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**Policy Change and Regulation of Primary Care Prescribing and
Dispensing in Macedonia – A Qualitative Study**

By:

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Abstract

Background. Former socialist countries' transitions to market economies have had significant implications for health service policy and delivery. This study uses the transition in Macedonia as a case study setting to explore how such changes and related policies have been perceived to impact upon an important area, the prescribing and supply of medicines. This study focuses on the key primary care policies relating to limitations to prescribing volume and dispensing policy enforcement.

Study aims were to explore experiences and perceptions of how privatisation and regulation policies influenced the prescribing and dispensing of medicines from the perspectives of primary care physicians, pharmacists, patients and elite group stakeholders.

Methods. A qualitative design was used utilising semi-structured interviews with a purposive and snowball sample of 17 doctors, 12 pharmacists, 14 patients and 13 elites. Interviews were conducted face-to-face and fully recorded and transcribed and then analysed using a thematic analysis approach.

Findings. Differing but often negative perspectives emerged, with primary care provider physicians and pharmacists feeling pressure from both regulatory and governmental bodies and patients qua their expectations and medicines demands. Physicians and pharmacists felt detached from policies and that guidance was lacking. Disempowerment and threats to professional autonomy resulted, with unethical

implications for irrational prescribing and supplying medicines without prescriptions. Elites considered recent policy changes as necessary although they, and other participants, made comparisons to the previous system which was viewed with nostalgia, as being fairer. Mandatory prescription enforcement appeared ineffective with patients being able to obtain medicines, although patients reported new pressures in negotiating medicine supply and justifying self-medication practices. Lack of coherent policy implementation was a recurring theme.

Discussion and Conclusions. Increasing regulation, marginalised professionals and patients led to numerous negative experiences. Using a Habermasian perspective, policy changes within Macedonia reflect a system that threatens individuals' lifeworlds; new policies represent juridification and professionals' perception of being isolated, uninvolved and unsupported, reflecting disruption of communicative acts and justice. This study suggests the need to improve communication between different stakeholders and involve practitioners and patients to ensure policy change is sensitive, and not a threat, to individuals' autonomy.

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Publications

Journal articles:

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Table of Contents

Abstract.....	2
Acknowledgements	4
Publications.....	5
Table of Contents	6
List of Tables	11
List of Figures	11
Abbreviations.....	12
Glossary of Terms.....	13
CHAPTER 1: Introduction.....	19
1.1. Overview	19
1.2. Rationale for studying prescribing and dispensing of medicines in transition economies.....	20
1.3. My background and research interests	21
1.4. Thesis outline	22
CHAPTER 2: Health system reforms, prescribing and dispensing medicines in Macedonia 25	
2.1. Overview of health reform and privatization in transition countries	25
2.2. Health reform and primary care privatization in Macedonia	27
2.2.1 Health reform in Macedonia	27
2.2.2 Privatization of primary healthcare in Macedonia.....	28
2.2.3 Capitation payment in primary healthcare in Macedonia	29
2.3. Prescribing and dispensing in primary healthcare in Macedonia	31
2.3.1 Overview of prescribing and dispensing policies	31
2.3.2 Prescribing policy changes	33
2.3.3 Dispensing policy changes.....	36
2.3.4 Prescribing and dispensing levels in privatized primary health care.....	38
2.4. Summary of chapter	41
CHAPTER 3: Literature review	43
3.1. Introduction	43

3.2. Literature search strategy	43
3.2.1 Search methods.....	44
3.2.2 Database search strategy.....	44
3.2.3 Inclusion and exclusion criteria.....	46
3.2.4 Results of literature search.....	47
3.3. Medicines: An overview	48
3.4. Regulating medicines supply and demand	51
3.4.1 Regulating medicines supply.....	52
3.4.2 Regulating medicines demand.....	53
3.5. Prescribing of medicines	54
3.5.1 Rational prescribing.....	54
3.5.2 Autonomy and prescribing.....	57
3.5.3 Rational prescribing and relationship to changes in behaviour.....	59
3.6. Overview of factors influencing prescribing in primary healthcare	62
3.6.1. Providers' experience factors.....	63
3.6.2. Regulatory factors and system's influence on prescribing.....	65
3.6.3. Patients' influence and physician-patient relationship.....	66
3.7. Rational dispensing and challenges to legal supply	68
3.8. Medicine supply and Habermas' System and Lifeworld	71
3.8.1 Habermas' theory of communicative action and healthcare.....	72
3.8.2 The Lifeworld: patients' role in prescribing and dispensing.....	76
3.9. Prescribing and dispensing in transition countries	78
3.9.1 Primary care and system/lifeworld interactions.....	78
3.9.2 Primary care in transition countries.....	80
3.9.3 Privatisation of primary care in transition countries.....	82
3.9.4 Prescribing and dispensing in primary care in transition countries: system and lifeworld perspective.....	84
3.10. Research questions	88
3.11. Summary of chapter	88
CHAPTER 4: Methodology	92
4.1. Introduction	92
4.2. Choice of qualitative methodology	93

