

**The International Experience with Reference Pricing -
Implications for Central Eastern Europe.**

A case study on Romania and Poland

Draft 2

Bogdan Chiritoiu MD, MA

Content

Executive Summary

Introduction

Chapter I. Government Intervention in the Pharmaceutical Market

- 1.1. Health and pharmaceutical market failure
- 1.2. The increasing trend of health expenditure
- 1.3. Government intervention. Cost containment
- 1.4. Over-regulation?
- 1.5. Objectives of regulation
- 1.7. Conclusions

Chapter II. International Experience with Reference Prices

- 2.1. What is reference pricing
- 2.2. Logic of the scheme. Expected results
- 2.3. Advantages of the scheme
- 2.4. Practical results of RP
- 2.5. What did happen
- 2.6. Why did it fail
- 2.7. Adverse reactions
 - 2.7.1. Cost-shifting
 - 2.7.2. Quality of healthcare
 - 2.7.3. Implications on equity
 - 2.7.4. Effects on innovation
 - 2.7.5. Effects on stakeholders
- 2.8. Could it work?
- 2.9. Conclusions

Chapter III. Reference Pricing in Central Easter Europe.

- 3.1. Health reform in CEE
 - 3.1.1. Health status
 - 3.1.2. Structure of the health system
 - 3.1.3. Recommendations for reform
 - 3.1.4. Main features of reform
 - 3.1.5. The pharmaceutical market
- 3.2. Reference pricing in Poland
 - 3.2.1. Health system
 - 3.2.2. Pharmaceutical market
 - 3.2.3. Pharmaceutical reimbursement
- 3.3. Reference pricing in Romania
 - 3.3.1. Health system

- 3.3.2. Pharmaceutical market
- 3.3.3. Pharmaceutical reimbursement - until 1998
- 3.3.4. Recent changes - reference pricing

Chapter IV. The impact of Reference Prices in Central Eastern Europe. Discussion and Recommendations

- 3.1. Cost containment and regulation trap
- 3.2. Adverse reactions
- 3.3. Industrial policy and intellectual property
- 3.4. How to make RP work better
- 3.5. Alternative cost containment
- 3.6. Conclusions

Bibliography

Executive Summary

Background

- Reference pricing is a reimbursement method for pharmaceutical products by which
 - ⇒ *interchangeable* drugs are clustered together
 - ⇒ the payer reimburses a single reference price for any product in the cluster
 - ⇒ producers freely decide the price they are going to ask
 - ⇒ the consumer pays the difference between the producer and the reimbursed price
- According to the clustering criterion employed, there are three main variants of the RP system
 - ⇒ phase 1 - same molecule drugs are grouped together
 - ⇒ phase 2 - therapeutical class grouping (e.g. ACE inhibitors)
 - ⇒ phase 3 - clinical indication grouping (e.g. drugs that lower blood pressure)
- Following its introduction in Germany in 1989, variants of RP has been put in place in Netherlands (1991), Sweden (1993), Denmark (1993), New Zealand (1993), British Columbia (Canada) (1995) and Australia (1998)
- Under the influence of these models, and with the recommendations of the World Bank, the scheme is being introduced in the transition economies of Eastern Europe. RP exists in Poland, Czech Republic, Slovakia, it has recently been adopted in Romania (and is under consideration in Lithuania)

Objectives of the paper

- Assess the effectiveness of RP as a cost-containment instrument and its effects upon the health sector stakeholders
- Evaluate the behaviour of RP in the specific environment of Central Eastern Europe and its consistency with the health priorities of these countries

Approach

- Analysed the consequences of RP in Germany, the country that first introduced the system, where there is a longer time span to observe the effect, and on which there is the most abundant literature
- Qualified the German case, using the experience of other western countries that employed RP
- Described the RP schemes in Poland and Romania
- Estimated the consequences of RP in the CEE countries

- Formulated recommendations

Findings - RP

- RP was not effective as a cost-containment tool: it had a one-off effect, and did not limit the rate of growth in the public expenditure on drugs
- The main explanations are:
 - ⇒ RP covers only part of the market
 - ⇒ affects mainly prices and not volume
 - ⇒ there are shifts in the consumption pattern towards drugs not covered by the scheme
 - ⇒ RP creates price floors that over time forgo possible savings
 - ⇒ the implementation is marred by legal and political challenges
- Side effects
 - ⇒ cost shifting to other areas of the healthcare budget
 - ⇒ probable negative impact on the quality of care due to changes in medication and more limited access to drugs for some patients
 - ⇒ potential loss of revenues, and uncertainty due to shorter product life-cycles for the innovative pharmaceutical companies
 - ⇒ disappointed with the modest cost-containment results some governments introduced stricter legislation (e.g. hard prescribing budgets)
- There is a trade-off between the cost-containment effects and the negative impact on stakeholders: i.e. wider the clusters employed, larger are the price cuts, and more serious the side-effects
- The reimbursement policy must be co-ordinated with the whole of the health policy, to avoid cost-shifting and inefficiency

Findings - CEE

- No evidence of a cost-containment success, and no reason to expect one
- The clustering employed so far is narrow (e.g. Romania uses phase 1, Poland a close to molecule grouping phase 2)
- A tightening of regulation (e.g. introduction of prescribing budgets) is possible due to lack of cost-containment results
- The management of reference pricing is a difficult task due to poorly developed administrative capacity in CEE countries
- The negative impact on access to medication for patients (resulting in lower quality of care and cost-shifting) is a more serious problem than in western countries due to:
 - ⇒ higher differences between branded and generic products (70% compared with 30%)

⇒ lack of incentives for international producers to lower their price to the reference level (parallel trade, international comparisons, big price differences)

Recommendations

1. Eliminate artificially low reference prices:
 - ⇒ grant full and retroactive product patent recognition
 - ⇒ liberalise the domestic pharmaceutical industry (i.e. privatisation, lift price controls, eliminate direct and indirect subsidies)
 - ⇒ require bioequivalence for generic products
 - ⇒ eliminate ineffective products from the reimbursement list
2. Redesign the payment system for distributors by:
 - ⇒ allowing pharmacists to keep part of the difference between the reimbursed and the charged price, in order to give them an incentive to shop around for the best deal
 - ⇒ paying pharmacists and retailers by flat rather than proportional margins deregulating the distribution sector in order to promote competition
3. Decentralise the negotiations of the reimbursement list to the level of the newly created regional health funds, in order to break the government monopsony and improve the market structure

Conclusive remarks

- Proportional co-payments are the reimbursement method most consistent with the functioning of a market in pharmaceuticals
- Due to the tradition of informal payments for health services and the large present out-of-pocket expenditure on drugs, CEE countries are better prepared to accept co-payments
- No matter what cost containment policy will be chosen, pharmaceutical expenditure will remain a main component of the health budget, due to the reform priority of replacing in-patient with out-patient care, and drugs being relatively more expensive when compared with the low domestic wages of the health sector

Introduction

Over the last decade reference pricing (RP) has become one of the favourite reforms in drug reimbursement in OECD countries. In spite of the controversies over the policy and its questionable cost-containment effectiveness, governments all over Central Eastern Europe (CEE), prompted by consultants from international organisations, are now introducing such systems. The current literature on reference pricing does not discuss the specific problems of CEE countries. The paper addresses this missing link: it presents a review of the international experience with reference pricing, and analyses the impact of the policy in CEE, with the focus on Poland and Romania. Poland, currently the fashionable success story of post-communist transition, is the largest market in Central Eastern Europe and a prime candidate to accession in the European Union. In contrast to Poland, Romania, while physically the second country of the region, did not negotiate the transition very successfully: it is lagging in economic and political development, and is part of a later wave of European integration. Reference pricing was introduced in Poland in 1995. Romania adopted it only in 1998 and, faithful to its cautious approach to change, has chosen a less radical model of RP.

The essay discusses the aim of reference pricing, analyses its effectiveness in reaching its goal, and the broader consequences of the policy. Further, it presents the specific features of CEE healthcare, assesses the relevance of reference pricing given the priorities for these health systems, and finally discusses the effects of reference pricing in a CEE context.

To this end, the essay is structured in four chapters. The first places reference pricing in the wider context, by analysing the features of the pharmaceutical market and the rationale for government intervention. The next chapter reviews the literature on reference pricing, with an emphasis on the German experience - where RP was first introduced, and where there is more documented evidence about its effects. The third chapter briefly presents the health reform process in CEE, and then introduces the reference pricing schemes of Poland and Romania. The paper concludes with a section dedicated to analysis and recommendations.

The study argues that reference pricing has a limited scope what precluded important cost-containment effects in the countries where it was implemented. There are no reasons to expect a better performance in the CEE countries. So far, CEE has implemented the softer versions of reference pricing: Romania is using the least controversial phase 1, while Poland implemented phase 2 but with narrowly defined therapeutical classes. There is a danger that disappointed with the failure to produce savings, governments will turn to more stringent regulation, similar with the German experience, either by widening the scope of reference pricing, or introducing new regulation (e.g. hard prescribing budgets). Both would have negative consequences on the quality of care received by patients and on the innovative pharmaceutical companies. Anyhow, the specific market conditions in CEE prevent international companies lowering the price in response to the reference price, and therefore limit the access of patients to these medicine.

The study formulates a series of recommendations that could improve the working of reference price. The exclusion from the reimbursement list of ineffective and lower quality drugs would both save money and eliminate artificially low reference prices. In order to encourage distributors

to dispense cheaply the redesigning of their payment system is needed - especially, allowing pharmacists to keep part of the difference between the reimbursement and the charged price, paying pharmacists and wholesalers a flat rather than proportional margin, and / or liberalising the distribution system. The introduction of decentralised social insurance is an opportunity to water-down the monopsony of the government in the pharmaceutical market, by moving the negotiations for the reimbursement list to the level of the regional health funds. Finally, the full recognition of international patents and the liberalisation of the domestic pharmaceutical industry will make reference pricing less distorting and will be beneficial over the longer term from an industrial policy perspective.

