. Longmal, London 1969

Kapteyn, P.J.G. and P. Verloren van Themaat. *Introduction to the Law of the European Communities. From Maastricht to Amsterdam.* L.W. Gormley (ed.) Kluwer Law International, London 1998

Karpen, U. *Gesetzgebungs-, Verwaltungs-, und Rechtssprechungslehre. Beiträge zur Entwicklung einer Regelungstheorie.* Nomos Verlag, Baden Baden 1989

– *Legislation in European Countries* (ed.). Nomos Verlaggesellschaft Baden-Baden 1996, pp. 479-490

– and P. Delnoy (eds). *Contributions to the Methodology of the Creation of Written Law.* Nomos Verlagsgesellschaft, Baden-Baden 1996

Kaser, M. *Health care in the Soviet Union and Eastern Europe.* Croom Helm London 1976

Kellermann, A.E., G.C. Azzi, S.H. Jacobs and R. Deighton-Smith (eds). *Improving the Quality of Legislation in Europe.* Kluwer Law International, The Hague 1998

– J.W. de Zwaan and J. Czuczai (eds). *EU Enlargement – The Constitutional Impact at EU and National Level.* TMC Asser Press, The Hague 2001

Kennedy, I. and A. Grub. *Medical Law.* London, Buttersworth 1994

– *The unmasking of Medicine* London, Allen and Unwin 1981

Kindermann, H. Plan und Methode det Gesetzgebungstheorie *Rechtstheorie* (1978) Heft 2, pp. 229-235

King, T. The European Community and human rights in Eastern Europe, in: *Legal issues of European integration* (1996) Iss. 2, p. 125

Kissimova-Skarbek, K. *Health care reforms in the CCEE/NIS, European Health Policy Conference: Opportunities for the Future.* Conference Proceedings 5-9 december 1994 Vol. V. World Health Organization, Regional Office for Europe, Copenhagen 1995, pp. 227-234

Kiss, L. Einige Fragen der Rechtsstaatlichkeit und der Gesetzgebung in Ungarn. *Osteuroparecht* (1990) Iss. 1, pp. 12-22

– Rechtliche Vorbereitungen in der Republik Ungarn auf der Beitritt zur Europäischen Union in: *Der Beitritt der Staaten Ostmitteleuropas zur Europäischen Union und die Rechte der deutschen Volksgruppen und Minderheiten sowie der Vertriebenen.* D. Blumenwitz, G.H. Gornig, D. Murswiek. Köln Verlag Wissenschaft und Politiek 1997, pp. 89-98

Koch, I.E. Social rights as components in the civil right to personal liberty: Another step forward in the integrated human rights approach? *Netherlands Quarterly of Human Rights* (2002) Iss. 1, pp. 29-51

König, K. Evaluation als Kontrolle der Gesetzgebung in: *Gesetzgebungslehre: Grundlagen, Zugänge, Anwendung.* W. Schreckenberger, K. König W. Zeh (eds). Stuttgart Kohlhammer, 1986, pp. 96-108

Krems, B. *Grundfragen der Gesetzgebungslehre erörtert anhand neuerer Gesetzgebungsvorhaben insbesondere der Neuregelung des Bergschadenrechts.* Duncker und Humblot, Berlin 1979

Krieken, P.J. van (ed.) *Health, Migration and Return. A handbook for a multidisciplinary approach.* T.M.C. Asser Press, The Hague 2001

Krizova, E. *Health Care Reforms in Central and Eastern Europe: Outcomes and Challenges.* E. Krizova and J. Simek (eds) Charles University Press, Prague 2000

– The Patients' Rights as an Important Issue in the Process of Civic Emancipation in the Czech Republic in: *The Right to Health Care in Several European Countries.* A.P. den Exter and H.E.G.M. Hermans (eds) Kluwer Law International, The Hague 1999

Kuile, B.H. ter, F.M. du Pré and K. Sevinga. Health Care in Europe after 1992: The European Dimension in: *Health Care in Europe after 1992.* H.E.G.M. Hermans, A.F. Casparie and J.H.P. Paelinck (eds). Dartmouth Aldershot 1992

Kulcsár, K. *Modernization and Law.* Budapest 1992

Kummeling, H.R.B.M. and S.C. Bijsterveld (eds). *Grondrechten en zelfregulering* (Constitutional rights and self-regulation, in Dutch). Tjeenk Willink Deventer 1997

Lafitsky, V. Law and Legislation in the Soviet Union and Russia, in: *Legislation in European Countries.* U. Karpen (ed.). Nomos Verlaggesellschaft, Baden-Baden 1996, pp. 365-387

Lamers, L.M. *Capitation payments to competing Dutch sickness funds based on diagnostic information from prior hospitalization,* Erasmus University Rotterdam (Diss.), the Netherlands 1997

Langner, P. *Zero-Base Budgeting und Sunset Legislation. Instrumente zur Rückgewinnung öffentlicher Handlungsspielräume?* Nomos Verlaggesellschaft Baden-Baden 1983

Laufs, A. *Arztrecht.* Beck Verlagbuchhandlung, München 1988

Lawson, R. Positieve verplichtingen onder het EVRM: opkomst en ondergang van de "Fair Balance"-test (Positive commitments under the ECHR: Genesis and downfall of the "fair balance"-principle, in Dutch). *NJCM*-Bulletin (1995) Iss. 5, pp. 558-573

Leary, V.A. Judiciability and Beyond; Complaint Procedures and the Right to Health in: *The Review* (1995) Iss. 55, pp. 105-122

Leenen, H.J.J. Sociale grondrechten en gezondheid (Social Constitutional rights and health care, in Dutch). Hilversum, DeBoer/Brand 1966

- G. Pinet and A.V. Prims (eds). Trends in Health Legislation in Europe. Paris: Masson/World Health Organization 1986
- Gevers, J.K.M. and G. Pinet. The rights of patients in Europe: a comparative study. Deventer Kluwer Law and Taxation Publishers 1993
- Recht op zorg voor de gezondheid (Right to care for health. Preliminary advice, in Dutch). Pre-advies Utrecht 1997
- Health law and health legislation: possibilities and limits in: *Health Legislation at the Dawn of the XXI^st^ Century. International Digest of Health Legislation.* World Health Organization. (1998) Special Issue Iss. 1, pp. 77-88
- The Right to Health Care in the Netherlands in: *The right to health care in several European countries.* A.P. den Exter and H.E.G.M. Hermans (eds), Kluwer Law International, The Hague 1999, pp. 31-38

Leino-Kilpi, H (ed.) *Patient's Autonomy, Privacy and Informed Consent.* IOS Press Amsterdam 2000

Lenaerts, K., P. van Nuffel and R. Bray. *Constitutional Law of the European Union.* Sweet and Maxwell London 1999

Leidl, R. ed. *Health Care and its Financing in the Single European Market.* IOS Press Amsterdam 1998

Letowska, E. The Polish Ombudsman and Human Rights in: *Ombudsman in Europe – The Institution.* F. Matscher (ed.) Engel Verlag, Kehll am Rhein 1994, pp. 57-71

- and J. Letowski. Transformation of the law: A "craving" for judge-made law. In: *Poland towards to the Rule of Law.* Polish Academy of Sciences, Warsaw 1996, pp. 117-130
- A Constitution of Possibilities. East European Constitutional Review. (1997), Iss. 2-3, pp. 76-81

Light, D. Countervailing powers. A framework for professions in transition in: *Health professions and the State in Europe.* T. Johnson, G. Larkin, M. Saks (eds). Routledge, London/New York 1995, pp. 25-41

Lindblom, C.E. The science of muddling through in: *Public Adm. Review* (1959) pp. 79-88
- Still muddling, not yet through in: *Public Adm. Review* (1979), pp. 517-526

Llewellyn, K. The Normative, the Legal and the Law Jobs. Yale Law Journal (1940)

Lokin, M. Evaluatie van wetgeving: van praktijk naar beleid (Evaluation of Legislation: From Practice to Policy, in Dutch) *Regelmaat* (1997), pp. 131-132

Longley, D. *Health Care Constitutions*. Cavendish Publishing 1996

Luarasi, A. Albania in the Beginning of the Legal Reform in: *Legislation in European Countries*. U. Karpen (ed.) Nomos Verlaggesellschaft Baden-Baden 1996, pp. 43-52

Maihofer, W. Gesetzgebungswissenschaft in: *Gesetzgebung: kritische Überlegungen zur Gesetzgebungslehre und zur Gesetzgebungstechnik*. G. Winkler, B. Schilcher (eds). Springer Verlag 1981, pp. 12-33

Majnoni d'Intignano, B. *Health Care Financing in Europe, Health Care Reforms in Europe* (proceedings of the first meeting of the working party on health care reforms in Europe), Madrid 1992.

Malenovsky, H.E.J. Treaties in the Czech Republic: Unresolved "division of labour" between Parliament and the Constitutional Court in: *Constitutional Reform and International Law in Central and Eastern Europe*. R. Müllerson, M. Fitzmaurice and M. Andenas (eds). Kluwer Law International, The Hague 1998, pp. 279-286

Marauhn, T. Wirtschaftliche und soziale Rechte im Spiegel der Verfassungsrechtsprechung mittel- und osteuropäischer Staaten unter vergleichender Berücksichtigung der deutschen Verfassungsgerichtsbarkeit in: *Grundfragen der Verfassungsgerichtsbarkeit in Mittel- und Osteuropa*. Springer Berlin 1998, pp. 145-200

Maresceau, M. and E. Montaguti. The relations between the European Union and Central and Eastern Europe: A legal appraisal. *Common Market Law Review* (1995) Iss. 6, pp. 1327-1369

Massaro, T.A., J. Nemec and I. Kalman. Health System Reform in the Czech Republic. Policy Lessons from the Initial Experience of the General Health Insurance Company. *JAMA* (1994) Iss. 23, pp. 1870-1874

Mayntz, R. Die Implementation politischer Programme: Theoretische Überlegungen zu einem neuen Forschungsgebiet in: *Implementation politischer Programme*. R. Mayntz. Verlagsgruppe Athenäum 1980, pp. 236-249

McGoldrick, D. *The Human Rights Committee. Its Role in the Development of the International Covenant on Civil and Political Rights*. Clarendon Press, Oxford 1991

McKee, M, J. Healy. Health sector reform in Central and Eastern Europe: the professional dimension. Health Policy and Planning (1997) Iss. 4, pp. 286-295

Mei, A.P. van der and L. Waddington. Public Health and the Treaty of Amsterdam. *European J. Health Law* (1998) Iss. 2, pp. 129-154

– Free Movement of Persons within the European Communnity – Cross-Border Access to Public Benefits. Diss. Maastricht University 2001

Meulen, J.W. van der. *Euregions across the Polish borders* (in Dutch), Netherlands Institute for International Relations "Clingendael", The Hague 1997

Meijers, H., A Nollkaemper. De universele verklaring van de Rechten van de Mens bevat thans bindend verdragsrecht (Presently, the Universal Declaration includes binding treaty law, in Dutch) *NJB* (1997) Iss. 25, pp. 1113-1115