4.2.1 Epistemological position	94
4.2.2 Rationale for choice of semi-structured interview method	97
4.3. Data collection	100
4.3.1 Sampling	100
4.3.2 Sample size	103
4.3.3 Research instruments.....	105
4.3.4 Incentives for participants.....	106
4.3.5 Interviewing	107
4.3.6 Reflecting on interviewing and data collection process.....	110
4.3.7 Recording, transcribing and translation	112
4.4. Data analysis	114
4.4.1 Description of thematic analysis	114
4.4.2 Data familiarization	115
4.4.3. Generating initial codes	117
4.4.4. Development of themes.....	119
4.4.5. Reviewing and refining of themes.....	120
4.4.6 Presenting the data findings and write-up.....	121
4.5. Quality and credibility of this research	122
4.6. Research ethics and confidentiality	124
4.7. Dissemination of findings	127
4.8. Summary of chapter	128
CHAPTER 5: Findings	130
5.1. Introduction	130
5.1.1 Overview of chapter	130
5.1.2. Approaches to data presentation	131
5.1.3. Summary of key themes.....	132
5.2. Reflections on past and present policies	136
5.2.1 Nostalgia for the past system.....	137
5.2.1.1 Reflections on the past system	137
5.2.1.2 Autonomy in prescribing and obtaining medicines within the past system	141
5.2.2 Reflections on recent policies: necessity for change and qualified acceptance	148
5.2.3 Summary of policy perceptions.....	159

5.3. Policy implementation problems: lack of involvement and support	160
5.3.1 Lack of involvement in policy making	162
5.3.2 Providers' lack of support and detachment	167
5.3.3 Unwillingness to share responsibility	178
5.3.4 Summary of theme findings	184
5.4. Pressures in practice	185
5.4.1 Providers' professional disempowerment	186
5.4.2 Patients' negotiation of medicine supply	193
5.4.3 Summary of pressures in practice	200
5.5. Summary of chapter	201
CHAPTER 6: Discussion	205
6.1. Introduction	205
6.1.1 Overview of chapter	205
6.1.2 Observations	206
6.2. The significance of findings in this research	208
6.2.1 Reflections on past and recent policies: nostalgia for the past.....	209
6.2.2 Reflections on professional autonomy.....	214
6.2.3 Involvement in policy making	216
6.2.4 Lack of support in policy implementation and detachment	219
6.2.5 Perceived reasons for inadequate policy implementation and accepting responsibility	221
6.2.6 Non-prudent dispensing and illegal medicine supply	224
6.2.7 Providers' perceived pressures in practice from the system	226
6.2.8 Providers' perceived pressures in practice from patients.....	227
6.2.9 Patients' perceived pressures: Negotiating medicine supply	229
6.3. Medicine supply policy changes - a Habermasian perspective.....	230
6.3.1 Considering participant groups through a Habermasian perspective.....	231
6.3.2 System and lifeworld perspectives.....	233
6.4. Methodological challenges and limitations of the study	236
6.4.1 Methodological challenges	236
6.4.2 Limitations of this study	238
6.5. Future research questions	239