The drugs reimbursement method most consistent with the functioning of the pharmaceutical market are proportional co-payments. The tradition of large informal payments for health services and the very significant out-of-pocket expenditure on drugs make co-payments politically more acceptable in CEE countries, than in is the case in the west. No matter what cost-containment policy is chosen, the context of low wages in the domestic health sector and internationally priced drugs, together with the priorities of health reform that emphasise market mechanisms and the move from in-patient to out-patient care will result in the pharmaceutical expenditure remaining a major component of the health budget of CEE countries.

Chapter I. Government Intervention in the Pharmaceutical Market

This chapter introduces the arguments used to justify government intervention for limiting the expenditure on pharmaceutical products. First, I describe the sources of failure in the pharmaceutical market that could lead to an excess expenditure, and the main mechanisms of government cost-containment. Then I qualify some of these alleged market failures and discuss the risks of over-regulating the industry. Finally, I mention the competing objectives of government policy, and in this context I briefly talk about the role of patent protection, that will play significant part in the argument of the paper.

1.1. Health and pharmaceutical market failure

The two practically exclusive funding sources for health services are public bodies (either taxation or tax-like social insurance) or private risk-related insurance, with fee for service paid by the consumer being rather marginal. Consequently, the cost perceived by consumer (i.e. patient) is zero. In such an institutional set-up, consumer demand is unrestrained by the cost of the medical procedure, and will grow until the (medical) benefit to the patient of an extra intervention will be zero¹. This is what Paul Krugman (1994) calls the “flat curve” of medical

¹ To be more exact, the patient still pays a cost apart from that of the medical act – e.g. time spent, travel cost etc. The demand will be expected to stabilise where the marginal benefit from the health service will equal this marginal cost, that actually is different from zero.

expenses. It is obvious that the equilibrium level will be substantially above what the maximisation of social welfare would require.

In addition, the prescription of health care is mainly in the hands of providers (i.e. health professionals) who have a built-in incentive to stimulate the demand for their services (Helms, 1981). The technical nature of the medical knowledge results in an asymmetry of information between the patient and the health professional. Moreover, the nature of the health market impedes the normal mechanism for accumulation of knowledge by the consumer: trial and error. During his/her lifetime a patient will encounter many different conditions, often not repeated, so there is little opportunity for accumulating information. More important, the risk involved in a wrong decision is prohibitively high, as one might not live to err again (Mossialos, 1993).

In addition to the failures of the health care market, there are specific traits of the pharmaceutical industry that depart from perfect competition. The large expenditure required for developing and marketing a new drug results in high barriers to entry. More important, the pharmaceutical market is very segmented in different drug classes, therefore reducing further the competition, and granting to certain companies a quasi-monopoly position in some of these sub-markets. This is reinforced by the patent system that allows up to 20 years of monopoly for the patent owner. (Taggart, 1993). The role of patents will be discussed in the section 1.7.

1.2. The increasing trend of health expenditure

The last two decades have seen a steep rise in the health expenditure (measured as percentage of GDP) in all developed countries. This trend has been somewhat restrained in the mid 1990s, but it is still worrying for public finances. It is admitted that, for whatever reason, in aggregate countries start to spend a higher percentage of GDP on health as they get richer (OECD, 1994). Nevertheless, the expenditure increases have raised concerns about the sustainability of the trend. The factors held accountable for this evolution included the rising expectations and the ageing of population. However, Abel-Smith (1994) finds that the single largest cause of increased health expenditure was the cost of new technology (i.e. including drugs).

1.3. Government intervention. Cost containment

The alleged market imperfections and the pressures on the public purse created the rationale for government intervention to contain the rise of healthcare costs. Due to the importance of the drug bill for the health systems (10 - 20% of the total health expenditure in western Europe - WHO, 1996), the relative transparency of this expenditure, and the perception of the pharmaceutical companies as enjoying excessive profits, the industry is particularly targeted by cost containment.

Cost containment measures can be directed at reducing either the supply or the demand for health goods and services. Since the industry is the supplier of drugs, those measures targeted directly at it represent a supply side intervention. The expenditure on drugs depends on the volume of

consumption and the price per unit and cost containment will target one of these two components. With the notable exception of United States², public cost containment of pharmaceutical expenditure is present under a form or another in most countries. Table 1.1 presents the cost-containment strategies used in European Union member states.

It is worth remembering that the imperfection of the health market has to do mainly with the lack of constraints on demand. Therefore, ideally the government intervention would be directed to demand measures, and there would be free pricing for medicines. However, there is a larger number of patients than health providers what makes demand side measures more difficult to administer. More significantly, political considerations dictate that the demand side measures directed at individual consumers (e.g. cost-sharing) could be only of a very limited nature. By contrast, supply side intervention targeting excessive profits by pharmaceutical companies could enjoy voter support.

² In US, the development of managed care (e.g. HMOs and PBMs) represent market answers to the original failures of the health market.

<i>Table 1.1 Alternative cost-containment strategies in the pharmaceutical sector in European Union countries</i>	
Supply-side strategies	
Fixed budgets for doctors	Fund-holding general practitioners in the United Kingdom
Indicative budgets for doctors	Germany, non-fund-holding general practitioners in the United Kingdom
Fixed budgets for pharmaceutical expenditure	Germany, Italy
Practice guidelines	France
Cost-effectiveness guidelines	United Kingdom
Prescription auditing	Several countries, but not in a systematic way, except in the United Kingdom
Disease management	Experiments in France and the United Kingdom
Positive and/or negative lists	All countries
Controlling the number of products	Denmark, Netherlands, Norway*
Development of a market for generics	Mainly Denmark, Germany, Netherlands, United Kingdom
Capitation or salary payment for first contact doctor	Several countries including Ireland, Italy, Netherlands, Spain, Sweden, United Kingdom
Ceilings on promotion expenditure	United Kingdom
Paying pharmacists on a flat rate, not percentage basis	Netherlands, United Kingdom
Demand-side strategies	
Cost sharing	All countries except the Netherlands
Health education programmes	Netherlands, United Kingdom
Developing a market for over-the-counter products	
Strategies aimed at the market as a whole	
Price controls	All countries, except Denmark, Germany, Netherlands, United Kingdom
Profit control	United Kingdom
Reference prices	Denmark, Germany, Netherlands, Sweden
Industry contributions when budgets are exceeded	Germany in 1993, France from 1995
Fixed or revenue budgets for the industry	France, Spain
Taxes on promotion expenditure	France, Spain, Sweden
Development of a market for parallel imports	Denmark, Germany, Netherlands, United Kingdom
Development of a market for generics	Mainly Denmark, Germany, Netherlands, United Kingdom

* not an EU country

Source: Mossialos E. and Abel-Smith B., *Cost-containment in the pharmaceutical sector in the EU Member States*, London: London School of Economics, 1996 (quoted in WHO 1996, p. 24)

1.4. Over-regulation?

While the case for intervention is serious, many authors seem to over react to these facts. After all, many of the imperfections of the health market are common to the other insurance markets (i.e. third-party payer) while its asymmetry of information can be found in different industries, all functioning relatively efficient under free market conditions.

The over reaction to the perceived failures of the pharmaceutical market, might have resulted in the over-regulation of the industry. Beyond the general case that can be made for the efficient allocation of resources, the risk is that a too restrictive legislation would encourage the companies to exploit commercially their already successful drugs, while restraining from the large and risky investments in research and development required for new, potentially life-saving innovative medicines.

Directing cost-containment to the pharmaceutical expenditure is a questionable priority. Drugs are, in some respects, variable costs, and therefore seem a soft target for expenditure cuts. Conversely, savings from reducing personnel expenditure or closing hospitals are more complicated, and carry more political risks. However, it is accepted that drugs are cost-effective when compared with therapeutical alternatives, like hospital care. Therefore increases in the pharmaceutical bill could still result in overall savings in the health budget.

The idea of excessive profits does not hold to a close examination. The real test is whether the rate of return on capital (RoC) is higher in the pharmaceutical industry when compared with the economy average (Statman, 1983). As Myers (1997) states, because accounting standards do not

record research and development as an investment, the result in an R&D intensive industry (like the pharmaceuticals) is the undervaluation of assets and consequently the overvaluation of the RoC rate. This lower than apparent return has to be compared with a higher than the economy average cost of capital for R&D, because of the higher risk involved. But even if with these corrections the industry enjoys 'excessive' profits, these would only signal that the industry is under-funded what could determine new entries on the market that would bring the rate of return towards the 'normal' level.

The real problem is that, while the pharmaceutical industry is oligopolistic, the insurer (payer) is practically monopolistic (i.e. monopsony) in the European countries. This could lead to counter-productive excesses. Governments face a free rider incentive. Once a drug is available, all the research and development expenses incurred by the originator company become sunk costs, and therefore the producer has the incentive to supply the drug as long as the price is higher than the variable manufacturing cost (i.e. marginal cost). In consequence a government could try to get the drug at a price close to the manufacturing cost, and expect the company to cover its research and development investment by charging a higher price in another country³. But if all the governments behaved like this, the company will not be able to cover its investment, will run a loss, and therefore will have no incentive to invest in developing new drugs (Reekie, 1997).

³ Professor Danzon from Wharton School, Pennsylvania University, in a lecture at Merck Whitehouse, in August 1998, claimed that this is actually the case, with American consumers paying a proportional larger share of research costs than European ones.

1.6. Objectives of regulation.

In addition, there are a few things worth mentioning when talking about regulation of the pharmaceutical industry. On one hand, there are measures aimed to promote the objectives of health policy. Classically, these are described as achieving an efficient use of resources in health care, both at the micro-level (e.g. individual operation or health organisation) and at the macro-level (usually described as percentage of GDP dedicated to health expenditure in the public and private sector), while providing for equity as well as for choice for patients and responsiveness to their needs (Mossialos, 1993).