Mikule, V. and V. Sládecek. *Ústavni soudnictvi a lidská práva: Predpisy – documenty – komentáre – poznámky* (The Constitutional Judiciary and Human Rights: Legal Texts – Documents – Commentaries – Notes), Prague 1994

Miller, T.S. *The Birth of the hospital in the Byzantine Empire.* Baltimore Johns Hopkins University Press 1985

Ministry of Health and Social Welfare. *Directions of Change in the Organisation and Financing of Health Care Services* (in Polish). Ministry of Health and Social Welfare, Warsaw 1990

– *National Health Programme* (in Polish), Ministry of Health and Social Welfare, Warsaw 1990

Molinari, P.A. Le droit a la sante: de la solennite des enonces aux enjeux de l"exercice (The right to health: From the solemnity of declarations to the challenges of the practice) *Recueil international de legislation sanitaire* (1998) Iss. 1, pp. 41-58

Montgomery, J. *Health Care Law.* Oxford University Press 1997

– Recognising a Right to Health in: *Economic, Social and Cultural Rights: Progress and Achievement.* R. Beddard and D Hill (eds.) London: MacMillan 1992, pp. 184-203

Mountford, L. *Health care without frontiers? The development of a European market in health services?* London Office for Economics 2000

Mossialos, E. and J. Le Grand (eds). *Health Care and Cost Containment in the European Union.* Ashgate, Aldershot 1999

– McKee M, W. Palm, B. Karl, and F. Marhold. *The influence of EU law on the social character of health care systems in the European Union.* Report submitted to the Belgian Presedency of the European Union. Brussels 19 november 2001

Müller-Graff, P-C. Legal Framework for EU-CEEC Relations in: *Enlarging the European Union. Relations between the EU and Central and Eastern Europe.* M. Maresceau (ed.) Longman, London 1997, pp. 27-40

National Centre for Health System Management. *Study concerning adaptations of the Polish Health Policy and Legislation to the requirements of EU Membership* (Polish), Warsaw 1995

National Economic Research Associates (NERA). *Financing Health Care. The Health Care System in Hungary.* London, October 1998

– *Financing Health Care with Particular Reference to Medicines. The Health Care System in Poland.* London, November 1998

Nelson, J.M. Pension and Health Care Reforms in Hungary and Poland. *Discussion Paper Series No. 52.* Collegium Budapest Institute for Advanced Study (1998), pp. 1-51

Newhouse, J.P. Rate Adjusters for Medicare under Capitation. *Health Care Financing Review.* Annual Supplement (1986) pp. 45-55

Nickless, J. Kohll and Decker: a new hope for third-country nationals. *Eurohealth* (1999) Iss. 1, pp. 20-22

– Smits/Peerbooms: Clarification of Decker and Kohll? *Eurohealth* (2001) Iss. 4, pp. 7-10

Noll, P. *Gesetzgebungslehre.* Rowohlt, Hamburg 1973.

Nollkaemper, P.A. De grenzen van een juridische wetgevingsleer (the limitations of a legal law-making doctrine, in Dutch) in: *NJB* (1988), pp. 966-970

Nys, H. *Patiënt en Europa op zoek naar een Europees geneeskundig dienstverleningsrecht* (Patient and Europe in pursuit of a European medical provision right, in Dutch), Inaugural lecture University Maastricht 2000

Office of the Parliamentary Commissioner for Data Protection and Freedom of Information. *First Report of the Parliamentary Commissioner Hungary,* 1995. Budapest, Office of the Parliamentary Commissioner for Data Protection and Freedom of Information, I. Székely (ed.) 1996

Okechukwu, S.N. *The Right to Life and the Right to Live. Ethics of International Solidarity.* Peter Lang, Frankfurt am Main 1990

Ooik, R.H. van. Een activiteit waarbij onder bezwarende titel een dienst wordt verricht ten behoeve van de ontvanger, zonder dat materiële goederen worden geproduceerd of overgedragen". Over de Jany-uitspraak en prostitutie als economische activiteit (in Dutch). *NTER* (2002) Iss. 1-2, pp. 1-7

Orosz, E. *Hungarian Health Care System in Transition: economic exigencies – faltering health policy – distrustful public.* Workshop National Academy of Sciences/National Research Council Commission on Behavioural and Social Sciences and Education, Task Force on Economies in Transition, Washington DC, september 19-20 (1996)

– and Ellena, G. and M. Jakab. *World Bank Report Hungarian Health Care System in Transition: The Unfinished Agenda.* July 1997, pp. 1-27
Osiatynski, W. Social and Economic Rights in a new Constitution for Poland, in: Western Rights? Post-Communist Application. A. Sajó ed. Kluwer Law International, The Hague 1996, pp. 233-269
Öhlinger, T. *Methodik der Gesetzgebung: Legistische Richtlinien in Theorie und Praxis.* Springer Verlag, Wien 1982
Paaso, I. Current challenges to the principles of medical law and their new interpretation. *Medicine and Law* (1995) Iss. 7-8, pp. 611-622
Palm, W., J. Nickless, H. Lewalle and A. Coheur. *Implications of recent jurisprudence on the coordination of health care protection systems. General report produced for the Directorate-General for Employment and Social Affairs of the European Commission.* Association Internationale de la Mutualité (AIM), Brussels, May 2000
Pataki, J. *The Constitutional Court's search for Identity.* Report on Eastern Europe June 21
Peers, S. An ever Closer Waiting Room? The Case for Eastern European Accession to the European Economic Area. *Common Market Law Review* (1995) Iss.1, pp. 187-214
Pellonpää, M. Social and Cultural Rights in: R.St. J. Macdonald, F. Matscher and H. Petzold (eds). *The European System for the Protection of Human Rights.* Martinus Nijhoff Publishers, Dordrecht 1993, pp. 865-874
Plato *Politeia* V transl. by G. Koolschijn. Athenaeum, Amsterdam 1981
Potucek, M. The health care reform in Czechoslovakia after 17 november 1989. *J. Public Health Medicine* (1991), Iss. 4, pp. 290-294
– *Not Only the Market. The Role of the Market, Government and Civic Sector in the Development of Postcommunist Societies.* Central European University Press, Budapest 1999
Pozdzioch, S. New legislation in the field of public health law in Poland. *European J. Health Law* (1995) Iss. 2, pp. 261-267
Preker, A. and R.G.A. Feachem. Health and Health Care in: *Labor Markets and Social Policy in Central and Eastern Europe. The Transition and Beyond.* N. Barr (ed) Oxford University Press 1994, pp. 288-321
Prudil, L. Patients' Right in the Czech Republic in the Last Decade in: *European Centre for Advanced Legal Studies Yearly* (in press).
– and A.P. den Exter. The Czech Republic in: *International Encyclopaedia of Medical Law.* H. Nys (ed.) Kluwer Law International, The Hague 2001
Ragazzi, M. *The Concept of International Obligations Erga Omnes.* Clarandon Press, Oxford 1997
Ramcharan, B.G. *The Right to Life in International Law.* International Studies in Human Rights. Dordrecht, Martinus Nijhoff Publishers 1985
Rawls, J. *A Theory of Justice.* Harvard University Press, Cambridge 1971

Redelbach, A. Protection of the right to life by law and by other means in: *Ramcharan B.G. The Right to Life in International Law.* International Studies in Human Rights. Martinus Nijhoff Publishers, Dordrecht 1985

Ringeling, A. Wetsevaluatie (Evaluation of Legislation, in Dutch) *Regelmaat* (1995), pp. 45-56

Rödig, J. Gesetzgebungstheorie als praxisorientierte rechtswissenschaftliche Disziplin auf rechtstheoretischer Grundlage, in: *Vorstudien zu eigner Theorie der Gesetzgebung.* J. Rödig, E. Baden and H. Kindermann (eds) Bonn 1975, pp. 11-18

Roemer, R. Law and Health Policy in: *Legal Aspects of Health Policy. Issues and Trends.* R. Roemer and G. MacKray (eds). Greenwood Press Westport 1980, pp. 437-446

- Health Legislation as a Tool for Public Health and Health Policy in: *Health Legislation at the Dawn of the XXIst Century. International Digest of Health Legislation.* World Health Organization. Special Issue. (1998) Iss. 1, 1998, pp. 89-100

Roggemann, H. (ed.) *Die Verfassungen Mittel- und Osteuropas. Einführung und Verfassungstext mit Übersichten und Schaubildern.* Berlin Verlag 1999

Roscam Abbing, H.D.C. Volksgezondheid in het Verdrag van Amsterdam – Een beknopte analyse (Public Health and the Treaty of Amsterdam, in Dutch), in: *Tijdschrift voor Geneeskunde* (1998) pp. 75-80

- Public Health and the Treaty of Amsterdam: A short analysis). *European J Health Law* (1998) pp. 171-176
- The Convention on Human Rights and Biomedicine. An Appraisal of the Council of Europe. *European J Health Law* (1998) Iss. 5, pp. 377-387
- Patient in Europe of the 21st century: a health legal consideration, in: The future of European integration (in Dutch). *Ars Aequi* (2001) pp. 72-80
- Health, human rights, and health law: the move towards internationalization, with special emphasis on Europe in: *Health Legislation at the Dawn of the XXIst Century. International Digest of Health Legislation.* World Health Organization. Special Issue (1998) Iss. 1, pp. 101-112
- *International organizations in Europe and the right to health care.* Kluwer Deventer 1979

Rosenthal, U., M.P.C.M. van Schendelen and A.B. Ringeling. *Openbaar Bestuur: organisatie, politieke omgeving en beleid* (Public Administration: organisation, political environment and policy, in Dutch). Samsom Tjeenk Willink 1987

Ruiter, D.W.P. Wetgevingswetenschap of wetgevingsleer (law-making science or doctrine, in Dutch) in: *Nederlands Juristenblad* (1988) pp. 978-979

Sajó, A. How the rule of law killed Hungarian welfare reform. *East European Constitutional Review* (1996) pp. 31-41