6.6. Summary of chapter	242
CHAPTER 7: Conclusions and recommendations	244
7.1. Conclusions	244
7.2. Current policy insights	246
7.3. Policy recommendations	247
7.3.1 Involvement of stakeholders in policymaking.....	248
7.3.2 Provision of information on policy changes	249
7.3.3 Involvement in policy implementation	249
7.3.4 Guidelines and communication training for providers	250
7.3.5 Patients' literacy and awareness raising campaigns	251
7.4. Final reflections	252
APPENDICES	253
Appendix A: ETHICS APPROVALS	253
Appendix B: INFO SHEET FOR PARTICIPANTS	255
Appendix C: CONSENT FORM.....	258
Appendix D: INTERVIEW SCHEDULE QUESTIONS FOR ELITES	259
Appendix E: INTERVIEW SCHEDULE QUESTIONS FOR PHYSICIANS	261
Appendix F: INTERVIEW SCHEDULE QUESTIONS FOR PHARMACISTS	263
Appendix G: INTERVIEW SCHEDULE QUESTIONS FOR PATIENTS	265
REFERENCES	267

List of Tables

Table 1. Preventive goals in primary healthcare in Macedonia (2009 and 2014).....	30
Table 2. Summary of policy changes in prescribing and dispensing in primary care in Macedonia	32
Table 3. Prescribed and dispensed medicines covered by the Health Insurance Fund, 2008-2014	39
Table 4. Key words used in electronic databases search	45
Table 5. The four types of engaged interaction between system and lifeworld and the outcomes summarized by Barry et al (2001)	75
Table 6. Sampling rationale for interviewees – Elite stakeholders	104
Table 7. Interviewees’ characteristics – Elites (educational background)	104
Table 8. Interviewees’ characteristics – Primary care physicians	105
Table 9. Interviewees’ characteristics – Pharmacists.....	105
Table 10. Interviewees’ characteristics – Patients	105
Table 11. The six phases of thematic analysis.....	115
Table 12. An example of analysis conducted on a section of transcript, together with the resolved interpretation in the final column	118
Table 13. Summary of key themes and sub-themes and relationship to participants...	133
Table 14. Summary of key recommendations	247

List of Figures

Figure 1. Development of primary healthcare in Macedonia	29
Figure 2. Policy changes for rational prescribing in primary healthcare in Macedonia ...	32
Figure 3. Simplified flowchart of prescribing and dispensing in Macedonia.....	37
Figure 4. Prescribed and dispensed medicines by ATC groups covered by the Health Insurance Fund.....	39

Abbreviations

ATC	Anatomical Therapeutic Chemical classification system
DRG	Diagnosis-related groups
EI	Elite interviewee
EML	Essential Medicines List
GP	General practitioner
HIF	Health Insurance Fund
MALMED	Macedonian Agency for Medicines and Medical Devices
MoH	Ministry of Health
OTC	Over-the-counter (medicines)
Pat	Patient
PCP	Primary care physician
Ph	Pharmacist
PML	Positive Medicines List
PC	Policy change
PHC	Primary healthcare
RTP	Research training programme
WHO	World Health Organisation

Glossary of Terms

The Glossary of terms was prepared based on the materials used in this thesis, with intention to clarify meanings and uses of particular terms in the context of this research.

Anatomical Therapeutic Chemical (ATC) Classification System - system used for the classification of medicines. First published in 1976, the system divides medicines into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics.

Appropriate prescribing - defined with various terms referring to the result or what should result as outcome of prescribed medicine or treatment (Buetow et al 1997). Although suggested by some scholars that for specific purposes can be synonymized with 'rational prescribing', the term 'appropriate prescribing' refers to a different concept explaining what results, or should result as the outcome of the prescribing, for which purpose 'rational prescribing' is not always 'appropriate' (Buetow et al 1997). As will be explained later in this thesis, the 'rational prescribing' and 'appropriate prescribing' are distinguished, but mainly for the purpose of providing theoretical understanding of the two concepts; otherwise, the thesis is not concerned with doing particular research on their distinctions, and therefore, commonly used in the research is the term 'rational prescribing'.

Culture - Culture in its wider definition presents 'that complex whole which includes knowledge, belief, art, morals, law, custom and any other capabilities and habits acquired by man as a member of society' (Taylor 1871). Culture is also defined as

cultivated behaviour representing the totality of a person's learned, accumulated experience, which is socially transmitted through communication.

Essential Medicines List (EML) - also called 'list of essential medicines' and 'essential drug list', as defined by the World Health Organisation consists of medicines that 'satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.' (WHO 2016).

Fee-for-service - model of payment in the health systems, used both in primary or hospital care in which services are unbundled and paid for separately. The model is based on payment dependent on the quantity of care, rather than quality of care (Berenson and Rich 2010).