The second concern of regulation is the industrial policy. Governments are interested in a strong pharmaceutical industry, able to provide exports and high quality (i.e. high value added) jobs. In this respect, the key of success of the industry is considered the capacity to produce innovative drugs, which in its turn requires a strong research and development effort (Towse, 1995). There is some tension between the two sets of objectives. Countries with a strong pharmaceutical industry tend to be more lenient on drug cost-containment⁴.

⁴ For exemplification, Mossialos in Green (1997) states that the British profit control (PPRS) was generous in the profit ceilings allowed, and did not really enforce even these ones.

1.7. Intellectual property

An essential instrument for promoting a research intensive industry is the protection of intellectual property through patents. Granting a patent actually offers the company a monopoly for a certain period of time over the production of the respective drug, allowing the company to acquire significant revenues above the manufacturing cost. This addresses a different failure of the pharmaceutical market: in the absence of patents, research discoveries represent a public good, and therefore private companies have no incentive to make the large research and development investments for new drugs, that according to Danzon (1997b) account at discounted present value for 30% of the total cost of a drug.

Patents are filed for New Chemical Entities (NCEs), that require up to ten years of development to become marketable drugs. Patents used to be granted for 15 years. Recently, the return on the capital invested in research and development seems to have declined (Balance, 1992)⁵. Possible causes are represented by the growing maturity of the industry, but also by the costs incurred from lengthier and more complicated testing procedures required for certification. One of the consequences of the latter is the reduction in the effective life of the patent – the time from the marketing of the drug to the termination of the monopoly. These factors led governments to introduce Supplementary Protection Certificates (SPC) to prolong the validity of patents with another 5 years, up to an effective life patent of 15 years (Towse, 1995).

!8. Conclusions

The guiding principle is providing the best possible health care at the lowest possible cost. Because costs are easy to quantify, while measuring health outcomes is an inexact science (even more so estimating the dynamic consequences of present decisions) it is tempting to focus on cost containment. Guaranteeing patient safety, and keeping costs within affordable limits are legitimate concerns, but equally so is the need to provide new remedies for what are today inadequately treated or non-curable diseases. An unbalanced approach, focused entirely on today's health bill does not provide for the long-term interests of the patients.

⁵ However, this is questioned by other authors. For exemplification see Reekie (1997)

Chapter II. International Experience with Reference Prices

After I addressed the rationale of cost-containment in the first chapter, I discuss now one of these cost-containment measures: reference pricing. Because the policy was first introduced in Germany in 1989, there was a longer period to observe the effects and thus most of the literature on reference pricing is based on the German case. For these reasons, I shall stay in this pattern in the following analysis. I first define reference pricing, and explain how its cost-containment effect was supposed to come about. I then look at the German experience and analyse why the policy failed to contain the drug expenditure. Next, I discuss the effects of reference pricing beyond the financing area: its impact on health sector stakeholders and upon quality of care. Finally, I examine how the cost-containment performance of reference pricing could be improved and what are the trade-offs involved.

2.1. What is reference pricing

Reference pricing is a reimbursing method for financing drug expenditure. In a nutshell, reference pricing consists of clustering a number of interchangeable drugs, and establishing a single price (i.e. ‘reference price’) at which these drugs will be reimbursed by the third party payer (social insurance or government agency). There is free pricing, so producers may set any price they see fit for their drugs, and the consumer / patient will bear the difference between the

reference and the market price. There are two crucial aspects of the scheme: the criteria for drug clustering, and the method for calculating the reference price.

According to the answer at the first question, there are three broad types of reference pricing (named in literature 'phases', even if there is no necessary chronological succession between them). Phase I represents grouping together drugs with the same active ingredient. Phase II groups together drugs with the same mechanism of action - i.e. within the same therapeutical class (e.g. ACE inhibitors). Phase III reference pricing clusters together drugs for the same clinical indication (e.g. lowering blood pressure).

Connected to this decision, is the question whether to include in the clusters only off-patent drugs (branded and generics) or group on and off-patent products together - the option applies only in the case of phase II and III models, because by definition on-patent products have a unique molecule.

The answer to the second point is less straightforward, as there are a variety of methods employed to decide the price level. The most consistent with the logic of the scheme would be the lowest price in the respective category, but the average between the lowest two (e.g. Denmark), a weighted average (Germany) or a certain percentage over the lowest price are also employed (Danzon, 1997b). Comparisons with prices in other countries could also be a considered.

2.2. Logic of the scheme. Expected results.

Policy makers expect the result of reference price to be a lower and more predictable drug expenditure. Reference pricing aims to lower the drug bill (especially the one faced by the third party payer) by two mechanisms. The difference between the reimbursed and the market price represents a co-payment the patient has to bear. As such it is expected that reference pricing reduces overall drug consumption and shifts it towards cheaper drugs. It is also argued that RP provides predictability of drug expenditure for the third party payer (at a given reimbursement price, assuming the volume constant, the drug budget can be determined) (IHSM, 1997).

2.3. Advantages of the scheme

RP has a certain number of advantageous side-effects. It is expected to create a competitive market in pharmaceuticals and in addition provides a mechanism for setting drug prices. Until the introduction of RP, competition in the medicine market was restricted to quality. Doctors were prescribing the drugs that in their view best served the clinical needs of their patients, but there was no incentive to take into account the price of the drug being prescribed. Consequently, in some countries the government intervened and decided what price the manufacturer would be allowed to charge⁶. The negotiation process was lengthy, bureaucratic and the final decision was arbitrary. RP allows the government to get out of this corner. There is one price for all producers.

⁶ Conversely, a country like Germany that had no price controls recorded higher than international average prices and drug expenditure.

If some of them believe their product deserves better, they can ask for a higher price, and let the consumer decide if the extra-benefit is worth the extra-cost.

2.4. Practical results of RP

The practical results with reference pricing did not match the theoretical expectations. Reference pricing enjoyed wide attention after it was introduced in Germany in 1989. Variants of the system has been put in place in Netherlands (1991), Sweden (1993), Denmark (1993), New Zealand (1993), British Columbia (Canada) (1995) and Australia (1998) (Danzon, 1997b). Under the influence of these models, and with the recommendations of the World Bank, the scheme is being introduced in the transition economies of Central and Eastern Europe. RP exists in Poland, Czech Republic, Slovakia, it has recently been adopted in Romania, and is under consideration in Lithuania. However, other countries that had considered RP decided against it, notably France, Finland and Italy. Reference pricing is strongly opposed by the pharmaceutical industry (see PhRMA position paper, 1995) and has encountered criticism from medical groups - see CCS (1997).

The introduction of reference pricing in Germany started with 10 products in phase 1 in 1989, increased with 62 more in 1990 - 1991. Phase 2 was implemented in 1991 and phase 3 in 1992 (Zweifel, 1996). The clustering proved controversial, especially for phase 2 and 3. Following a court decision, from 1996 onwards on-patent products can no longer be covered by reference pricing. By January 1997, the scheme covered 183 active ingredients in phase 1, 23 groups with

166 active ingredients in phase 2, and 27 combinations of active ingredients in phase 3. These products accounted for 60% of expenditure and 64% of the volume of the prescription market (Danzon, 1997b). The reference price was set somewhere in the range of the actual prices, sometimes above the average retail price in the cluster. Higher prices were granted in clusters with few generics in order to induce new entrants to the market. (ibid.)

The results of the scheme in terms of reducing the expenditure of drugs have been disappointing. They seem to be mostly of a one-off nature. German drug expenditure stagnated in 1989 (the year of the introduction of RP) but resumed its rate of growth afterwards (Zammit-Lucia, 1996). The signal of the failed expectations in reference pricing is that in 1993 Germany adopted new stringent cost-control measures for pharmaceuticals (Zweifel, 1996) - most significant was the introduction of hard overall limits in prescribing budgets. A confirmation of the lowered hopes invested in the scheme is that Denmark prognosed savings from RP of only 1% of the drug expenditure (OECD, 1994).

2.5. What did happen

Based on the German experience, the consequences of reference pricing look to be a convergence of prices in the cluster towards the reference price. There is no effect on lowering the volume of consumption. Moreover, there is a shift of consumption towards new and more expensive products, not covered by the scheme. The market share in value terms of the drugs under reference price declined from 66% in 1988 to 37% in 1995 (Danzon, 1996 b).

2.6. Why did it fail

There are a serious of factors that can explain why the expected savings did not come about. While some of them could be reasonably assumed as temporary factors, others point to fundamental flaws in the model.

Reference pricing had a difficult delivery. It encountered the opposition of health stakeholders, and it presented administrative problems. The latter is a significant matter especially in countries with an underdeveloped administrative capability and poor information technology, as is the case in CEE. More important, the concept itself of interchangeability of drugs, on which the system is based, is difficult to operationalise and was successfully challenged, inclusive in courts. In time, the administrative hurdles could be overcome, and perhaps even acceptable clustering of drugs could be entertained⁷.

Concerning the basic failures of the model, first of all, the expectation that reference pricing could make a substantial impact over the overall drug budget looked unrealistic from the very beginning. It must be remembered that reference pricing only applies to the reimbursed prescription market. By its own design, it leaves out the privately financed over the counter market and the non-reimbursed prescription market and, more significant, the publicly financed hospital market (a large market in some countries, as CEE). Moreover, when patented drugs are

excluded, this leaves out another approximately 30% even of the reimbursed prescription market (Danzon, 1997b).