– On Old and new Battles: obstacles to the rule of law in Eastern Europe. *Inquiry* (1995) Iss. 22, pp. 97-104
– *Western Rights? Post-Communist Application.* Kluwer Law International, The Hague 1996
Saltman, R.B. and J. Figueras (eds). *European Health Care Reform: Analysis of Current Strategies.* WHO regional Office for Europe, Copenhagen 1997
Sarnecki, P. Gesetzgebungsqualität und Gesetzgebungsverfahren in Polen in: *Gesetzgebungsverfahren und Gesetzgebungsqualität.* H. Schäffer (ed.) Manz Vienna 1992, pp. 37-40
Sauer, F. The European Community's Pharmaceutical Policy in: *Health Care in Europe after 1992.* H.E.G.M. Hermans, A.F. Casparie and J.H.P. Paelinck eds. Dartmouth Aldershot 1992, pp. 133-139
Schäffer, H. Rationalisierung der Rechtssetzung in: *Theorie der Rechtssetzung.* H. Schäffer (ed.) Manz Verlag, Wien 1988
– and A. Rácz. *Quantitative Analysis of Law: A comparative empirical study. Sources of Law in Eastern and Western Europe.* Akadémiai Kiadó, Budapest 1990
– *Gesetzgebungsverfahren und Gesetzgebungsqualität.* Manz, Vienna 1992
Schelleová, I. Organization of Judiciary in: *Survey of Lectures on Czech Law.* Masarykova univerzita Brno (1995), pp. 69-87
Schut, F.H. and H.E.G.M. Hermans. Managed Competition Reforms in the Netherlands and Its Lessons for Canada. *Dalhousie Law J.* (1997) Iss. 2, pp. 437-469
Schreckenberger, W. Krise der Gesetzgebung? in: *Gesetzgebungslehre: Grundlagen, Zugänge, Anwendung.* W. Schreckenberger, K. and W. König (eds). Stuttgart Kohlhammer 1986, pp. 21-41
Schwartz, H. In Defence of Aiming High. *East European Constitutional Review* (1992) Fall, pp. 25-28
Schwarze, J., U. Becker and C. Pollak. *The implementation of community law. Studies in the legislative and administrative policies of the European Community and its member states.* Nomos Verlagsgesellschaft Baden Baden 1994
Segest, E. Consumer Protection and the free movement of medical practitioners in the European Union. *European J. Health Law* (1997) Iss. 4, pp. 267-272
Seneca Ad Lucilius, *de Ira* transl. by J.W. Basore. J.E. Page (ed.) Heinemann London 1961
Sheiman, I. Excessive State Commitments to Free Health Care in the Russian Federation: Outcomes and Health Policy Implications in: A.P. den Exter and H.E.G.M. Hermans (eds). *The Right to Health Care in Several European Countries.* Kluwer Law International, The Hague 1999, pp. 101-114
Simon, H.A. *Administrative behaviour.* New York, 1965.

Sinuraya, T. Decentralisation of the Health Care System and Territorial Medical insurance Coverage in Russia: Friend or Foe? *European J. Health Law* (2000) Iss. 7, pp. 15-27

Sluyters, B. *Geknipt Verband* ("Die zersplitterte Zusammenhänge"), inaugural lecture Leiden University, Kluwer Deventer 1985

Sokalska, M.E. Editorial, *European J. Health Law* (1994) Iss. 1, p. 324

Sólyom, L. and G. Brunner (eds). *Constitutional Judiciary in a New Democracy. The Hungarian Constitutional Court.* University of Michigan Press, 2000

Soveroski, M. *Agenda 2000: An Appraisal of the Commission's Blueprint for Enlargement.* European Institute of Public Administration, Maastricht 1997

Somerville, M.A. Autonomy in health care, in: *Gezondheidsrecht in perspective* (health law in perspective). J.H. Hubben and H.D.C. Roscam Abbing (eds). De Tijdstroom 1993, pp. 73-87

Stalev, Z. Legal Framework and Problems of Legislation in Bulgaria in: *Legislation in European Countries.* U. Karpen (ed.). Nomos Verlaggesellschaft, Baden Baden 1996, pp. 95-113

Stark, S. Path Dependence and Privatization Strategies in East Central Europe. *East European Politics and Societies* (1992) Iss. 6, p. 19

Starmans, R. Leidl and G. Rhodes. A comparative study on cross-border hospital care in the Euregio Meuse-Rhine. *European J. Public Health* (1997) Iss. 3 supplement, pp. 33-41

Steyger, E. *Europe and its Members: a Constitutional Approach.* Dartmouth, Aldershot 1995

Swaan, A. de. Medical Police, Public Works and Urban Health in: *In Care of the State. Health Care, Education and Welfare in Europe and the USA in the Modern Era.* A. de Swaan (ed.) Polity Press Cambridge 1988

Swanborn, P.G. *Methoden van sociaal-wetenschappelijk onderzoek; inleiding in ontwerpstrategieën* (Methods of social-scientific research, in Dutch). Boom, Meppel 1984

Szurgacz, H. Entwicklungen im Polnischen Sozialrecht unter besonderer Berücksichtigung der Krankenversicherung und der Sozialhilfe in: *Rechtsberatung und Verwaltingsförderung in Mittel- und Osteuropa: Vorträge und Diskussionen im Zweiten Werkstattsgespräch zur Verwaltungs förderung der Hochschule für Verwaltungswissenschaften* Speyer, München 1994, pp. 174-175

– Das System sozialer Sicherheit in Polen in: *Soziale Sicherheit in Mitteleuropa.* T. Tomandl and W. Mazal (eds.), Orac Verlag Wien 2000, pp. 109-146

Temkin, O. and C.L. Temkin (eds). *Ancient Medicine.* Baltimore, Johns Hopkins University Press 1967

Temmink, H.A.G. Kroniek van het Europees Recht (in Dutch). *Nederlands Juristenblad* (2001) Iss. 31, pp. 1497-1505

Toebes, B.C.A. *The Right to Health as a Human Right in International Law.* Intersentia Hart, Antwerpen 1999
- Het Recht op Gezondheid: Zoektocht naar de Betekenis van een Norm (The Right to Health, in Dutch). *NJCM-Bulletin* (2000) Iss. 7-8, pp. 1158-1169

Tomasevski, K. Health Rights in: *Economic, Social and Cultural Rights. A Textbook.* A. Eide, C. Krause, A. Rosas. Martinus Nijhoff Dordrecht 1995, pp. 125-142

Topinska, I. Public vs. private safety net, past and recent trends in Poland in: *Social Protection for Countries in Transition from Planned to Market Economy.* Jate Press Szeged 1994, p. 136

Tragakes, E. Health care reforms in CCEE/NIS: Issues of Spending, Health Insurance and Efficiency in: *European Health Policy Conference: Opportunities for the Future.* Copenhagen 1994 Vol. V., pp. 55-74

Tranöy, K.E. Patient's Rights. Vital needs, human rights, health care law. *Medicine and Law* (1996) Iss. 2 pp. 183-189

Tröster, P. Das System sozialer Sicherheit in Tschechien in: *Soziale Sicherheit in Mitteleuropa.* T. Tomandl and W. Mazal (eds.), Orac Verlag Wien 2000, pp. 205-240

Twinning, W. *Karl Llewellyn and the Realistic Movement.* Weidenfeld and Nicholson, London 1973

Tymowska, K. Changes in Access to Health Care Services in Poland in: *The Right to Health Care in several European Countries.* A.P. den Exter and H.E.G.M. Hermans (eds). Kluwer Law International, The Hague 1999, pp. 127-138
- Health care under transformation in Poland. *Health Policy.* (2001), pp. 85-98
- and V. Malin and A. Alaszewski (eds). *The Contracting System in the Health Sector in England and Poland.* Olympus, Warsaw 1996

Varga, C. Transition to Rule of Law. On the Democracies Transformation in Hungary, Budapest 1995

Vass, L. Changes in Hungary's Governmental System in: *The Emergence of East Central European Parliaments: The First Steps.* Á. Ágh (ed.) Hungarian Centre of Democracy Studies Foundation, Budapest. 1994, pp. 186-197

Velden, W.G. van de. *De ontwikkeling van de wetgevingswetenschap, een rechtstheoretisch onderzoek* (The development of the science of legislation: A legal theoretical inquiry, in Dutch). Koninklijke Vermande, Lelystad 1988

Ven, W.P.M.M. van de. Market-Oriented Health Care Reforms: Trends, and Future Options. *Soc. Sc. Med.* (1996) Iss. 5, pp. 655-666
- and R.C.J.A. van Vliet, E.M. van Barneveld and L.M. Lamers. Risk-Adjusted Capitation: Recent Experiences in the Netherlands, *Health Affairs* (1994) Iss. 5, pp. 120-136

– and F.T. Schut. Should Catastrophic Risks be included in a Regulated Competitive Health Insurance Market? *Soc. Sc. Med.* (1994) Iss. 10, pp. 1459-1472

Veprek, J., Z. Papes and P. Veprek. *Czech Health Care in Economic Transformation.* CERGE-EI, 1994

Vienonen, M.A. and W.C. Wlodarczyk. Health care reforms on the European scene: evolution, revolution or seesaw? *World Health Statistics Quarterly* (1993), Iss. 1, pp. 166-169

– and J. Springett. Public Health, Primary Health Care and Health Insurance: How to bring the quest for health gain into the health sector reform in central and eastern Europe? *Eurohealth* (1998-1999) Iss. 6, pp. 17-21

Visegrády, A. Some problems of judge-made law in Central and Eastern Europe, in: Tanulmányok Benedek Ferenc Tiszteletére Pecs, *Studia Iuridica* 123, Janus Pannonius Tudományegyetem 1996, pp. 303-309

Vlemminx, F. *Het profiel van de sociale grondrechten* (The profile of social constitutional rights, in Dutch). Tjeenk Willink, Zwolle 1994

Volkai, J. *The Application of the Europe Agreement and European Law in Hungary: The Judgement of an Activist Constitutional Court on Activist Notions.* Harvard Jean Monet Working Paper (2000) 8/99. Harvard Law School, Cambridge USA, pp. 1-40

Vyborná, O. The Reform of the Czech Health Care System. *Eastern European Economics* (1995) Iss. 3, p. 80

Vyver, J.D. van de. The right to medical care. *Medicine and Law* (1989) Iss.7, pp. 579-583

Wagner, B. *Appeal as means of control of judicial decisions from the scope of social insurance. Yearbook of Polish Labour Law and Social Policy* (1994), Spec. Iss. 102-109

Waltos, S. *Introduction to the Collection of Penal Law.* Park Publ., Bielsko-Biela 1993

Williams, G. *The sanctity of life and the Criminal Law.* Faber and Faber London 1958

Winter, H.B. *Evaluatie in het wetgevingsforum. Een onderzoek naar de relatie tussen evaluatie en kwaliteit van wetgeving* (Evaluation in the legislative forum, in Dutch). Kluwer, Deventer 1996

Winterstein, A. Nailing the Jellyfish: Social Security and Competition Law. *European Common Law Review* (1999) Iss.6, pp. 324-334

Wlodarczyk, C. W. and I. Koprowska. Health Care Reform in Poland in: *Health Care Reforms in Central and Eastern Europe: Outcomes and Challenges.* E. Krizová and J. Simek (eds), Charles University Press, Prague 2000, pp. 107-121

– Healthcare reform in: *The Second Wave of Polish Reforms.* L. Kolarska-Bobinska (ed.) Institute of Public Affairs, Warszawa 2000, pp. 19-34

World Bank. *Health System Reform.* The World Bank, Washington DC 1992
World Health Organization. *Strengthening Ministries of Health for Primary Health Care.* Technical Report Series No. 766. WHO Geneva 1988
Wróblewski, J. *Einführung in die Gesetzgebungstheorie.* Manz, Wien 1984
– *Meaning and Truth in Judicial Decision.* ed. by Aulis Aarnio Juridica, Helsinki 1983
– *Contemporary Models of the Legal Sciences.* Ossolineum, Wroclaw 1989
Wronkowska, S. and A. Gwizdz. Current Problems of Legislation in Poland in: *Legislation in European Countries.* U. Karpen (ed.) Nomos Verlaggesellschaft, Baden Baden 1996, pp. 330-347
– and M. Zielinski. *Problemy I zasady redagowania tekstów prawnych*, Warsaw 1993
Zarkovic, G, A. Mielck and J. Beckmann M. *Reforms of the Health Care Systems in Former Socialist Countries: Problems, Option, Scenarios.* Medis Institut für Medizinische Informatik und Systemforschung 1994
Zweig, F. M. *Evaluation in Legislation*, Sage Publications Beverly Hills 1979.