Medicine (drug) - also referred to as drug, pharmaceutical drug, pharmaceutical, medication or medicament, is commonly defined as any chemical substance intended for use in the medical diagnosis, cure, treatment, or prevention of disease. For the purposes of this research, the terms the above terms will be used interchangeably as synonyms.

Patient-based capitation model – a model for healthcare services payment, in which a physician receives a payment that is dependent on the number and type of patients registered with the physician's practice (Chaix-Couturier et al 2000).

Positive medicines list (PML) – List of medicines that are recognized by the government as reimbursable under health insurance. Some of the medicines on the positive list can be obtained with certain co-payment, defined based on separate criteria. The

positive medicines list is based on the Essential Medicines List (EML). In this paper, it is used synonymously with the term 'positive list'.

Prescribing – term referring to recommending substance or action as something beneficial. In medical terms, prescribing (of a health practitioner) refers to advice and authorization for use of a medicine or treatment for someone, especially provided to the patient in writing. For the purposes of this research, the term 'prescribing' will be generally used for prescribing of medicines.

Prescribing culture – literature defines this term as decision making, including prescribing based on different influences (Maddox 2011; Hall et al 2003) from the society, including others' prescribing behaviour and patients, guided by informal rules (Bishop et al 2011; Cavazos et al 2008), and not necessarily evidence based (Ljungberg et al. 2007), and sometimes stretching beyond clinical appropriateness (e.g. Fontana et al 2000; Wood et al 2007).

Prescribing of medicines - one of the most frequent therapeutic decisions made by general practitioners (Bakker et al 2007), representing a focal point of contact between physicians and patients and being used as one of the indicators of the quality of medical care (Harding et al 1985).

Primary healthcare - often used for describing a narrow concept of family doctor-type services delivered to individual patients or first point of contact with the healthcare system. Primary Health Care is otherwise a broader concept, which in addition to primary care services includes health promotion and disease prevention, and also population-level public health functions, reflecting the approach to service provision for a community proposed in the WHO 1978 Alma Ata Declaration (WHO 1979). For the purposes of this research, the term 'primary healthcare' will mostly be used in its

narrow definition of provision of services by primary healthcare providers (general practitioners, family physicians, pharmacists) to patients.

Privatization - a process of transferring ownership of a business, enterprise, agency or public service from the public sector (government) to the private sector (business). Privatization has different forms, one of which is **concession**, i.e. an exclusivity contract between private and public sector for operation of public utility or delivery of public service for an agreed number of years. *In the case of Macedonia, although called privatization, the reform of primary healthcare by all characteristics is more a concession type of transformation.*

Public policy - principled guide to action taken by the administrative executive branches of the state with regard to a class of issues in a manner consistent with law and institutional customs. The foundation of public policy is composed of national constitutional laws and regulations. Public policy is considered strong when it solves problems efficiently and effectively, serves justice, supports governmental institutions and policies, and encourages active citizenship (Norwich University 2016).

Public policy analysis - problem-solving discipline that draws on theories, methods and substantive findings of the behavioural and social sciences, social professions and social and political philosophy. Process-wise, public policy analysis is multidisciplinary inquiry designed to create, critically assess and communicate information that is useful in understanding and improving public policies (Dunn 2004). For the purposes of this research, public policy analysis is used to define the discipline and the process referring to public policies relating to health, health systems and health policies.

Rational prescribing - described in various terms referring to the process whereby prescribing decisions are made, based on the medical indication, necessity and known effectiveness of the prescribed medicine or treatment. Although suggested by some scholars that for specific purposes can be synonymized with 'appropriate prescribing', the term 'appropriate prescribing' refers to a different concept explaining what results, or should result as the outcome of the prescribing, for which purpose 'rational prescribing' is not always 'appropriate' (Buetow et al 1997). As will be explained later in this thesis, 'rational prescribing' and 'appropriate prescribing' are distinguished, but mainly for the purpose of providing theoretical understanding of the two concepts; otherwise, the thesis is not concerned with doing particular research on their distinctions, and therefore, commonly used in the research is the term 'rational prescribing'.