A second point is that drug expenditure is the result of two factors: the price of drugs and the volume of consumption. For whatever reason, patients have been unwilling to pay a co-payment over the reference price. Faced with losses in market share, producers were forced to lower their price towards the reference level (Danzon, 1996b). The consequence is that the consumers received what they wanted: a zero co-payment, and as a consequence reference pricing had no effect on the volume of consumption. Therefore, the only mechanism left for the RP to reduce overall drug expenditure was the price component of the reimbursable prescription expense.

These savings were partly off-set by the strategy of pharmaceutical companies to introduce new products, outside the scheme, and to increase the marketing effort in order to shift consumption from the older products covered by the scheme towards the new excluded ones (Zammit-Lucia, 1996). In order to keep their patients happy by avoiding co-payments, doctors also had an incentive to shift their prescription pattern towards the products excluded from the scheme.

In addition to the unfounded expectations about savings, the claim for reference pricing to increase competition in the pharmaceutical market is also flawed. RP practically introduces a price floor, below which no producer has the incentive to go. This means that over time RP prevents savings from the reduction in price of older products and efficiency increases, that would come about in a truly competitive environment (ibid.).

⁷ The trend in medical research however, fuelled by advances in genetics, is to customize the therapy for the

Apart from the failure of its designed purpose - containing pharmaceutical expenditure - additional criticism can be laid upon reference pricing.

2.7. Adverse reactions

2.7.1. Cost shifting

An often neglected concept is that cost containment of the pharmaceutical bill is not an aim in itself, the real objective is to contain overall health expenditure. Therefore, even if the drug bill goes down but this results in higher expenditure in other sectors of the health systems, cost containment has failed. There are two mechanisms by which RP can shift costs to other areas of health care. First, given the high price differentials between on-patent and generic products, reference prices practically takes off insurance the expensive drugs, due to the high effective co-payment (in one frequently cited case in Netherlands, the co-payment was 97% of the drug price - Zammit-Lucia, 1996). This creates an incentive for patients who need this drug, to move from ambulatory to in-patient care, where the drug is available for free. Hospital care is very expensive⁸, as it includes much more than the cost of the drugs administered, what means that there is a net loss for the health system. Alternatively, denying patients the best drugs can result in a lower quality of care (e.g. negative side effects), which in turns can increase the frequency of

individual patient.

⁸ In the range of a few hundred US\$ per patient and day.

visits to doctors and the risk of requiring hospital care, both resulting in overall net financial losses for the health system.

At the heart of these objections is the fact that drugs are a bad priority for cost containment, as I mentioned in the previous chapter. Over the last two decades, OECD countries have made efforts to reduce the length of stay in hospitals, and to downsize their in-patient sectors. The implication is that, as health care shifts to the primary sector, drug bills could be expected to increase, fact acknowledge recently by a British health minister (Scrip, 08/03/98). Therefore, stringent drug cost containment measures could be actually self-defeating. It is methodologically difficult to substantiate the cost-shifting resulting from less availability of drugs, but the study by Soumerai (1994) on patients in US suffering from schizophrenia found evidence to support this hypothesis.

2.7.2. Quality of healthcare

The declared objective of health policy is to provide the best possible care at the lowest possible cost. This goal is no closer whether the reduction in resources spent on health results in a decrease of quality. Reference pricing distorts the clinical decision by forcing the patient and the doctor to think, apart from what the medical interest would require, to what the patient can afford. In addition to the economic constraints brought by the financial welfare of the patient, there is a time price paid by the doctor who has to explain the alternatives to the patient. In this context, there is an incentive for the doctor to prescribe a drug that does not require a co-

payment, whether or not the patient would have been willing to pay it. This model of imperfect agency of doctors for their patients was supported by the research of Danzon (1996b) on the German reference pricing and prescription budgets.

Both mechanisms are conducive to the patient receiving sub-optimal drug therapy. The effects are more serious more questionable the interchangeability of the drugs in the respective cluster is: i.e. they are more serious for phase II and III reference pricing. But there are problems even when phase I is employed. The clusters include variations of the basic active ingredient (e.g. different salts of the same compound) which sometimes have different bioequivalence (Garattini, 1997). Moreover, the mode and frequency of administration are important characteristics as they influence the effectiveness of the drug and the patient compliance with the treatment - e.g. the mode of administration (as in the case of asthma inhalers).

2.7.3. Implications on equity

For those who define equity as “equal care for equal need”, the introduction of any restrictions of health care according to the ability of patient to pay a co-payment is inequitable. Health policy is particularly vulnerable to such charges because those who most need health care, are generally the least able to pay for it: the very young, the old, the poor and chronically ill. The alternative is to grant exemptions from co-payments to these categories, but since they represent most of health services consumption, this would undermine the cost-containment rationale of the measures.

Apart from this problem that concerns co-payments in general, reference pricing is vulnerable to horizontal definitions of equity too. A patient could be required to pay a co-payment because the drug he reacts best to happens to be more expensive than the drug other patients with the same condition react best to.

2.7.4. Effects on innovation

Reference pricing results in shifting the competition in the pharmaceutical market from quality to price. This rewards the producers of cheaper products - the generic copies or 'me too' drugs that can afford to ask for a lower price because they do not have to recover large research and development investments. For the research based pharmaceutical companies, the life-cycle of their products is cut short, and the economic value of their patent is eroded (Danzon, 1996b). This institutional set-up represents a disincentive for companies to undertake the risky long term effort of developing new truly innovative drugs. The consequence in the long run will be fewer innovative drugs that could both improve the quality of care and, by replacing other more expensive or less effective treatments, might reduce costs as well.

2.7.5. Effects on stakeholders

In summarising the effects of reference pricing on stake-holders, one must remember that reference pricing was introduced as a cost-containment measure, therefore the payers were destined to be the main beneficiaries. However, the evidence so far suggests that RP cannot achieve its target. The limited scope of the scheme made big savings beyond its reach in the first place. The administrative costs and the shift in the pattern of prescribing eroded what savings might have been. Finally, the effective introduction of price floors reduces the scope for future savings, based on increases in manufacturing efficiency and obsolescence of the older products.

Medical practitioners see their clinical freedom eroded and patients face potential detrimental changes in medication and co-payments. Generic producers could see an initial increase in market share, but as the market leaders respond by cutting their prices the consumption pattern stabilises. The longer term advantage is that there practically is a guaranteed price floor for their products. On the other hand, this could prevent their ability to compete on price with the innovative products in the future. The research based companies are faced either with a significant loss of market share if they keep the price above the reference level, or, by reducing their price, as they most often actually behaved, they have sharply lowered revenues. Even if they can compensate for these by shifting the demand towards new products, not included in the scheme, they face a more unsecured environment, what will curtail the research effort, with negative consequences on innovation.

2.8. Could it work?

The failures of reference pricing to produce significant savings in the drug bill have been identified as: addressing too narrow a segment of the market, and allowing shifts in the consumption pattern, and from a dynamic perspective, introducing price floors. This allows the identification of mechanisms to improve the efficacy of RP as a cost-containment tool.

The possible solution for the first two shortcomings is to incorporate the whole reimbursable market. This implies including on-patent products and moving to phase II or III of the system. This is impractical for a number of reasons. First, developing clusters of interchangeable drugs based on therapeutical class (phase II) and especially on medical indication (phase III) is highly questionable from a clinical perspective. Second, putting together generic and on-patent products implies a de-insurance of the expensive drugs, what would shift costs in other areas of the health system. Alternatively, if producers respond by lowering the price to the reference level, it erodes the economic significance of the patent, with serious consequences for the incentive to invest in innovation.

Two alternative ways can be designed to deal with price floors. One variant is to allow pharmacists to substitute inside a cluster, and to keep (at least part of) the difference between the reference and the producer price - e.g. Netherlands. The downside is that this does not respect the doctor's prescribing, and therefore requires as narrow as possible a cluster in terms of clinical action. The other variant is to use the lowest price in the cluster as a criterion for establishing the

reference price, and to frequently re-negotiate the price, what would create an incentive for producers to reduce their asking price in order to increase market share (as in New Zealand - Woodfield, 1997). The disadvantage in this case is that frequent price modifications imply high information costs for doctors and patients.

Another of the shortcomings of the model, doctors' distorted prescribing due to imperfect agency, has a market solution in the competition between providers (i.e. the possibility for the patient to change the general practitioner or specialist), but this is counter balanced by the asymmetry of information between the doctor and the patient.

One of the possibilities for improving the reference price is to couple it with a more restricted positive list, purged of the older, less effective and normally cheaper drugs, that would artificially lower the reference price. Given the objections to putting together on and off-patent products, one alternative is to create generic, respective patented only clusters - this is obviously applicable in the case of phase II or III models only.

One policy that works in the opposite direction to the incentives put in place by the reference price is giving pharmacists an interest in dispensing more expensive drugs. This is the case with paying pharmacists a proportional margin with the price of the drug dispensed. Perverse incentives are present in regression schemes too: pharmacists have the interest to sell smaller packages, that being cheaper qualify for a higher percentage fee. While this might reduce some of the volume of consumption, it also results in more expensive drugs being dispensed and higher

pharmacists fees. The least distortive schemes are probably a flat fee per drug dispensed, perhaps adjusted for the package size, or capitation.

2.9. Conclusion

The classical institutional structure of the pharmaceutical market results in competition on quality, with little concern for price. Reference pricing, trying to redress this, shifts completely the emphasis on price competition, with practically no incentives for incremental quality improvements. This undermines the incentive for innovation in the industry, with serious risks for the welfare of patients over the longer run. The right balance can be struck by a finance method that incorporates cost-effectiveness measures, and addresses the whole health system, not only the drug market. As a final remark, carefully designed policies must be given time to work, and governments must avoid the regulation trap - by which new regulation is brought to improve the previous one, close its loopholes, with the result of creating a regulatory jungle that suffocates the industry, confuses the patients and health professionals and undermines the stability of the health system.