SAMENVATTING

Gezondheidszorgwetgeving in Midden- en Oost-Europa. Toetsing van een rechtstheoretisch model

Dit proefschrift is het resultaat van een onderzoek naar een rechtstheoretisch wetgevingsmodel voor de regulering van de gezondheidszorg in enkele voormalig Oostbloklanden. Het onderzoek had als doel na te gaan of, en zo ja, in welk opzicht een nader ontwikkeld rechtstheoretisch wetgevingsmodel een bruikbaar kader vormt voor het toetsen van de opzet en inhoud van een nieuw wettelijk systeem voor de gezondheidszorg. Toetsing behelst hier het vergelijken van het feitelijke wetgevingsproces met de ontwikkelingsstadia zoals die in het rechtstheoretisch model worden onderscheiden, alsmede het beoordelen van de inhoud van wetgeving aan de hand van rechtstheoretische uitgangspunten van het gezondheidsrecht. Het idee dat aan de probleemstelling ten grondslag ligt, betreft het rationaliseren van de gezondheidszorgwetgeving door middel van een rechtstheoretische analyse van de knelpunten die zich kunnen voordoen bij de introductie van nieuwe wetgeving. De waarde van een dergelijk normatief model is gelegen in de verschillende functies van het recht in de gezondheidszorg (zoals de waarborg- en de ordenende functie), waarbij zowel aan internationale als nationale rechtsbronnen betekenis wordt toegekend. Deze rechtsbronnen bevatten de uitgangspunten waaraan onder andere economische beleidsdoelstellingen, zoals kostenbeheersing en efficiency, kunnen worden beoordeeld. Bovendien stellen deze uitgangspunten grenzen aan het beperken van de toegankelijkheid, de kwaliteit, en de structuur en financiering van de zorg.

De betekenis van rechtstheoretische uitgangspunten voor de gezondheidszorg komt mede tot uitdrukking in wetgeving die verschillende aspecten van gezondheidszorg regelt, zoals wetgeving inzake gezondheidsbescherming, de organisatie en structuur van voorzieningen, de financiering van de zorg, de kwaliteit van zorg en beroepenwetgeving, en de rechten van patiënten. Het gevaar bestaat dat in transitielanden dergelijke wetgeving op een ongecontroleerde wijze totstandkomt, zonder dat er sprake is van vooraf bestudeerde uitgangspunten, beleidsdoelstellingen en prioriteiten. Aangezien op dit moment vooral economische ontwikkelingen de hoogste beleidsprioriteit lijken te hebben, is onderzocht of wetgeving op het gebied van de gezondheidszorg aansluit bij de beleidsprioriteiten. Vooral op het terrein van de financiering van de zorg doen zich knelpunten voor ten aanzien van individueel geformuleerde aanspraken van verzekerden. In het huidige wettelijke systeem is het de vraag of in het bijzonder de introductie van marktwerking in de gezondheidszorg zonder

meer een oplossing kan zijn voor de problemen op het gebied van planning en kostenbeheersing in de zorg in Midden- en Oost-Europa. Toetsing van de opzet en inhoud van gezondheidswetgeving in drie voormalig Oostbloklanden aan de geformuleerde uitgangspunten van het ontwikkelde model moet duidelijk maken of de in gang gezette hervormingen aldaar passen binnen het rechtstheoretische kader.

Teneinde de probleemstelling te kunnen onderzoeken is in deel I aan de hand van ontwikkelingen in de rechtswetenschappelijke literatuur en internationale rechtsbronnen een theoretisch kader ontwikkeld voor de opzet en inhoud van wetgeving in de gezondheidszorg. De grondslag hiervoor wordt gevormd door Noll's *Gesetzgebungslehre* waarin een gefaseerde, cyclische wetgevingsmethode werd ontwikkeld om het besluitvormingsproces met betrekking tot de totstandkoming van wetgeving te rationaliseren, dat wil zeggen het systematisch en wetenschappelijk toetsen aan democratische rechtsnormen. Deze benadering van het wetgevingsproces, weergegeven in de vorm van een iteratief model, wordt deels bevestigd door de Poolse rechtstheoreticus Wròblewski ("Einführung in die Gesetzgebungstheorie"), alsmede hedendaagse wetgevingsjuristen (Van der Velden, Eijlander, etc.). De relevantie van een dergelijk model betreft het doen van normatieve uitspraken omtrent de rationaliteit, effectiviteit en consistentie van wetgeving.

Kritiek op de door Noll ontwikkelde methode betreft verschillende aannames waaronder de fictie van de individuele, alwetende wetgever en de rationaliteitsnotie van wetgeving. Hoewel de veronderstelling van het wetgevingsproces als een rationeel controleerbare activiteit meer een juridische fictie is dan politieke realiteit, is het streven naar een zekere mate van rationaliteit legitiem. Een dergelijk beperkte rationaliteitsnotie, aldus Nollkaemper, benadrukt naast de normatieve en juridisch-functionele functie, de politieke (instrumentele) functie van het recht. Het inherent politieke karakter van wetgeving komt tot uitdrukking in de invloed van verschillende actoren en de noodzaak tot het sluiten van compromissen, hetgeen kan interfereren met het rationeel-analytisch wetgevingsconcept. Niettemin is het ontwikkelde model niet bruikbaar om uitspraken te doen omtrent de mate waarin dergelijke politieke overwegingen rationele wetgeving beïnvloeden. Het benoemen van niet-juridisch functionele motieven kan niettemin tot op zekere hoogte bijdragen tot het optimaliseren van weloverwogen besluitvorming.

Gezien het streven naar rationaliteit is systematische evaluatie van de juridische norm noodzakelijk. Een dergelijke geïnstitutionaliseerde vorm van toetsing omtrent de effectiviteit kan naast aanpassing van de individuele norm, consequenties hebben voor het wetgevingsbeleid. Een dergelijke aanname is gebaseerd op "der Interdependenz von Einzelregelungen im Gesamt der Rechtsordnung".

Toepassing van de wetgevingsmethode binnen het gezondheidsrecht vereist een nadere invulling van het relevante rechtstheoretische kader. Normatieve beginselen die ten grondslag liggen aan het gezondheidsrecht zijn het recht op gezondheidszorg en het individuele zelfbeschikkingsrecht ofwel autonomie van de patiënt. Deze unieke gezondheidsrechtelijke beginselen, alsmede afgeleide waarden definiëren primair het normatieve kader van wetgevingsbeleid op het terrein van het gezondheidsrecht. Vastgelegd in verschillende (bindende) verdragsteksten, constituties en nationale wet- en regelgeving fungeren deze uitgangspunten als functies van het gezondheidsrecht ("law-jobs"). Deze functies zijn historisch gegroeid en zijn te typeren als waarborg- en instrumentele functies. Geclassificeerd in clusters van het gezondheidsrecht beschrijven deze functies een conceptueel kader dat overheidsingrijpen rechtvaardigt op het terrein van de volksgezondheid (bescherming, preventie en bevordering), organisatie en structuur van voorzieningen, financiering van de zorg, beroepsgroepen, kwaliteit van zorg en rechten van patiënten. Een dergelijk theoretisch kader van rechtsbeginselen en functies van het gezondheidsrecht omvat de verschillende kwaliteiten van wetgeving en is in het bijzonder relevant voor het structuren en analyseren van stelselhervormingen in transitielanden.

Begin jaren negentig hebben veel Oost-Europese landen geopteerd voor de invoering van een sociaal zekerheidssysteem gebaseerd op het zogenaamde Bismarck-model van verplichte sociale verzekeringen voor ziekte en andere risico's. De overgang van een oorspronkelijk Semashko-model, waarin het verzekeringselement ontbrak, naar een Bismarck-model met gereguleerde marktwerking heeft grote consequenties voor de opzet en inhoud van wet- en regelgeving op het terrein van de gezondheidszorg. In die context reikt het ontwikkelde rechtstheoretisch kader de leidende constitutionele beginselen aan die fungeren als normatieve standaarden voor de opzet en inrichting van wetgeving op het terrein van de gezondheidszorg.

In het laatste hoofdstuk van deel I wordt het gezondheidsrechtelijke kader geïntegreerd in het algemene wetgevingsmodel. In een dergelijk model vindt de synthese plaats tussen het wetgevingsproces, te weten de totstandkoming van de wettelijke norm, de inhoud van de wettelijke norm en het wetgevingsbeleid. Deze benadering impliceert een stapsgewijze en daarmee meer consistente benadering van het besluitvormingsproces aangaande voorgenomen hervormingen in gezondheidswetgeving en het daaraan ten grondslag liggende wetgevingsbeleid. Dit is noodzakelijk aangezien in veel Midden- en Oost-Europese landen het wetgevingsbeleid op het terrein van de gezondheidszorg getypeerd wordt als "crisis-management". Geconfronteerd met snelle en ingrijpende veranderingen in de gezondheidszorg wordt wetgeving gekenmerkt door onvoldoende

doordachte maatregelen, hetgeen samengaat met een gebrekkige systematiek binnen het wetgevingsbeleid.

Een belangrijk aspect in het debat over de noodzakelijke hervormingen in de gezondheidszorg betreft dan ook het verbeteren van de consistentie en samenhang van wetgeving. Het ontwikkelde model beoogt aan die discussie een bijdrage te leveren. Het formele theoretisch wetgevingsmodel, gerelateerd aan een rechtstheoretisch kader van normatieve parameters fungeert als methodologisch instrument en tracht het ongestructureerde wetgevingsproces nader te ordenen. Het gefaseerde model dwingt de wetgever tot een meer systematische en consistente benadering van het wetgevingsproces, waarbij het rechtstheoretische kader de primaire taken en functies van de overheid op de verschillende terreinen van het gezondheidsrecht weerspiegelt en vorm geeft. De samenhang tussen de normerende en legitimerende functies van het recht, welke tot uitdrukking komen in wetgeving, en het daaraan ten grondslag liggende wetgevingsbeleid kan leiden tot spanningen tussen de traditionele waarborgfunctie en instrumentele beleidstaken. Het cyclische model brengt deze conflicten tot uitdrukking in de relatie wetgeving-wetgevingsbeleid. Spanningen tussen enerzijds het garanderen van toegang tot zorg en kostenbeheersing anderzijds, kunnen nopen tot aanpassing van wetgeving, respectievelijk beleidswijziging. Een dergelijke rationele en systematische benadering van het wetgevingsproces impliceert een incrementele benadering van het besluitvormingsproces, zowel qua vorm als inhoud. Het ontwikkelde model voorziet daarin door uit te gaan van een geleidelijke herziening van het wettelijk kader naar een meer marktgericht gezondheidszorgstelsel, rekening houdend met de geformuleerde taken en verantwoordelijkheden van de overheid op het terrein van de gezondheidszorg.