Transition countries (transition economies) – countries (and their economies) changing from a centrally planned command economy to a market economy. Transition economies undergo a set of structural transformations intended to develop market-based institutions (Leave 2010; Kornai and Eggleston 2001). According to the literature, the transition countries comprise 29 economies of Central and Eastern Europe and the Former Soviet Union, divided into three groups: i) Central Eastern Europe and Baltic States: Croatia, Estonia, Hungary, Latvia, Lithuania, Poland, Slovak Republic and Slovenia; ii) South-Eastern Europe: Albania, Bosnia and Herzegovina, Bulgaria, Macedonia, Montenegro, Serbia, and Romania; and iii) Commonwealth of Independent States: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. In addition, the

European Bank of Reconstruction and Development (EBRD) also categorises Turkey and Mongolia in this group (Carvalho et al 2013).

CHAPTER 1: Introduction

1.1. Overview

This first chapter sets out the reasons for studying prescribing and dispensing practices and attitudes during a period of significant changes within a healthcare system, my relationship to the topic and an overview of the structure of the thesis.

This research explores the subjective effects of healthcare reforms in transition countries, namely those that have experienced a shift from command to market economy. Through the use of qualitative research it provides a greater understanding of the effect of this transition on healthcare services provision, and especially medicines supply at the level of prescribing and dispensing, as viewed by a range of stakeholders.

Specifically, this research explores the effects of policy changes relating to prescribing and dispensing of medicines in primary care in Macedonia on the practices and attitudes of policy makers, physicians, pharmacists and patients in terms of medicines provision. Particular focus is chosen for two reasons: i) as a country, Macedonia has undergone major privatization reform, explained in detail further in this thesis, and ii) as a sub-setting, a significant proportion of prescribing and dispensing happens at the primary healthcare level. I have undertaken the research using semi-structured interviews. I hope that this knowledge will inform better design and implementation of future policy changes in Macedonia as well as in other countries undergoing healthcare reform.

1.2. Rationale for studying prescribing and dispensing of medicines in transition economies

Healthcare reforms and privatization in transition economies have been the focus of previous research (Kornai and McHale 2000; Leive 2010). These have been analysed mostly from a financial perspective or in relation to health outcomes (Janssen and van der Made 1990; Quercioli et al 2013). However, there is little published evidence on effects of privatisation on social and behavioural aspects such as the attitudes of primary care providers (i.e. physicians and pharmacists) and patients (Butler et al 1998; Ong et al 1995; Emanuel and Emanuel 1992). This research seeks to address this omission and does so using a further specific focus, which is argued to have been absent in transition country policy change research, namely the supply of medicines. Medicines represent an important, tangible aspect of all health systems and several aspects of their control and supply have been argued to have considerable significance for different stakeholders (Whyte, van der Geest and Hardon 2002; Britten 2008). Involving prescribing doctors, dispensing pharmacists and consuming patients, the supply of medicines will be argued to be an important trajectory for framing the impact of policy reform and is worthy of empirical investigation.

Undertaking such research, is innovative and can directly inform the on-going debates about the significant changes to healthcare systems aimed at improving effectiveness of the use of limited resources to address increasing demands for healthcare (Maarse 2006; Higgs and Jones 2001, p.144). Such issues have been rarely subject to qualitative research in transition economies, resulting in very limited existing literature exploring transition economies. Further research using qualitative methods allows for an in-depth

cultural and sociological exploration of the policies and policy responses within the unique contextual circumstances of these countries.

1.3. My background and research interests

My interest in studying prescription practices within primary healthcare stems from my background as a pharmacist and my experience in researching healthcare reforms in Macedonia since its independence. In the past years of my work, I have explored a number of cases when policies were adopted based on other countries' best practices or on international experts' advice, without prior thorough assessment of their likely effects on society or on the individual. Most often the response was either partial compliance or continuation of previous practices, leading to recurrent failure of implementation. The prescribing and dispensing policies are one such example, where sequential changes made to address failure have not produced the desired results, with continuing high levels of antibiotic use (Radoshevic et al 2009; Ivanovska et al 2013). This is particularly observable within prescribing and dispensing of antibiotics, for example, which in Macedonia continues to be an issue; the extremely high levels of antibiotic prescribing and self-medication are contributing to the global concern of increasing antimicrobial resistance (Angelovska et al 2016).