Chapter III. Reference Pricing in Central Eastern Europe

The third chapter is discussing reference pricing in the context of health reform in Central Eastern Europe. I first look at the challenges faced by these countries in term of health status and provision of health services. Then, I present the pattern of reforms in these health systems and discuss common features of the pharmaceutical market. The largest part of the chapter describes in more details the reference price schemes introduced in Poland and Romania. Since the policy has been put into place relatively recently, there are no evaluations offered. The analysis of the data presented and the conclusions of the study are reserved for the final chapter.

3.1. Health reform in CEE

Central Eastern Europe represents practically the former satellites of the Soviet Union. For the purpose of the paper, I have used the restricted definition of CEE as comprising six states: Poland, Hungary, the Czech Republic, Slovakia, Romania and Bulgaria⁹. After the collapse of communists regimes in 1989, all countries of the region have embarked on a troubled transition from state socialism towards a system based on liberal democracy and free market. The speed of political and economic changes have differed from country to country, as has the priority attached to reforming the health system. This depended on the economic situation of the country

⁹ Alternatively, the term could include (some parts of) former Yugoslavia, the three Baltic states (Lithuania, Latvia and Estonia) and even Russia, Belarus and Ukraine.

and the ideology of the government. More stable economies, and more pro-market governments have decided to tackle sooner the socialist inheritance in health. The most obvious example, on both accounts, was the Czech government of Vaclav Klaus. Poland had a radical approach to economic transformation but left health reform a lower priority. At the opposite pole, Romania had both a more cautious approach to change in general and (possibly as a consequence) had to face prioritarily an unbalanced macro economic climate. The result is that changes in healthcare have proceeded slowly, and it is only this year that reforms are actually being implemented. Notwithstanding the pace of change, all CEE countries present similarities in the starting point of reforms (both in health status and structure of the health system) and in the overall direction of change.

3.1.1. Health status

Health economics studies found that the best predictor of health status in a country is the GDP (per capita, at purchasing parity value - ppp) (Chellaraj, 1996). From this perspective, the socialist countries performed better than their wealth would have predicted. Compared to these predictions, they had higher health expenditure, longer life expectancy, and lower IMR (infant mortality rate). Their great success was in the 1960s when they successfully controlled communicable diseases morbidity through public health measures, resulting in a dramatic decrease of the rate of mortality caused by these. In addition, they provided universal coverage, and are perceived to have performed well on equity grounds (Ensor, 1993). However, since 1960s CEE life expectancy rates started to fall behind those from Western Europe. The opinion

of the experts is that they failed to cope with the rise of the non-communicable diseases as the main source of mortality, mainly self-inflicted through diet, pollution and other life-style factors (Ensor, 1993). From an epidemiological perspective, CEE countries face similar challenges as the developed world, but have fewer resources to deal with them.

3.1.2. The structure of the health system

All CEE countries had soviet-style, state-owned integrated health systems (Ensor, 1993). Health facilities were owned mainly by the central government, care was financed by national taxation, practitioners were paid (low) fixed salaries, and the management of the system was centralised within the Ministry of Health. The main complaints raised against such an institutional set-up were widespread bureaucracy and inflexibility, unresponsiveness to the needs of the patients and lack of choice of services¹⁰. The salaried system did not reward performance by the doctors (but the gratuities system partly mitigated this shortcome, with obvious effects on equity however). And there was no competition between providers. The socialist healthcare systems were provider-focused, and their performance was characterised by poor emphasis on primary and preventive care, and high inpatient to outpatient ratio (IHSM, 1997).

3.1.3. Recommendations for reform

The recommendations from foreign institutional consultants focused on tackling these problems by improving efficiency and increasing the emphasis on primary care and on public health (prevention) initiatives. The increase in efficiency was envisioned through decentralisation of ownership: either outright privatisation or transfer of ownership from the central government to the local authorities, and increased competition between providers through the payment system: capitation for general practitioners, outcome-based for specialists and case-mix for hospitals. With regards to financing, the recommendations converged towards the replacement of tax financing with mandatory (social) insurance, supplemented by co-payments, and complemented by excluding non-essential services from coverage. However, the need for a careful approach towards reforms was also emphasised. (Preker, 1994)

3.1.4. Main features of reform

In the main, reforms in all CEE countries have followed along these lines. Tax financed systems are replaced by social insurance - in effect ear-marked taxes - with the objective to solve the perceived under-funding of the healthcare system (Ensor, 1993). To foster competition between providers, all systems introduced purchaser-provider separation. But the countries differed over the decision to have competition between purchasers as well. They maintained the right of patients to choose their provider at all levels: primary, specialist and hospital care. Still, patients are required to register with one primary care doctor, who acts as gate-keeper to other services, via the referral system. (McKee, 1994).

¹⁰ In contrast, it must be mentioned that there was practically free choice of specialist or hospital, but limited by

3.1.5. The pharmaceutical market

Compared with western European countries, CEE spend proportionally more on drugs (see table). An important factor behind this spending pattern is the fact that, because of very low wages personnel expenditure takes a lower share than in west, while many drugs are priced at international standards. This pattern was accentuated in the transition period, when in order to preserve the volume of services provided, in spite of lower real resources (due to declining GDP), the wage share of public health expenditure declined (Chellaraj, 1996). Two consequences are significant for the topic of this paper. First, being a higher segment of total health expenditure, cost containment of drug expenditure is a top concern for governments - moreover, because around half of the drugs are imported, pharmaceutical consumption affects the trade balance too. Second, cost-effectiveness of drugs is lower when compared with local labour intensive therapeutical alternatives (e.g. hospital care). In addition, the poor administrative infrastructure limits the ability to implement sophisticated policies.

The level of development of the local pharmaceutical industry differs across the countries of the region. There are some common traits, however. First, there are no local innovative pharmaceutical companies - what reduces the urgency of rewarding innovation and protecting intellectual property. Actually, patent legislation has been in place all over the region, but was based on process patents instead of product ones, what made it practically ineffective. While the

geographical availability and reduced resources of the system.

legislation has been updated in the early 1990s, it means that, for a long time, locally manufactured copies of internationally on-patent drugs will still be legally available. Not having to recover sunk development investments and with low production costs, they are much cheaper than the original products, and some of them are of a good quality as well. These copies cannot however be sold in the west, so their market is restricted to the home country, and those with compatible legislation.

All six CEE countries have the accession to the European Union as a key political priority. The European Agreements of early 1990s granted them associate status with EU, and are gradually creating a free trade area (between each CEE state and EU). In addition, the Central European Free Trade Area (CEFTA) agreement complements the relation with EU by extending the absence of tariffs to the trade between CEE states. In the spring of 1998, the European Council decided to start accession negotiations with Poland, Hungary and the Czech Republic (together with Estonia and Slovenia). Romania, Bulgaria and Slovakia, together with other applicants, have been invited to a permanent conference, and their progress on economic (for the first two countries) and political reform (for the latter) will be periodically reviewed to decide when accession negotiations should begin. The preparations for EU accession imply the harmonisation of national legislation with the European legislation (*acquis communautaire*) - including patent protection. Moreover, the negotiation process makes the CEE countries vulnerable to pressure from interest groups from Member States (e.g. the European pharmaceutical industry). With almost 100 million consumers, CEE markets have a strategic importance, but the current low level of economic development (i.e. buying power) puts them in a weak bargaining position.

From an industry perspective, penetrating the small CEE markets is subordinated to preserving the rich western ones.

3.2. Reference Pricing in Poland

3.2.1. Health System

Until 1997 the health system was tax financed from the central budget, services were provided mainly by integrated organisations (ZOZ - Zakład Opieki Zdrowotnej) paid by historically based budgets, and the personnel received fixed salaries. The 1997 Health Insurance Act provided for the implementation until 1999 of payroll based social insurance, managed by non-competing regional health funds, each covering a county - voivodship¹¹. Primary care is provided on local basis on the structure of existing ZOZ, secondary care at regional level, and tertiary care is under central government control. GPs are paid by either capitation or fee for service, specialists by fee for service, and hospitals by prospective budgets. (NERA, 1997)

¹¹ The reform of public administration in 1998 has reduced the number of voivodships from 49 to 16 (interview with Helena Brus).

3.2.2. Pharmaceutical market

The Polish pharmaceutical market was estimated for 1996 at \$ 1.4 - 2.1 billion at retail prices, and \$1.2 billion at ex-manufacturer prices, making it the second largest market in Eastern Europe after Russia. The per capita expenditure was \$35 (compared with \$75 in Hungary) and is expected to rise as GDP continues to grow and the population ages. Reimbursable drugs represented 60% of the total pharmaceutical market by value, in 1995. The prescription market is divided equally between foreign and domestic producers in value terms; the latter have 75% in volume terms. Public reimbursement in 1996 amounted to \$780 million, from \$696 million in 1995, and represented 37% of the total pharmaceutical market, and 61% of spending on prescriptions. Drug reimbursement represented 12.9% of the health expenditure in 1996, and adding the hospital drug expenditure it rises to 16.7%. (NERA, 1997) - compared to 10-20% in western Europe (WHO, 1996).

The wholesale margin is 14.3%, high by European standards. Pharmacists are paid a regressive margin of 25-45% of the wholesaler price, what affected their incomes in periods of high inflation. The discounts that wholesalers or pharmacists negotiate may be retained. The trend for hospital supply is to use tender or negotiations at the central government level. There is no effective monitoring of prescriptions. The non-taxable promotional activities are restricted to 2% of turnover - substantially below what international producers actually spend. There is implicit preference for the local industry in deciding inclusion on the reimbursement list. On the other hand, local manufacturers have the prices administratively fixed by the Ministry of Finance. The

pricing decisions are taken mainly on a cost-plus basis, however there are cases when producers are forced to run losses for manufacturing certain drugs. (NERA, 1997)

Similar to the other CEE countries, the protection of intellectual property was restricted to process patents. The new law on patent protection of 1992 made the shift to product patents, but applies only to patents filed from 1993 (ibid.). Given the up to ten year period of drug development (between the discovery of the New Chemical Entity and the marketing of the drug), in practice only drugs launched after the year 2000 will be protected. Also, given patent protection of up to 20 years (through Supplementary Protection Certificates - SPC), copies of products under protection elsewhere will still be legally available in Poland as late as 2012.