Deel II omvat een globale toetsing van het model in drie rechtsstelsels in Midden- en Oost-Europa, te weten in Hongarije, Tsjechië en Polen. Onderzocht wordt of, en zo ja, in welk opzicht het analytische model een deugdelijk instrument is voor het toetsen van de wetgevingspraktijk in Midden- en Oost-Europa. Teneinde deze vraag te kunnen beantwoorden, wordt in drie opeenvolgende hoofdstukken het rechtstheoretische wetgevingsmodel beoordeeld op haar volledigheid en effectiviteit. In de geselecteerde rechtsstelsels hebben zich de meest vergaande wijzigingen voorgedaan op het terrein van de gezondheidszorg. De gesignaleerde problemen komen dan ook pregnant naar voren en dienen als voorbeeld voor andere landen in die regio, zoals Bulgarije, Roemenië en Slowakije. Tevens worden bovengenoemde landen als eerste geconfronteerd met de invoering van het Europees gemeenschapsrecht wanneer zij toetreden tot de Europese Unie, hetgeen de wetgever wederom noopt tot ingrijpende veranderingen in het wettelijk kader.

De opzet van dit tweede deel is steeds identiek. In eerste instantie worden de voornaamste rechtsbronnen van nationaal gezondheidsrecht onderzocht, geclassificeerd volgens de door Roemer onderscheiden functies ("law-jobs") van het gezondheidsrecht. Op basis van deze analyse is het mogelijk de huidige stand van wetgeving in de betreffende landen op een systematische manier te beoordelen en uitspraken te doen omtrent gesignaleerde tekortkomingen en mogelijke inconsistenties in het wettelijk kader, alsmede het formuleren van suggesties voor het verbeteren van de wetgevingskwaliteit.

Vergelijking van de uitkomsten heeft verschillende resultaten opgeleverd. Zo rechtvaardigen de aard en de omvang van de gesignaleerde veranderingen de conclusie dat er sprake is van een "wetgevingsrevolutie", waarbij het "socialistische" gezondheidszorgmodel ingeruild werd voor een meer "Westers" marktgericht model. De invoering van een parlementaire democratie, de rechtsstaat en fundamentele mensenrechten en vrijheden resulteerde in majeure aanpassingen in het gezondheidsrechtelijk wettelijke kader. Naast constitutionele wijzigingen zijn tevens belangrijke hervormingen doorgevoerd in wet- en regelgeving op het terrein van de volksgezondheid, de structuur en financiering van de gezondheidszorg en de rechtspositie van de patiënt. Andere gemeenschappelijke tendensen betreffen de toegenomen aandacht voor maatregelen in verband met de bevordering van de gezondheid en bescherming tegen bepaalde ziekten, de omslag van een centralistisch naar een meer gedecentraliseerd en geprivatiseerd raamwerk van gezondheidszorgvoorzieningen, gecombineerd met een stelsel van sociale ziektekostenverzekeringen, uitgevoerd door al dan niet zelfstandig opererende fondsen die zorg inkopen bij (individuele) zorgaanbieders, alsmede het vastleggen van algemene patiëntenrechten in (grond)wettelijke kaders als direct gevolg van de ratificatie van diverse internationale verdragen.

De classificatie naar clusters van wetgeving maakt duidelijk dat de beschreven ontwikkelingen in grote lijnen de systematiek van het model volgen. Een dergelijke constatering bevestigt de relevantie van het rechtstheoretische model voor de wetgevingspraktijk. Toetsing van de belangrijkste nationale rechtsbronnen aan de rechtstheoretische uitgangspunten door middel van een systematische analyse van huidige (en toekomstige) knelpunten en lacunes in wetgeving maakt het mogelijk uitspraken te doen omtrent de noodzakelijke juridische randvoorwaarden voor het invoeren van een meer gereguleerde vorm van marktwerking in de gezondheidszorg, alsmede de noodzakelijke juridische veranderingen te structureren.

Echter, in enkele opzichten wijkt de wetgevingspraktijk wel af van het idealiter geschetste patroon. Tsjechië is daarvan het meest pregnante voorbeeld. Reeds in een vroeg stadium van het transitieproces werd een

stelsel van sociale ziektekostenverzekeringen geïntroduceerd, geënt op het model van concurrerende ziektekostenverzekeraars in de Verenigde Staten. Invoering van een dergelijk nieuw stelsel in Tsjechië had dramatische gevolgen voor het waarborgen van de financiering van het systeem. Achteraf laten de gesignaleerde juridische problemen zich grotendeels herleiden tot onvoldoende doordachte wetgeving met betrekking tot de financiering van de zorg in samenhang met een vrijwel ongeclausuleerde privatisering van gezondheidszorgvoorzieningen, alsmede de te beperkte taakopvatting van de overheid in de gezondheidszorg.

Tevens blijkt dat wetgeving op het terrein van de volksgezondheid, ondanks de sterk verouderde wetgeving, geen of nauwelijks prioriteit heeft bij de wetgever, zowel in Tsjechië als Polen. Het begrip volksgezondheid was vooralsnog gebaseerd op de socialistische benadering welke de nadruk legde op beschermende maatregelen. Alarmerende gegevens omtrent de gezondheidstoestand van de bevolking, alsmede nieuwe inzichten betreffende preventie en bevordering van de volksgezondheid en de ratificatie van de Europa-Overeenkomsten, inclusief volksgezondheidsbepalingen, noopte eind jaren negentig tot herziening van het (wetgevings)beleid. Opmerkelijk zijn ook de nieuwe wettelijke regelingen betreffende het institutionele kader voor de volksgezondheid (herstructurering gezondheidsdiensten) evenals de invoering van gezondheidsbevorderende maatregelen zoals anti-tabakswetgeving en de modernisering van arbeidsomstandighedenwetgeving met gezondheidsgerelateerde bepalingen.

Gezondheidsrechtelijke hervormingen in Hongarije daarentegen benadrukken al in een vroeg stadium het belang van moderne volksgezondheidswetgeving. Anders dan in Tsjechië, is de herziening van de structuur- en financieringswetgeving in Hongarije minder ingrijpend en wordt gekenmerkt door een meer geleidelijke invoering van een sociaal ziektekostenverzekeringsmodel, alsmede de vastlegging van fundamentele patiëntenrechten in wetgeving. Niettemin wordt het ontbreken van adequate kwaliteitswetgeving als een belangrijke omissie in het Hongaarse wetgevingsbeleid gekwalificeerd. Deze constatering wordt bevestigd door recent onderzoek naar een Hongaars kwaliteitszorgsysteem, uitgevoerd door Gulácsi. Dergelijke bevindingen op grond van het rechtstheoretische model activeert de wetgever tot normerend ingrijpen.

Naast beoordeling van het gezondheidsrechtelijke kader, leert toetsing van het rechtstheoretische wetgevingsmodel aan de wetgevingsactiviteit echter dat de cyclische benadering van het juridisch besluitvormingsproces niet als zodanig door de praktijk wordt onderschreven. In het bijzonder een deugdelijke probleemanalyse voorafgaand aan, alsmede in de eindfase van het wetgevingsproces lijkt in de huidige wetgevingsactiviteit te ontbreken. Onderzoek leert evenwel dat de voornaamste problemen met

de totstandkoming van wetgeving zich juist hier voordoen. Geconstateerd wordt dat de juridische agenda van de wetgever in de onderzochte rechtsstelsels gedomineerd wordt door instrumentele waarden, zoals het realiseren van kostenbeheersing in de gezondheidszorg. Normatieve waarden lijken hieraan ondergeschikt. Deze eenzijdige benadering vindt zijn doorslag in de daarop gebaseerde wet- en regelgeving hetgeen tot grote problemen kan leiden in geval van toetsing aan (constitutionele) rechtsnormen.

Tevens geeft de gebrekkige kwaliteit van wetgeving regelmatig aanleiding tot nieuwe wetgeving dan wel aanpassing van de vastgestelde norm ("legisferitis"). Dergelijke reparaties duiden op een niet adequate analyse van mogelijke knelpunten en (neven)effecten voorafgaand aan de totstandkoming van de betreffende norm. Het belang van een dergelijk onderzoek speelt met name in het geval van ingrijpende juridische veranderingen (wijzigingen in het financieringssysteem, invoeren van een (selectief) contracteerbeleid, introduceren van patiëntenwetgeving, etc.). Lacunes in wetgeving dan wel vage normstelling als gevolg van ondeugdelijk onderzoek leiden tot handhavings- en toezichtsperikelen.

Ten slotte blijkt een systematische toetsing omtrent de effectiviteit de vastgelegde norm afwezig ("wetsevaluatie"). Hierdoor lijkt een dynamische benadering van het wetgevingsproces grotendeels te ontbreken. Niettemin vindt toetsing, hoewel op incidentele basis en met de nodig restricties, wel plaats in de vorm van rechterlijke toetsing, in het bijzonder door het Constitutionele Hof. In enkele gevallen van rechterlijke toetsing bleek dat strijdigheden met grondrechten leidde tot herziening van wetgeving (sbeleid). Hoewel de wetgevingspraktijk de cyclische benadering van het formele wetgevingsmodel niet dan wel slechts in beperkte mate lijkt te ondersteunen, doet het niets af aan de relevantie van een dergelijk rechtstheoretisch model; het structureren en systematiseren van de besluitvorming in het wetgevingsproces, teneinde de prioriteiten en de daarop gebaseerde beslissingen op basis van rationele juridische argumenten te kunnen beoordelen.

Naarmate de complexiteit van de besluitvorming toeneemt en de consequenties van bepaalde besluiten ingrijpender worden dan wel niet op voorhand duidelijk zijn, zal ook het streven naar rationele wetgeving toenemen. Een dergelijke situatie doet zich voor wanneer de betreffende landen zich aansluiten bij de Europese Unie. Op grond van de geratificeerde Europa-Overeenkomsten zijn de associatielanden gehouden zich te conformeren aan de uitgangspunten van het Europees gemeenschapsrecht. Daarnaast zullen de associatielanden op het moment van toetreding tot de Europese Unie, het "*acquis communautaire*" in zijn geheel moeten hebben vertaald in nationaal recht. Het doorvoeren van een dergelijke ingrijpende wijzigingen in bestaande wet- en regelgeving stelt de kandidaat-lidstaten

voor nieuwe problemen. Gezien de uitkomsten in de delen I en II met betrekking tot herziening van het wettelijk kader en de relevantie van het rechtstheoretische model, luidt in deel III de vraag of, en zo ja, in welk opzicht het ontwikkelde model tevens kan bijdragen aan de invoering van het communautaire recht in de nationale rechtsorde. Een positief antwoord zou uitsluitsel moeten geven over de wetenschappelijke betekenis van het model met betrekking tot het conformeren aan het gemeenschapsrecht alsmede het belang voor de wetgevingspraktijk in de kandidaat-lidstaten.

De relevantie van het model betreft onder andere de bestudering van Europeesrechtelijke implicaties, namelijk het systematisch problematiseren van mogelijke juridische gevolgen voor de nationale wetgeving in de kandidaat-lidstaten op het terrein van de gezondheid(szorg) in geval van toetreding tot de Europese Unie, waarbij het rechtstheoretische kader, aangevuld met Europeesrechtelijke uitgangspunten, fungeert als toetsingskader. Een dergelijke analyse informeert de kandidaat-lidstaten omtrent de voorwaarden van toetreding en mogelijke suggesties voor noodzakelijke aanpassingen van het wettelijke kader. Aangezien de nieuwe toetreders het acquis reeds op onderdelen hebben verwezenlijkt, is daarnaast evaluatie van de huidige stand van zaken inzake de implementatie voorwerp van onderzoek. Toetsing van het wettelijk kader aan het gezondheidsacquis verschaft de nodige informatie omtrent mogelijke problemen dan wel hiaten in het transitieproces, hetgeen aanpassing van wetgeving noodzakelijk kan maken.

De uitkomsten geven aan dat de meeste problemen zich voordoen op het terrein van de interne markt, in het bijzonder inzake de vrij verkeer bepalingen en de daarop gebaseerde uitspraken van het Europese Hof van Justitie. Weliswaar erkent het Hof de bevoegdheid van de (kandidaat)lidstaten met betrekking tot de inrichting (en de financiering) van hun nationale stelsels van sociale zekerheid, niettemin behoren zij daarbij de uitgangspunten van het gemeenschapsrecht te eerbiedigen. Een dergelijke benadering, primair georiënteerd op communautair economische principes stelt (kandidaat-)lidstaten voor de nodige problemen. Daaraan ligt ten grondslag het feit dat er binnen het huidige gemeenschapsrecht geen sprake is van een interne markt voor stelsels van gezondheidszorg.

Duidelijk is dat bij afwezigheid van een dergelijk gemeenschappelijk referentiekader, respectievelijk onduidelijkheden omtrent de precieze effecten van het gemeenschapsrecht op het wettelijk kader van de gezondheidszorg, nieuwe toetreders vooralsnog aangewezen zijn op een integrale toetsing van (mogelijke) effecten van het gemeenschapsrecht, waarbij tevens rekening gehouden moet worden met recente communautaire ontwikkelingen zoals de totstandkoming van het Handvest van grondrechten in de Europese Unie. Op grond van dit Handvest zal het Europese

Hof, zo is de verwachting, in toenemende mate betrokken worden in communautaire mensenrechtenkwesties. Voor kandidaat-lidstaten geeft dit Handvest een nieuwe dimensie aan het "approximation of laws" proces, in het bijzonder met betrekking tot mensenrechten in de gezondheidszorg.

Gegeven het betrekkelijk instabiele wettelijk kader en eerdere negatieve ervaringen met de invoering van een stelsel van sociale ziektekostenverzekeringen is behoedzaamheid geboden bij het omzetten van EG-recht in nationaal recht. Een dergelijke weloverwogen benadering ter zake van de aanpassing van nationale wetgeving naar Europees recht ligt ten grondslag aan het ontwikkelde cyclische model. De dynamische, gefaseerde benadering van het wetgevingsproces voorziet in een systematische toetsing aan het gezondheidsacquis, waarbij gesignaleerde problemen vervolgens tot eventuele bijstelling van (prioriteiten in) het harmonisatiebeleid leiden, alsmede het expliciet beargumenteren van aanpassingen in wetgeving op grond van redenen ontleend aan het gezondheidsrechtelijk normatieve kader. Een dergelijke stapsgewijze benadering beoogt, zowel qua inhoud als procedure, rationalisatie van het acquis wetgevingsproces in de kandidaat-lidstaten, alsook het versterken van de kwaliteit (effectiviteit) van wetgeving.

ZUSAMMENFASSUNG

Gesundheitsgesetzgebung Mittel- und Osteuropa. Anwendung eines rechtstheoretischen Modells

Diese Dissertation ist das Ergebnis der Forschung nach einem rechtstheoretischen Gesetzgebungsmodell für die Regulierung des Gesundheitswesens in einigen ehemaligen Ostblockstaaten. Das Ziel der Untersuchung war festzustellen, ob, und wenn ja, auf welche Weise ein näher bestimmtes rechtstheoretisches Gesetzgebungsmodell einen brauchbaren Rahmen formt, um die Organisation und den Inhalt eines neuen gesetzlichen Systems für das Gesundheitswesen zu prüfen. Überprüfung bedeutet hier das Vergleichen des faktischen Gesetzgebungsprozesses mit den Entwicklungsstadien so wie diese in dem rechtstheoretischen Modell ausgearbeitet werden sowie das Beurteilen des Inhalts der Gesetzgebung anhand von rechtstheoretischen Ausgangspunkten des Gesundheitsrechts. Der Gedanke, der der Problemstellung zugrunde liegt, betrifft das Rationalisieren der Gesetzgebung im Gesundheitswesen mittels einer rechtstheoretischen Analyse der Problempunkte, die bei der Einführung neuer Gesetzgebung auftreten können.

Der Wert eines dergleichen normativen Modells liegt in den verschiedenen Funktionen des Gesundheitsrechts (sowie die Gewährleistungs- und Ordnungsfunktionen), wobei sowohl internationalen als auch nationalen Rechtsquellen Bedeutung zuerkannt wird. Diese Rechtsquellen beinhalten die Ausgangspunkte, woran unter anderem wirtschaftspolitische Zielstellungen, sowie Kostenbeherrschung und Effizienz beurteilt werden können. Außerdem stellen diese Ausgangspunkte Grenzen an der Einschränkung der Zugänglichkeit, der Qualität, und der Struktur und Finanzierung des medizinischen Sektors.

Die Bedeutung rechtstheoretischer Ausgangspunkte kommt für das Gesundheitswesen unter anderem zum Ausdruck in Gesetzgebung, die verschiedene Aspekte des Gesundheitswesens regelt, wie die Gesetzgebung in Sachen Gesundheitsschutz, die Organisation und die Struktur von Einrichtungen, die Finanzierung der Pflege und die Berufsgesetzgebung sowie die Rechte von Patienten. Es besteht die Gefahr, dass in „Übergangsländern" eine derartige Gesetzgebung auf unkontrollierte Weise zustande kommt, ohne dass Ausgangspunkte entwickelt und Zielstellungen und Prioritäten festgestellt wurden.

Angesichts der Tatsache, dass es im Moment so scheint, als ob vor allem ökonomische Entwicklungen höchste politische Priorität genießen, wurde hier untersucht, ob Gesetzgebung auf dem Gebiet des Gesundheitswesens bei den politischen Prioritäten anschließt. Vor allen Dingen auf dem Gebiet

der Finanzierung der Pflege tauchen Probleme auf bezüglich individuell formulierter Ansprüche von Versicherten. Im heutigen gesetzlichen System stellt sich die Frage, ob im Besonderen die Einführung der Marktwirkung im Gesundheitswesen ohne weiteres eine Lösung bieten kann für die Probleme auf dem Gebiet von Planung und Kostenbeherrschung bei der Pflege in Mittel- und Osteuropa. Die Prüfung des Aufbaus und des Inhalts der Gesundheitsgesetzgebung in den drei ehemaligen Ostblockländern an den formulierten Ausgangspunkten des entwickelten Modells soll deutlich machen, ob die dort in Gang gesetzten Reformen in den rechtstheoretischen Rahmen passen.

Um die Problemstellung untersuchen zu können, wurde in Teil 1 anhand von Entwicklungen in der rechtswissenschaftlichen Literatur und in internationalen Rechtsquellen ein rechtstheoretischer Rahmen für den Aufbau und den Inhalt der Gesetzgebung im Gesundheitswesen erarbeitet. Die Grundlage dafür wurde durch Noll's Gesetzgebungslehre gelegt, in der er eine phasierte, zyklische Gesetzgebungsmethode entwickelte, um den Entscheidungsfindungsprozess in Bezug auf die Entstehung von Gesetzgebung zu rationalisieren, welches ein systematisches und wissenschaftliches Prüfen an demokratische Rechtsnormen bedeutet. Die Betrachtungsweise des Gesetzgebungsprozesses, wieder gegeben in der Form eines iterativen Modells, wird zum Teil bestätigt durch den polnischen Rechtstheoretiker Wroblewski (Einführung in die Gesetzgebungstheorie) sowie durch heutige Gesetzgebungsjuristen (Van der Velden, Eijlander, etc.). Die Relevanz eines derartigen Modells liegt in der Aussagekraft über die Rationalität, Effektivität und Konsistenz von Gesetzgebung.

Kritik auf der von Noll entwickelten Methode betrifft verschiedene Annahmen worunter die Fiktion des individuellen, allwissenden Gesetzgebers und die Idee der Rationalität von Gesetzgebung gehören. Obwohl die Unterstellung des Gesetzgebungsprozesses als eine rationell kontrollierbare Aktivität mehr eine juristische Fiktion ist als eine politische Realität, ist das Streben nach einem gewissen Maß an Rationalität doch legitim.

Eine derartige beschränkte Rationalitätsannahme, so Nollkaemper, legt neben der normativen und juristischen Funktion den Nachdruck auf die politische (instrumentelle) Funktion des Rechts. Der inhärent politische Charakter der Gesetzgebung kommt zum Ausdruck im Einfluss verschiedener Aktoren und der Notwendigkeit zum Schließen von Kompromissen, die mit dem rationell-analytischen Gesetzgebungskonzept interferieren können. Dennoch ist das entwickelte Modell nicht tauglich um Aussagen zu machen über das Ausmaß, mit dem dergleiche politische Erwägungen rationale Gesetzgebung beeinflussen. Das Benennen von nicht

juristischen funktionellen Motiven kann dennoch in gewissen Masse an der Optimalisierung wohl überlegter Gesetzgebung beitragen.

Angesichts des Strebens nach Rationalität ist die systematische Evaluierung der juristischen Normierung notwendig. Eine derartig institutionalisierte Form der Prüfung der Effektivität kann neben der Anpassung der individuellen Norm, zu Konsequenzen führen in der Gesetzgebungspolitik. Eine solche Annahme ist basiert auf "der Interpendenz von Einzelregelungen im Gesamt der Rechtsordnung".

Die Anwendung der Gesetzgebungsmethode innerhalb des Gesundheitsrechts erfordert eine nähere Ausfüllung des rechtstheoretischen Rahmens. Normative Grundsätze die dem Gesundheitsrecht zugrunde liegen sind das Recht auf Gesundheitsfürsorge und das Selbstbestimmungsrecht oder auch die Autonomie des Patienten. Diese einzigartigen gesundheitsrechtlichen Prinzipien sowie die hiervon abgeleiteten Werte definieren primär den normativen Rahmen auf dem Gebiet der Gesundheitspolitik. Festgelegt in verschiedenen (bindenden) Vertragstexten, Konstitutionen und nationaler Gesetzgebung fungieren die Ausgangspunkte als Funktionen des Gesundheitsrechts ("law-jobs"). Diese Funktionen sind historisch gewachsen und sind als Gewährleistungs- und instrumentale Funktionen zu charakterisieren.