3.2.3. Pharmaceutical reimbursement

Reference pricing was introduced in 1995 and grafted upon the existing list-based reimbursement system. The model used is a combination of phase one and two reference price: “pharmacologically and therapeutically comparable” products (quote from NERA, 1997, p. 80). The clusters appear to be narrow - i.e. close to molecule grouping (interview with Helena Brus). The scheme initially covered only 50 products, but was gradually extended and currently includes 400. The reference price is the lowest price in the cluster. For all prescription pharmaceuticals there is a flat fee of Zł 1.5 (= \$0.5)¹². Clusters of reimbursable drugs are divided into three lists, and the reimbursement is a certain percentage of the cluster reference price

(NERA, 1997). The methodology used for equivalence of drugs with different molecules is similar to WHO's DDD (daily defined dosages) (interview with Lukas Pfister)¹³. List 1 includes 'essential' drugs (comparable with WHO classification - *ibid.*), reimbursed 100%. List 2 consists of supplementary drugs reimbursed 70% - that is where most branded products are. List 3 groups 'less effective' drugs which are reimbursed 50%. Finally there is a fourth negative list of non-reimbursable prescription drugs. The Ministry of Health revises the lists on an annual basis. Inclusion on the reimbursement list requires price negotiation with the ministry. Generics cost on average only 20-30% of the branded versions - compared with 70-80% for western Europe. (NERA, 1997). Due to the possibility of parallel trade, international companies cannot lower the price in the relatively small Polish market below the level in the richer and larger West European markets. The substantial difference between the generic and branded price is also a disincentive for innovative companies competing on price. The large co-payment that results from the imposition of the reference pricing affects severely their sales. (interviews with Lukas Pfister and Helena Brus)

There are a large number of exceptions. Mental and chronically ill patients (including tumours) pay lower co-payments, while war veterans and disabled have access to medicines for free. In addition there is means-tested drug financial aid administered by the Ministry of Health. (NERA, 1997). Until this year 'green' prescriptions were provided to patients who could not be treated

¹² The legal ceiling is 0.5% of the average wage, therefore would allow a doubling of the current amount.

¹³ DDDs were originally designed as a statistic tool to measure the volume of drug consumption (interview with Helena Brus). Popularised by WHO, DDDs are employed by some (mainly developing country) governments for price negotiations. It is however acknowledged, including by WHO, that they are poorly suited for this task. Alternatives include basing price comparisons on the cost of the whole therapy (i.e. daily dose multiplied by the length of the therapy), or adding the effectiveness parameter through NTT (numbers needed to treat - in order to achieve a certain outcome).

with reimbursed drugs and were unable to afford their medication. With the green prescription, patients paid only the flat-fee co-payment. Foreign companies preferred to have some of their drugs dispensed on the green prescriptions rather than having them introduced on list 2 or 3 of reimbursable drugs, where they had to compete on price with cheap generics (interview with Lukas Pfister). The scheme was administered by the doctors and is considered to have been frequently abused. While in volume terms it represented 2% of drug prescriptions in 1994, the cost of the scheme represented 10% of the total drug reimbursement, and in 1995 it amounted to \$80 million. (NERA, 1997).

3.3. Reference pricing in Romania

3.3.1. Health system

After much procrastination, Romanian health reform entered a dynamic phase with the adoption of the 1997 Law on Social Health Insurance. Romanian reforms follow a convergence track with the other Central East European countries. The soviet style health system is being replaced with payroll based social insurance, capitation for GPs and prospective budgets for hospitals become the main payment schemes for providers, and the reimbursement of drugs is based on reference pricing. There is no competition between insurers. The reform process is under way, but the indications are that within these broad categories the less controversial alternatives are being chosen. This confirms the cautious approach to reform Romania had so far and avoids the worst mistakes of other CEE countries - i.e. the over-shooting of public health expenditure in the first

phase of Czech reforms. As I wrote elsewhere, I expect that the social insurance will ameliorate the macro-efficiency dimension by reducing the under-funding, but the very limited scope for competition will restrict the improvements in micro-efficiency and patient choice. The mechanism designed for public involvement is corporatist and cumbersome. This will maintain the Romanian health system provider-focused and paternalist. (Chiritoiu, 1998)

3.3.2. The pharmaceutical market

The pharmaceutical market was estimated for 1997 at \$400 million, over three times the estimation for 1992 (NERA, 1998a). According to World Bank, the real public expenditure on drugs in 1995 was almost double the minimum recorded in 1993 (Chellaraj, 1997). In 1995, partially reimbursed medicines accounted for 56% of sales, totally reimbursed ones represented 35% and non-reimbursable prescriptions and OTC (over the counter) covered the rest of 9%. (NERA, 1998a). The OTC market increased 45% over the 1992 - 1996 interval. However, the estimates for 1997, put partially reimbursed drugs at 23%, totally reimbursed ones at 24% and OTCs at 53%. This marks a substantial shift towards private expenditure (NERA, 1998b). Hospitals represented 40% of the market in 1996 (NERA 1998a) and 30% in 1997 (NERA 1998b). The per capita drug expenditure is low in comparison with other CEE countries: \$13.2 in 1995, compared with \$94 in the Czech republic and \$83 in Hungary. The market is still supplied mainly by domestic producers, but in value terms the international manufacturers are quickly increasing their share. (NERA, 1998a)

There are a few elements worth noting about the pharmaceutical sector. First, it is the sector where privatisation went furthest. The retail sector is almost entirely private (90% according to IHSM, 1997). Private capital made inroads in whole-sales too (Cohen, 1996), but the former state monopoly still has a strong market position. The domestic manufacturers are up for sale this year¹⁴. This higher proportion of private capital in the sector means that it is more sensitive to market forces, and therefore the state has less scope for administrative decisions and more for using economic incentives.

Second, Romania has the record (together with the Czech Republic) of being the highest spender on drugs in CEE (calculated as a percentage of total health expenditure). While drug expenditure stayed relatively stable over the transition years, its level at 40% of health expenditure is about double of the average for the countries of the region. A large share of the drugs is supplied by international producers. This partly explains the high proportion of health resources devoted to medicines, by the fact that pharmaceuticals are priced at international standards, while the other health services are paid for at the much lower levels of the domestic economy. In addition, the (slight) real reduction in total health expenditure over the years since 1989 has been partly compensated by a reduction in the real wage level, what further enhanced the relative proportion of the drug bill. However, the very high proportion dedicated to the pharmaceutical expenditure, and the fact that much of it pays for imports, make this area of the health budget a priority target for cost-containment.

¹⁴ The American based ICN expressed its interest.

Concerning intellectual property, the introduction of product patent (as opposed to the previous process patent) was granted in 1991 (interview with Adrian Caretu). For the same reasons discussed in the Polish section, it will have practical effects only after 2000. Recently the government approved a transitory patent regulation, due to start in November 1998, that gives retroactive protection to products elsewhere on-patent on 21st January 1998 (NERA, 1998a). There are questions over the quality of the copies sold on the Romanian market, due to the fact that the National Drug Institute does not ask for bioequivalence data for product registration (interview with Adrian Caretu).

3.3.3. Pharmaceutical reimbursement - until 1998

The reimbursement system was based on a positive list, that suffered frequent (and confusing changes). The last such list, valid until March 1998, was drafted with expert support from WHO (World Health Organisation) and included 291 INN (international non-proprietary names). The reimbursement levels were established at 50% for the employed, 75% for the retired and the unemployed, and 100% for special social groups (children under 16, students, pregnant women, former political prisoners, and war veterans) and for those suffering from serious conditions (e.g. cancer, diabetes, glaucoma, Parkinson disease) (NERA, 1998b).

The lack of public funds lead to serious delays in reimbursing the pharmacist from the health budget for the price of 'compensated' drugs. This in turn led to many pharmacies refusing to dispense drugs under the reimbursement scheme, and patients were forced to pay the full price

(IHSM, 1997). NERA (1998b) cites a study that claims that less than half of reimbursable prescriptions are actually dispensed on reimbursable terms. The failure of the government to pay on time the reimbursements, and the payment of distributors (wholesalers and pharmacists) on regressive basis give them an incentive to dispense on out of pocket basis - non-prescription and cheap prescription drugs - (ibid.), and / or products with high profit margins - smaller packages of expensive drugs (interview with Adrian Caretu).

3.3.4. Recent changes - reference pricing

IHMS (1997) recommended the introduction of fixed negotiated prices (without mentioning any criteria for negotiating the price). However, the government preferred to introduce the reference price system. This system was promoted by the World Bank and was in accordance with emulating the German experience - the model for the Romanian health reform.

Reference pricing is actually provided for by the Law on Social Health Insurance, but the wording is vague. In addition to reference pricing, the law also states that pharmacists have the obligation to dispense the cheapest product when only the active substance is indicated, and to inform the patient of the replacement options (art. 48).

The main details of the scheme emerged only this spring, through a Government Decree. It adopted the model one of reference pricing - grouping according to the active substance. Some 159 international non-proprietary names (INN) have been designated, which accounted for 32.5%

of the total retail pharmaceutical market in 1997. The clusters include both generics and patented drugs - even if it means that some INN classes contain just one drug. The reimbursement level was established at 80% of the reference price. The main exceptions are children up to 16 years old and the war veterans, who have access to medicines for free. Reimbursement prices are supposed to be revised once a year, but this was not systematically observed in the past. Lacking computers, pharmacies find very difficult to administer the reference price system (interview with Adrian Caretu).