Klassifiziert in gesundheitsrechtliche Kluster beschreiben die Funktionen einen konzeptuellen Rahmen, der auf dem Gebiet der Volksgesundheit (Schutz, Vorsorge und Förderung), der Organisation und Struktur von Einrichtungen, der Finanzierung und der Qualität der Pflege und der Rechten von Patienten staatliches Eingreifen rechtfertigt. Ein derartiger theoretischer Rahmen von Rechtsgrundlagen und Funktionen des Gesundheitsrechts umfasst die verschiedenen Qualitäten der Gesetzgebung und ist im Besonderen relevant für das Strukturieren und Analysieren von Systemreformen in Beitrittsländern.

Anfang der neunziger Jahre optierten viele Osteuropäische Länder für die Einführung eines sozialen Sicherheitssystems basiert auf dem so genannten Bismarckmodell einer sozialen Versicherungspflicht für Krankheitsfälle und andere Risiken. Der Übergang von dem ursprünglichen Semashko-Modell, in dem das Versicherungselement fehlte, zum Bismarckmodel mit regulierter Marktwirkung, hat große Auswirkungen für die Organisation und den Inhalt der Gesetzgebung. In diesem Kontext gibt der entwickelte rechtstheoretische Rahmen die führenden konstitutionellen Grundsätze an, die als normative Standards für den Aufbau und die Einrichtung von Gesetzgebung auf dem Gebiet des Gesundheitswesens fungieren.

Im letzten Kapitel des ersten Teils wurde der gesundheitsrechtliche Rahmen integriert in das allgemeine Gesetzgebungsmodell. In diesem Modell findet die Synthese statt zwischen dem Gesetzgebungsprozess, das

heißt dem Entstehen der gesetzlichen Norm, des Inhalts der gesetzlichen Norm und der Gesetzgebungspolitik. Diese Strategie impliziert einen schrittweisen und damit mehr konsistenten Ansatz des Entscheidungsprozesses über die beabsichtigten Reformen in der Gesundheitsgesetzgebung und der daran zugrunde liegenden Gesetzgebungspolitik.

Dies ist notwendig, weil in vielen Mittel- und Osteuropäischen Ländern die Gesetzgebungspolitik auf dem Gebiet des Gesundheitswesen als "Krisenmanagement" klassifiziert wird. Konfrontiert mit schnellen und eingreifenden Veränderungen wird Gesetzgebung gekennzeichnet durch ungenügend durchdachte Maßnahmen, welche mit einer mangelhaften Systematik innerhalb der Gesetzgebungspolitik parallel gehen.

Einen wichtigen Aspekt in der Debatte über notwendige Reformen im Gesundheitswesen betrifft darum die Verbesserungen der Konsistenz und des Zusammenhangs von Gesetzgebung. Mit dem entwickelten Modell wird beabsichtigt einen Beitrag zu der Diskussion zu liefern. Das formelle theoretische Gesetzgebungsmodell, gemessen an einem rechtstheoretischen Rahmen von normativen Parametern fungiert als methodologisches Instrument und beabsichtigt den unstrukturierten Gesetzgebungsprozess näher zu ordnen. Das fasierte Model zwingt den Gesetzgeber zu einer mehr systematischen und konsistenten Herangehensweise, wobei der rechtstheoretische Rahmen die primären Aufgaben und Funktionen des Staates auf verschiedenen Gebieten des Gesundheitsrechts widerspiegelt und gestaltet. Der Zusammenhang zwischen normierenden und legitimierenden Funktionen des Rechts die mittels Gesetzgebung zum Ausdruck kommen, und die daran zugrunde liegende Gesetzgebungspolitik, kann zwischen traditionellen Garantiefunktionen und instrumentalen politischen Aufgaben zu Spannungen führen. Das zyklische Modell bringt diese Konflikte in im Verhältnis Gesetzgebung und Gesetzgebungspolitik zum Ausdruck. Spannungen zwischen dem Zugang zur Pflege einerseits und der Kostenbeherrschung andererseits, kann zu gesetzgeberischen Anpassungen bzw. Kursänderungen führen. Eine derartig rationelle und systematische Beschauung des Gesetzgebungsprozess, impliziert auch diese zunehmende Betrachtung des Entscheidungfindungsprozesses sowohl qua Form als auch qua Inhalt. Das entwickelte Modell entspricht dem dadurch dass es ausgeht von einer allmählichen Umwälzung des gesetzlichen Rahmens in ein mehr marktgerichtetes Gesundheitssorgesystem, während es die formulierten Aufgaben und Verantwortlichkeiten des Staates auf dem Gebiet des Gesundheitswesens berücksichtigt.

Teil II umfasst eine globale Überprüfung des Modells in drei Rechtssystemen in Mittel- und Osteuropa, das heißt Ungarn, Tschechien und Polen. Untersucht wird hier ob und wenn ja, in welcher Hinsicht das analytische Modell ein taugliches Instrument für die Prüfung der Gesetz-

gebungspraxis in Mittel-und Osteuropa ist. Um diese Frage beantworten zu können, wird in drei aufeinander anschließenden Kapiteln das rechtstheoretische Gesetzgebungsmodell hinsichtlich ihrer Vollständigkeit und Effektivität beurteilt. In den ausgewählten Rechtssystemen haben sich die größten Veränderungen auf dem Gebiet des Gesundheitswesens vollzogen. Die wahrgenommenen Probleme kommen so auch prägnant zum Ausdruck und dienen als Beispiel für andere Länder in der Region, wie Bulgarien, Rumänien und Slowakei. Ebenso werden die genannten Länder als Erstes mit der Einführung des Gemeinschaftsrechts konfrontiert, wenn sie der Europäischen Union beitreten, welche wiederum zu eingreifenden Veränderungen in ihrer gesetzlichen Systematik führt.

Der Aufbau des zweiten Teils ist jeweils gleich. In erster Instanz werden die vornehmlichen Rechtsquellen des nationalen Gesundheitsrechts untersucht, klassifiziert nach den durch Roemer unterschiedenen Funktionen (lawjobs) des Gesundheitsrechts. Basierend auf diese Analyse ist es möglich, den jetzigen Stand der Gesetzgebung in den betreffenden Ländern auf eine systematische Art und Weise zu beurteilen und Aussagen zu machen bezüglich der signalisierten Unzulänglichkeiten und möglichen Inkonsistenzen im gesetzlichen System, sowie Empfehlungen zu formulieren für eine Verbesserung der Gesetzgebungsqualität.

Der Vergleich der Resultate hat zu verschiedenen Ergebnissen geführt. So rechtfertigen die Art und der Umfang der signalisierten Veränderungen die Schlussfolgerung, dass von einer "Gesetzgebungsrevolution" die Rede ist, wobei das "sozialistische" Gesundheitssorgmodell ersetzt wird durch ein mehr "westliches" marktorientiertes Modell. Die Einführung einer parlamentarischen Demokratie, des Rechtsstaates und grundlegenden Menschenrechten und Freiheiten resultierte in großen Anpassungen des gesundheitsrechtlichen gesetzlichen Rahmens. Neben konstitutionellen Veränderungen wurden ebenso wichtige Reformen in der Gesetzgebung auf den Gebieten der Volksgesundheit, der Struktur und Finanzierung des Gesundheitswesens und der rechtlichen Position des Patienten durchgeführt.

Andere gemeinschaftliche Tendenzen betreffen die zunehmende Aufmerksamkeit für Maßnahmen zur Förderung von Gesundheit und dem Schutz vor bestimmten Krankheiten, dem Umsturz von einem zentralistischen zu einem mehr dezentralisierten und privatisierten Rahmen von Gesundheitspflegeeinrichtungen, kombiniert mit einem System von sozialen Krankenkosten-Versicherungen, ausgeführt durch entweder oder nicht selbstständig operierende Fonds, die Pflege einkaufen bei (individuellen) Pflegeanbietern, sowie das Festlegen von allgemeinen Patientenrechten in grundgesetzlichen Zusammenhängen als direkte Folge von der Ratifikation diverser internationaler Verträge.

Die Klassifizierung in Gesetzgebungskluster macht deutlich, dass beschriebene Entwicklungen in grossen Linien die Systematik des Modells folgen. Eine edrartige Konstatierung bestätigt die Relevanz des rechtstheoretischen Modells für die Gesetzgebungspraxis. Die Prüfungder wichtigtigsten nationale Rechtsquellen an rechtstheoretischen Ausgangspunkten mittels einer systematischen Analyse von heutigen (und zukünftigen) Problempunkten und Lücken in der Gesetzgebung macht es möglich Aussagen zu machen über die notwendigen rechtlichen Voraussetzungen für die Einführung einer regulierten Form der Marktwirkung im Gesundheitswesen, und die notwendigen rechtlichen Veränderungen zu strukturieren.

Jedoch in einiger Hinsicht weicht die Gesetzgebungspraxis wohl ab von dem als ideal beschriebenen Muster. Tschechien ist dafür das meist prägnante Vorbild. Schon in einem frühen Stadium des Transponierungsprozesses wurde ein System von sozialen Krankenkosten-Versicherungen introduziert, die so waren wie das Modell von konkurrierenden Krankenkosten-Versicherungen in den Vereinigten Staaten. Die Einführung eines solchen neuen Systems hatte dramatische Folgen für die Gewährleistung der Finanzierung des Systems. Hinterher lassen sich die signalisierten Probleme größtenteils ableiten von undurchdachter Gesetzgebung bezüglich der Finanzierung der Pflege in Zusammenhang mit der so ziemlich unklausulierten Privatisierung von Gesundheitssorgeinrichtungen, sowie die beschränkte Aufgabenauffassung des Staates im Gesundheitswesen.

Ebenso scheint es, dass Gesetzgebung auf dem Gebiet von Volksgesundheit, dank der stark veralterten Gesetzgebung, bei dem Gesetzgeber keine oder kaum Priorität genießt, sowohl in Tschechien als auch in Polen. Der Begriff Volksgesundheit war bislang basiert auf der sozialistischen Herangehensweise, die den Nachdruck auf Schutzmassnahmen legte. Alarmierende Fakten bezüglich des Gesundheitszustandes der Bevölkerung, sowie neue Einsichten bezueglich der Vorsorge und die Förderung der Volksgesundheit und die Ratifizierung von europäischen Verträgen, inklusiv der Volksgesundheitsbestimmungen, führte Ende der 90iger Jahre zu Umwälzungen in der (Gesetzgebungs)politik. Bemerkenswert sind auch die neuen gesetzlichen Regelungen bezüglich des institutionellen Rahmens für die Volksgesundheit (Umstrukturierung von Gesundheitsdiensten) ebenso wie die Einführung von gesundheitsfördernden Maßnahmen wie die Anti-Tabak Gesetzgebung und die Modernisierung der Gesetzgebung über Arbeitsbedingungen mit gesundheitsrelatierten Bestimmungen.

Gesundheitsrechtliche Reformen in Ungarn dagegen betonen schon in einem frühen Stadium die Bedeutung der Volksgesundheitsgesetzgebung. Anders als in Tschechien, ist die Umwälzung der Struktur- und Finanzierungsgesetzgebung in Ungarn weniger eingreifend, sie wird

gekennzeichnet durch eine allmähliche Einführung eines sozialen Krankenversicherungmodells, sowie durch die Festlegung von fundamentalen Patientenrechten in der Gesetzgebung, Trotzdem wird das Fehlen einer adäquaten Qualitätsgesetzgebung als ein wichtiges Versäumnis in der ungarisch Gesetzgebungspolitik qualifiziert. Diese Konstatierung wird bestätigt durch jüngste Forschungen nach einem ungarischen Qualitätspflegesystem, welche durch Gulácsi ausgeführt wurden. Derartige Befindungen aufgrund des rechtstheoretischen Modells aktivieren den Gesetzgeber zu normierendem Eingreifen.

Neben der Beurteilung des gesundheitsrechtlichen Rahmens, lehrt die Überprüfung des rechtstheoretischen Gesetzgebungsmodells an die Gesetzgebungsaktivität jedoch, dass die zyklische Herangehensweise an den juristischen Entscheidungsprozess als solches nicht durch die Praxis unterschrieben wird. Insbesondere eine taugliche Problemanalyse, sowohl in der Beginn- als auch in der Endphase des Gesetzgebungsprozesses scheint in der heutigen Gesetzgebungsaktivität zu fehlen. Die Forschung lehrt ebenso, dass die vornehmlichen Probleme in der Entstehung von Gesetzgebung sich vor allen Dingen hier zeigen.

Es wird konstatiert, dass die juristische Tagesordnung des Gesetzgebers in den untersuchten Rechtssystemen durch instrumentelle Werte dominiert wird, wie das Realisieren der Kostenbeherrschung des Gesundheitswesens. Normative Werte scheinen diesen untergeordnet zu sein.

Dieses einseitige Herangehen findet seinen Durchschlag in der darauf basierten Gesetzgebung. Dieses Herangehen kann zu großen Problemen führen im Falle der Prüfung an (konstitutionellen) Rechtsnormen.

Ebenso gibt die mangelhafte Qualität der Gesetzgebung regelmäßig Anlass zu neuer Gesetzgebung sowie zur Anpassung der festgestellten Norm ("legisferitis").

Derartige Reparaturen deuten auf eine nicht adäquate Analyse von möglichen Problemen und (Neben-)Effekten vor dem Zustandekommen der betreffenden Norm. Die Bedeutung einer derartigen Untersuchung wird vor allen Dingen deutlich in Fällen von eingreifenden juristischen Veränderungen (Änderungen des Finanzsystems, Einführung einer selektiven Vertragspraxis, Einführung von Patientengesetzgebung, etc.).

Lücken in der Gesetzgebung sowie vage Normstellungen in Folge von untauglichen Untersuchungen führen zu Handhabungs- und Aufsichtsperiklen.

Abschließend erweist sich die systematische Überprüfung der Effektivität der festgelegten Norm als abwesend (Gesetzgebungsevaluierung). Dadurch scheint das dynamische Herangehen an den Gesetzgebungsprozess größtenteils zu fehlen. Trotzdem findet eine Überprüfung, obwohl nur gelegentlich und mit den notwendigen Ristriktionen, wohl statt in der Form einer gerichtlichen Überprüfung, insbesondere durch die Verfas-

sungsgerichte. In einzelnen Fällen gerichtlicher Prüfung schien es, dass Divergenzen mit Grundrechten zu Änderung der Gesetzgebungspolitik führte. Obwohl die Gesetzgebungspraxis die zyklische Herangehensweise des formellen Gesetzgebungsmodells nicht oder nur in beschränktem Ausmaß zu unterstützen scheint, ändert dies nichts an der Relevanz eines dergleichen rechtstheoretischen Modells; das Strukturieren und Systematisieren des Entscheidungsprozesses, um die Prioritäten und die darauf basierten Entscheidungen auf der Basis von rationellen juristischen Argumenten beurteilen zu können.

In dem Masse wie die Komplexität der Entscheidungsfindung zunimmt und die Konsequenzen bestimmter Beschlüsse eingreifender werden oder sich nicht gleich deutlich zeigen, wird auch das Streben nach rationeller Gesetzgebung zunehmen. Eine derartige Situation entsteht, wenn die betreffenden Länder der Europäischen Union beitreten. Aufgrund der ratifizierten Europa-Verträge sind die assoziierenden Länder gehalten, sich den Grundlagen des Europäischen Gemeinschaftsrechts anzupassen. Daneben werden die assozierenden Länder im Moment des Beitretens zur Europäischen Union das "*acquis communautaire*" in seiner Gesamtheit in nationales Recht umgesetzt haben müssen. Die Durchführung einer derartig eingreifenden Veränderung in bestehende Gesetzgebung stellt die zukünftigen Mitgliedstaaten vor neue Probleme. Angesichts der Ergebnisse in den Teilen I und II bezüglich der Revidierung des gesetzlichen Rahmens und der Relevanz des rechtstheoretischen Modells, lautet in Teil III die Frage ob, und wenn ja, in welcher Hinsicht das entwickelte Modell ebenso beitragen kann zu der Einführung des communautairen Rechts in die nationale Rechtsordnung.

Eine positive Antwort sollte Aufschluss geben können über die wissenschaftliche Bedeutung des Modells mit Bezug auf das Konformieren an Gemeinschaftsrecht sowie der Bedeutung für die Gesetzgebungspraxis in den Kandidatstaaten.

Die Bedeutung des Modells betrifft unter anderem das Studieren von europäischen Implikationen, nämlich das systematische Problematisieren von möglichen juristischen Folgen für die nationale Gesetzgebung in den Kandidat-Mitgliedstaaten auf dem Gebiet des Gesundheitswesens, im Falle des Beitritts zur Europäischen Union, wobei der rechtstheoretische Rahmen, angereichert mit Europäischen Ausgangspunkten fungiert als Prüfungskader.

Eine derartige Analyse informiert die Kandidat-Mitgliedstaten über die Voraussetzungen zum Beitritt und macht mögliche Vorschläge für die notwendige Anpassungen des gesetzlichen Rahmen.

Angesichts die neuen Beitrittsländer het "acquis communautaire" schon in Teilen verwirklicht haben, ist daneben Evaluierung des heutigen Stand der Dinge bezüglich der Implementation Untersuchungsthema. Die

Prüfung des gesetzlichen Rahmens auf das Gesundheitsacquis verschafft die notwendigen Informationen bezüglich möglicher Probleme und Lücken im Transponierungsprozess, die die Anpassung von Gesetzgebung notwendig machen.

Die Ereignisse geben an, dass die meisten Probleme auf dem Gebiet des internen Marktes auftauchen, insbesondere bei den Bestimmungen über den freien Verkehr und den darauf basierten Entscheidungen des Europäischen Gerichtshofes. Zwar kennt der Gerichtshof die Zuständigkeit der Mitgliedstaten in Bezug auf die Einrichtung (und die Finanzierung) ihrer nationalen Systemen von sozialer Sicherheit an, dennoch sind sie dabei gehalten die Ausgangspunkte des Gemeinschaftsrechts zu wahren. Ein derartiges Vorgehen, welches primär orientiert ist an den communautairen ökonomischen Prinzipien stellt die (Kandidat) Mitgliedstaten vor die notwendigen Probleme. Dem liegt die Tatsache zugrunde, dass innerhalb des heutigen Gemeinschaftsrechts kein interner Markt für Systeme des Gesundheitswesens besteht.

Deutlich ist, dass bei Abwesendheit eines derartigen gemeinschaftlichen Bezugsrahmen, bzw. bei Undeutlichkeiten bezüglich der genauen Effekte des Gemeinschaftsrechts auf das gesetzliche System des Gesundheitswesens, neue beitretende Länder zur Zeit noch angewiesen sind auf die integrale Prüfung von (möglichen) Effekten des Gemeinschaftsrechts, wobei ebenso neuere communautaire Entwicklungen berücksichtigt werden müssen sowie das Zustandekommen der Charta der Grundrechte der Europäischen Union. Auf Grund dieser Charta wird der Europäische Gerichtshof im zunehmenden Maße bezogen sein bei communautairen Menschenrechtsfragen. Für zukünftige Mitgliedstaten gibt diese Charta eine neue Dimension an der "approximation of laws" proces, insbesondere bzgl. der Menschenrechte im Gesundheitswesen.

Ausgehend von dem ziemlich instabilen gesetzlichen Rahmen und frühere negative Erfahrungen bei der Einführung eines System von sozialen Krankenkostenversicherungen ist Behutsamkeit geboten beim Umsetzen von Europäischen Recht in nationalem Recht. Ein derartiges wohlerwogenes Vorgehen über die Anpassung von nationaler Gesetzgebung an Europäischem Recht liegt dem entwickelten zyklischen Modell zugrunde.

Die dynamisch fasierte Annäherung an den Gesetzgebungsprozess bedeutet eine systematische Prüfung des Gesundheitsacquis, wobei signalisierte Probleme in Folge zu eventuellen Beistellungen von Prioritäten der Harmonisierungspraxis führen, sowie die explizite Begründung fuer Anpassungen in Gesetzgebungen basierend auf Gründe, die dem gesundheitsrechtlichen Rahmen entlehnt sind. Eine derartige schrittweise Annäherung bezweckt sowohl in Bezug auf den Inhalt als auch auf das Verfahren die Rationalisierung des Implementationsprozess in den

zukünftige Mitgliedstaaten, als auch das Verstärken der Qualität (Effektivität) von Gesetzgebung.

INDEX OF AUTHORS

INDEX OF SUBJECTS

This book examines the relevance of a theoretical model of health care law-making in several Central-Eastern European countries. Confronted with the legacy of the ancient regime, the countries selected shifted away from a 'socialist' model towards a more 'market-oriented' health care system.

From a legal perspective, this change of system imposed on government the need for drastic reforms starting with the introduction of a compulsory health insurance scheme based on the notion of solidarity. Future accession to the EU, requiring the incorporation of the acquis communautaire, has increased the complexity of legal reforms since.

Strengthening the reform process, the author developed a method of law-making based on legal-theoretical understanding. Case study research in three selected countries justifies the conclusion that the analytical model rationalises the law-making activity, including the 'EU law approximation process'.

What is more, it became apparent that the importance of this theoretical model is not restricted only to the selected countries but may also be a valuable instrument for other countries in transition in the region.

Health care law-making in Central and Eastern Europe - Review of a legal-theoretical model provides a unique resource for scholars and policy makers interested in legal reforms in Central-Eastern European health care systems.

André P. den Exter (1966) is a lecturer in health law at the Erasmus University Rotterdam, the Netherlands and founding member of the European centre for advanced legal studies in health care, at the same university.

ISBN 90-5095-253-4