In addition to the reference price list, there is a separate list of fully reimbursed drugs. These are 132 INNs prescribed for very serious diseases (e.g. cancer, tuberculosis, diabetes, AIDS etc.). Prices for domestic producers are regulated by the Office of Competition (from the Ministry of Finance) on a cost-plus basis, while foreign producers are allowed free pricing at entrance, but may not increase the price afterwards, and have to submit their prices in ten western countries for comparison. The hospital sector continues to provide medicines free at point of access. Hospitals are supplied by tenders for INNs. The system of paying the wholesalers and pharmacists was preserved on a regressive basis¹⁵. In addition to the cost-containment effects of reference prices, regional health authorities have the right to impose maximum prescribing monthly thresholds for physicians (both general practitioners and specialists) if they find it necessary for financial reasons. (ibid.).

Chapter IV. The impact of Reference Prices in Central Eastern Europe.

Discussion and Recommendations

4.1. Cost containment and regulation trap

Reference pricing has been introduced only in 1995 in Poland. In Romania, it was adopted in Spring of 1998, and at the time of writing we do not even have the first sales numbers after this date. It is therefore impossible to draw firm conclusions about effects of these new schemes. However there are no signs that the rate of growth of pharmaceutical expenditure in Poland has slowed down sustainably. As discussed in the section on the international experience with reference pricing, there are few reasons to expect that this will happen. Reference pricing applies only to part of the market and only to one of the components of the drug bill (i.e. price, while volume goes unaffected). Moreover, there is the danger that by targeting exclusively the pharmaceutical bill the only achievement will be to shift costs onto another component of health expenditure - resulting in net losses rather than savings. What is needed is a strategy that looks at the health expenditure as a whole. Moreover, seeing the health budgets only as an expenses list to be contained is short sighted: it ignores that there are social costs of disease - healthcare is an investment in human development.

¹⁵ 25% for a drug price of up to US\$ 5.7, 18% for a price of US\$ 5.7 - 11.5, and 12% over US\$ 11.5 (interview with Adrian Caretu).

The danger is that the government will fall into a regulation trap. Because reference pricing does not produce the expected savings, there will be a tendency to develop the regulation: refine it, close loopholes, make it more stringent - as occurred in Germany through the 1993 new regulations. In the words of Zweifel (1996), “regulation breeds regulation”. In the cases analysed, this could mean moving from first to second phase of reference pricing in Romania, broadening the therapeutical classes in Poland, and enforcing prescription budgets in both. By imposing tougher economic constrains on the medical autonomy, this would impact upon the quality of care received by patients (see Danzon 1996b), and would also go against the trend towards more market competition that underpins the current reforms in the health sector.

4.2. Adverse effects

Apart from these general remarks on reference pricing, there are a couple of points relevant to Central Eastern Europe, in particular. In large developed economies, the negative consequences of reference pricing affect especially innovative pharmaceutical companies. The documented reaction of pharmaceutical companies to the introduction of reference pricing in Germany was to reduce the prices towards the reference level (Danzon, 1996b). If this is the case, with no co-payment to pay, doctors will not change their prescribing pattern and patients their consumption pattern¹⁶. The losers are, *prima facie*, the innovative companies that had to cut their price towards the generic-based reference level. This has serious consequences on the incentive to innovate, as discussed before, but would not affect the health status of the patients over the medium term.

The situation is not the same for small markets, like those of Central Eastern Europe. As discussed in the section dealing with CEE, the priority for pharmaceutical multinationals is to safeguard their western markets. The practice of governments to use international price comparisons (sometimes called international reference) for negotiating prices with producers, is a disincentive for the latter to accept anywhere in the world prices lower than in their core markets. This is much more the case in CEE which, due to the special trade arrangements with EU, would be a major source of parallel exports. This practically rules out significantly lower prices in CEE than in EU¹⁷. Given the low generic (and copy) prices, and therefore low reference prices, patients face huge co-payments. In practice this means loss of market share for international companies, but also denying to patients access to more effective drugs. Therefore the impact of reference prices over the quality of care will be more serious in CEE than in western Europe.

4.3. Industrial policy and patent protection

The second particular aspect of CEE is intellectual property. Maintaining the current less-than-perfect patent protection offers the advantage of cheap copies of international products - what results in low reference prices. This is however a short term advantage for CEE countries. First, patent protection is going to come due to the requirements of European integration. Second, the

¹⁶ However, Danzon (1996b) found a market share gain for the generics.

¹⁷ In spite of the current emphasis on single markets, segmenting the pharmaceutical market could make economic sense. Ramsey pricing, states that for products with high joint costs (e.g. the pharmaceutical R&D) the optimal pricing is to charge consumers with high price elasticity of demand (e.g. the poorer patients of CEE) close to the

current arrangement is not an unqualified blessing: while it provides cheap versions of western drugs for the domestic market, it also closes the rich western market to domestic producers. CEE countries couple low wages with a good level technical education - these factors could support a successful generic industry. The present situation is a protectionist trap. The local manufacturers work under tight price controls - usually on a cost plus basis, but sometimes they are forced to produce some drugs at a loss (NERA, 1997). They are compensated by protectionist measures - e.g. favourable treatment in reimbursement decisions. In Romania, domestic production is one of the official criteria for reimbursement decisions (NERA, 1998b). For the government this has the advantage of keeping the reference price low, and limiting the consumption of imported drugs. However, the same policy starves the domestic industry, and acts as a disincentive to increased efficiency (because efficiency gains do not result in increased profits). This means that companies do not have the investment resources (and are under no pressure) to attain the GMP (Good Manufacturing Practice) international standard, and therefore are not accepted in important foreign markets. The deregulation of the domestic industry, coupled with the enforcement of international standards in intellectual protection, while painful on the short term, would create the premises of a strong local pharmaceutical industry - based on legitimate generic manufacturing and licensing from multinational companies.

marginal cost, and those whose demand is relatively price inelastic (e.g. more affluent western consumers) a higher price, that will cover most of the sunk cost (Danzon, 1997a).

4.4. How to make RP work better

Excluding old drugs with questionable effectiveness and the poor generic copies that do not achieve bioequivalence would save money, and eliminate a source of artificially low reference prices - what on the other hand would limit the savings.

Wholesale and retail margins are high in CEE countries (e.g. 14.3% for wholesalers, and 25-45% for pharmacists, in Poland) - tinkering with the payment system and / or allowing more competition could improve the situation. There are two objectives when designing the payment system for the distributors. On one hand, they must be given incentives to dispense cheaply. On the other hand, the economic interest of distributors must not be allowed to lower the quality of the medication received by the patient - if economic consideration need to be balanced with medical ones, the right persons to assess the trade off are the patient and the prescribing doctor, not the dispensing pharmacist. The second objective limits the right of substitution to the cases allowed by the doctor (e.g. when the doctor prescribed only the active ingredient, or specifically allowed for substitution). The first objective is satisfied when distributors are paid a flat fee, what gives less of an incentive to alter the medical prescription. In addition, when pharmacists are allowed to retain part of the difference between the reimbursement and the charged price they have the interest to dispense cheaper alternatives, and to shop for the best deals from the wholesalers. On the long run, the most economic solution is simply to deregulate wholesaler and pharmacist margins, and allow the market to operate - while still limiting the right to substitution.

The introduction of decentralised social security is an opportunity for improving the functioning of the pharmaceutical market, by moving the reimbursement negotiations to the health fund level. This will increase the transaction costs for both companies and health managers. But, it would create a market with multiple sellers and buyers, and thus break the government monopsony that is a source of abuse of market position. This is consistent with the general reform approach of using competitive mechanisms in the new health system. It would also allow for more diversity and experimentation over the list and system of reimbursement. The idea is under consideration in Poland (NERA, 1997), but not in Romania. Anyhow, due to the practically mandated absence of competition between health funds, the gains expected from this policy could not be very high.

4.5. Alternative cost containment

What are the alternatives for cost-containment? There are no easy solutions. The ideal approach is cost-effectiveness. The price of a drug would be related to the price of alternative medication or other medical intervention, that could achieve the same health outcome. While the logic is straightforward, the methodology involved could be beyond the current level of medical knowledge. Anyhow, it cannot be expected from the poor countries of Central Eastern Europe to pioneer such an approach. Reference pricing is already testing their administrative capability. Leadership must come from the developed world.

As mentioned in the first chapter, the most logical cost-containment measure are proportional co-payments. However, high co-payments would lower the quality of medication of patients and

could be considered inequitable. This could be partly mitigated by means-tested exemptions, but such exemptions would reduce the effectiveness of the co-payments. It is in the nature of the democratic process that once exemptions are granted to a certain social group, this opens the floodgates for demands from other social groups. This is more serious in the health field where most of expenditure is accounted for what are usually perceived as vulnerable groups: the old and the poor.

Unlike western Europe, CEE have a tradition of large out-of-pocket payments (especially the informal payments to health professionals). The administrative shortcomings mean that a large number of patients pay in full for their drugs, as is the case in Romania. Given this context, effective co-payments for drugs might not encounter such a strong opposition. From an economic point of view, co-payments make most sense where price elasticity is higher - as is the case with medicines, and less so for other health services like hospital care. Finally, by making the system more transparent and predictable, co-payments for drugs could also directly benefit patients.

4.6. Conclusions

A realistic position is to acknowledge that pharmaceutical expenditure is going to remain a significant component of health budgets. Due to low CEE wages, drugs are relatively more expensive than in western countries, and is to be expected to represent a higher percentage of total health expenditure. Since one of the aims of the reform process is to decrease the ratio of in-patient to out-patient, it is only consistent to accept this fact.

Selective Bibliography

Abel-Smith B., *Cost Containment and New Priorities in Health Care. A study of the European Community*, Aldershot: Avebury, 1992

Abel-Smith B., *Introduction to Health: Policy, Planning and Financing*, London and New York: Longman, 1994

Balance R., Pogany J, and Foster H., *The World's pharmaceutical Industries. An international perspective on innovation, competition and policy*, United Nations Industrial Development Organization, Brookfield (Vermont): Edward Elgar, 1992

Barr N., *The Economics of the Welfare State*, 2nd edition, Oxford et al.: Oxford UP, 1993

Canadian Cardiovascular Society (CCS), "A position paper on drug-pricing strategies for prescription pharmaceuticals in Canada", Quebec, Ontario, 1997

Chellaraj G., Adeyi O., Preker A.S. and Goldstein E., *Trends in Health Status, Services and Finance: The Transition in Central and Eastern Europe*, vol. I, World Bank Technical Papers, No. 341, World Bank, 1996

Chellaraj G., Adeyi O., Preker A.S. and Goldstein E., *Trends in Health Status, Services and Finance: The Transition in Central and Eastern Europe*, vol. II, World Bank Technical Papers, No. 348, World Bank, 1997

Chiritoiu B., "Reforming Romanian Health Care. Markets in Health and Lessons from Central Eastern Europe", unpublished paper, London School of Economics, 1998

Cohen L. C., *A Review of the Pharmaceutical Sector in Romania*, World Bank, 1996

Danzon P. M., "The Uses and Abuses of International Price Comparisons", in Helms, Robert, ed., *Competitive Strategies in the Pharmaceutical Industry*, Washington DC: AEI Press, 1996

Danzon P. M., "Reference Pricing and Physician Budgets: The German Experience in Controlling Pharmaceutical Expenditure", draft paper, University of Pennsylvania, 1996

Danzon P. M., *Pharmaceutical Price Regulation. National Policies versus Global Interests*, Washington DC: American Enterprise Institute, 1997

Danzon P. M., "Reference Pricing: Efficient Insurance Design or Monopsony Free Riding?", Conference of the Australian Pharmaceutical Manufacturers Association, September 1997

Deacon B., and Hulse M., "The Making of Post-Communist Social Policy: The Role of International Agencies" *Journal of Social Policy*, Vol. 26, Part 1, 1997.

Drummond M., Jonsson B. and Ruten F., "The role of economic evaluation in the pricing of and reimbursement of medicines", *Health Policy*, 1997, 40: 199 - 215

Ensor T., "Health system reform in former Socialist countries of Europe", *International Journal of Health Planning and Management*, vol. 8, 1993, pp. 169 - 187

Esping-Andersen G., *The Three Worlds of Welfare Capitalism*, Polity Press, 1990.

Esping-Andersen G. (ed.), *Welfare State in Transition: National Adaptation in Global Economies*, London: Sage, 1996

Evenimentul Zilei, Bucharest, 8th August, 1998

Figueras J., Saltman R. and Mossialos E., "Challenges in Evaluating Health Sector Reform: an Overview", LSE Health Discussion Paper No 8, May 1997.

Furnis J. and Zammit-Lucia J., "Reference Pricing: Worth the Risks?", Pfizer Forum, USA, 1997

Gambardella A., *Science and Innovation. The US pharmaceutical industry during the 1980s*, Cambridge et al.: Cambridge University Press, 1995

Garattini L. et al., "Is Reference Pricing Effective in Cost-Containment? The German Experience 1989 - 1992", *Pharma Pricing Review*, 1997, 2: 131 - 135

Grabowski and Vernon, "A New Look at the Returns and Risks to Pharmaceutical R&D", *Management Science*, Vol. 36, No. 7, 1990, pp. 804 - 821

Grabowski and Vernon, "Returns to R&D on New Drug Introductions in the 1980s", *Journal of Health Economics*, Vol. 13, 1994, pp. 383 - 406

Green D. G. (ed.), *Should Pharmaceutical Prices Be Regulated? The strengths and weaknesses of British Pharmaceutical Price Regulation Scheme*, Choices in Welfare No 40, Institute of Economic Affairs Health and Welfare Unit: London, 1997

Gross P. F. and Fortescue R., "Therapeutic pricing for prescribed medicines in Australia: review of similar reforms internationally and likely impact of the Government's 1997/1998 Budget Proposals", draft, Health Economic Monograph 70, 1997

Ham C., "Health care rationing", *British Medical Journal*, vol. 310, 1995

Helms R. B. (ed.), *The International Supply of Medicines. Implications for U.S. regulatory reform*, American Enterprise Institute: Washington and London, 1980

Helms, Robert B. (ed.), *Drugs and Health. Economic issues and policy objectives*, Washington and London: American Enterprise Institute, 1981

Honigsbaum F. et al., *Priority Setting for Health Care*, Oxford: Radcliffe Medical Press, 1995

Howells J. and Neary I., *Intervention and Technological Innovation, Government and pharmaceutical industry in UK and Japan*, London and Basingstoke: Macmillan, 1995

IHSM (Institute of Hygiene, Public Health and Health Services Management), BASYS, "REPEDE: Health Care Reform", Bucharest, 1997

IBRD, *World Development Indicators 1997*, Washington: IBRD, 1997

Jonsson B., "Pricing and Reimbursement of Pharmaceuticals in Sweden", *Pharmaeconomics*, 1996, 6: 51-60

Krugman P., *The Age of Diminished Expectation. US Economic Policy in the 1990s*, 2nd edition, London and Cambridge, Massachusetts: MIT Press, 1994

Le Grand J and Bartlett W. (eds.), *Quasi-Markets and Social Policy*, Macmillan Press, 1993.

Maasen B. M., "Reimbursement of Medicinal Products: The German Reference Price System", Centre for the New Europe, Belgium, 1996

McKee M., Bobak M., Kalina K., Bojan F. and Enachescu D., "Health Sector Reform in the Czech Republic, Hungary and Romania", *Croatian Medical Journal*, 35(4), 1994.

Mossialos E., Kanavos P., and Abel-Smith B., *Policy Options for Pharmaceutical Industry Research & Development in the European Community*, Occasional Papers in Health Policy No. 1, London: LSE Health, 1993

Mullen F., "Czech healthcare reforms since 1992: How successful have they been in achieving efficiency, responsiveness, choice and equity?", unpublished paper, LSE, 1998

Myers S. C. and Christopher D. H., "A Lifecycle Financial Model of Pharmaceutical R&D", MIT Working Paper, 1997

NERA (National Economic Research Associates), "The Health Care System in Poland", draft, 1997

NERA, "The Health Care System in Romania", draft, 1998

NERA, "Initial Thoughts on a Pharmaceutical Reimbursement Policy for Romania", London, 1998

OECD, *The Reform of Health Care Systems: A Review of Seventeen OECD Countries*, OECD Policy Studies No 5, 1995.

OECD, *New Directions in Health Care Policy*, OECD Policy studies No 7, 1995.

Parker J. E. S., *The International Diffusion of Pharmaceuticals*, London and Basingstoke: Macmillan, 1984

PhRMA, "Reference Pricing", position paper, 1995

Preker A. S. and Feachem R., "Health and Health Care" in Barr, Nicholas, ed., *Labor Markets and Social Policy in Central and Eastern Europe*, IBRD, New York et al.: Oxford UP, 1994

Preker A. S., Feachem R., *Market Mechanisms and the Health Sector in Central and Eastern Europe*, World Bank Technical Paper No 293, 1995.

Reekie D., "The PPRS: Regulation Without a Cause?" in Green (1997)

Saltman R. B. and Figueras J. (eds.), *European Healthcare Reform: Analysis of Current Strategies*, WHO Regional Publications, European Series No. 72, WHO 1997

Scrip, 8th August 1998

Soumerai S. S., "Effects of limiting Medicaid drug reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia", *NEJM*, 1994, 331-10: 650 - 655

Statman M., *Competition in the Pharmaceutical Industry: the declining profitability of drug innovation*, Studies in Health Policy, Washington: American Enterprise Institute for Public Policy Research, 1983

Taggart J., *The World Pharmaceutical Industry*, London and New York: Routledge, 1993

The Economist, "Health Care in America", March 7, 1998

Towse A. (ed.), *Industrial Policy and the Pharmaceutical Industry*, London: Office of Health Economics, 1995

Woodfield A., Fountain J., and Borren P., *Money and Medicines: An Economic Analysis of reference Pricing and Related Public Sector Cost-Containment Systems for Pharmaceuticals with Special reference to New Zealand*, Spectrum Print: Christchurch, New Zealand, 1997

World Health Organization, *European Health Care Reforms. Analysis of Current Strategies. Summary*, Copenhagen, 1996

World Health Organization European Regional Office, *Health in Europe*, on-line version

Zammit-Lucia J. and Dasgupta R., “Reference Pricing: The European Experience”, Health Policy Review Paper 10, Imperial College of Science and St. Mary’s Hospital, UK, 1996

Zammit-Lucia J., “Reference Pricing and Cross Border Reference Pricing System Reviewed”, Cambridge Pharma Consultancy, UK, 1996

Zweifel P. and Crivelli L., “Price Regulation of Drugs: Lessons from Germany”, *Journal of Regulatory Economics*, 1996, 10:257 - 273

Primary sources

Romanian government:

Ministerul Sanatatii, *Carta Reformei Sistemului Serviciilor de Sanatate din Romania*, 1997
Legea asigurarilor sociale de sanatate, *Monitorul Oficial al Romaniei*, 178, 1997

Interviews

Dr. Adrian Caretu, Country Manager, MSD Romania, August 1998

Dr. Lukas Pfister, Director Public Affairs, MSD East Europe, July 1998

Helena Brus, Director Industrial Policy, Merck & Co. Inc., September 1998