In trying to understand these failures of policy implementation in general, and the effects of primary care reform in particular, my research interest is focused on understanding the practices and attitudes of policymakers, physicians, pharmacists and patients relating to policy changes covering prescribing and dispensing of medicines. In addition, I would like to explore whether taking these practices and attitudes into

consideration could contribute positively towards policy design and implementation in Macedonia and other similar countries.

1.4. Thesis outline

Beyond this introductory chapter, the thesis is logically structured and divided into several parts. The following section provides an overview of the thesis.

The second chapter provides an overview of the health reforms in transition countries, followed by a description of the reforms, and particularly prescribing and dispensing policy changes, in Macedonia.

The third chapter, *Literature Review*, outlines the existing body of literature on prescribing and dispensing of medicines, models of prescribing and issues concerning prescribing and dispensing in primary healthcare. An overview of the literature on prescribing and dispensing in the specific context of transition countries is then provided.

The fourth chapter, *Methodology*, gives a critical overview of existing methodology and provides justification for choosing a qualitative research methodology and also the use of semi-structured interview methods in this research. This chapter provides details of all stages of the research process, including the rationale for choosing the groups of interest, sampling, interviewing, transcribing and translation. It describes how the data were interpreted and analysed using thematic analysis, followed by a critical reflection of quality and credibility in relation to this study and a consideration of research ethics issues that arose as part of this research.

The fifth chapter, *Findings*, provides an account of the discerned themes from the research, which were summarized as: i) reflections on past and present policies; ii) issues arising from implementation; and iii) pressures in prescribing and dispensing practice. As will be shown in this chapter, there is general understanding of the necessity for change, but different opinions and perceptions regarding the development and implementation of policies for prescribing and dispensing in primary care; nostalgia for the past system plays a key role in shaping these perceptions and the practice. There is also acknowledgement of lack of effective policy implementation, but reluctance from various groups to accept responsibility. Perceived disempowerment and reduced autonomy was articulated by providers as detachment from the system and increased pressures in practice, whereas for patients it provided justification for negotiating medicine supply and continuing self-medication practices.

Chapter Six, *Discussion*, contextualises the findings. Firstly, it compares and contrasts the findings with the literature identified in chapter three and it is argued that there are similarities to themes previously identified in other research and health systems. A second aim is to argue that an existing theory, namely Habermas's social theory of system and lifeworld, is an important way in which the findings can be interpreted. The chapter then goes on to consider the implications of the findings, not only for Macedonia, but other transition countries too.

The seventh and final chapter, *Conclusions and Recommendations*, summarises the research and offers several recommendations based on the emerging research findings of this study, at both policymaking and implementation levels. In terms of policymaking process, a recommendation is made to consider better involvement of providers in policymaking and providing them with more information on policy changes. In terms of

implementation, the key recommendations relate to: encouraging feedback about practice experiences from both providers and patients that would inform future policy formulation, providing additional education of providers in communication with patients, alongside continuing efforts for awareness raising and improving health literacy of patients.

Following the main body of the thesis, various supporting materials and information are provided in the *Appendices A to G*, including ethical approvals, research instruments, and information sheets provided to participants, as well as the consent form used to provide their participation under the principles of research ethics and guaranteed confidentiality.

CHAPTER 2: Health system reforms, prescribing and dispensing medicines in Macedonia

2.1. Overview of health reform and privatization in transition countries

Transition from planned to market economy has inevitably brought a new paradigm of system structure, operation, functions, reallocation of resources and thinking within the post-socialist societies (Krelle 2000). Countries deciding to make this shift have embarked on a process of massive reforms in the economy and virtually all sectors of the society. For some sectors, this transition was blueprinted with a relatively well-designed roadmap for the required reforms towards the desired deliberative democracy with equality and equity as main values. For example, market economy principles dictated liberalisation of production and markets, enabling competition and engagement of private capital (Kornai and McHale 2000). Accordingly, with more or less success, the transition countries have completed this process, at least from its regulatory and normative standpoint.

The health and social sectors, as dominant accomplishments of a welfare state in developed democracies, exhibit a variety of approaches in reaching the same goals, partly due to the nuances of economic and social contexts and partly as a result of the specific cultural fabric of particular states. While based on the same principles of equity and equality, individual societies value health differently, as illustrated by the fraction of resources they allocate for healthcare (Leive 2010). For example, in the EU average health expenditure in 2015 accounted for nearly 10% of GDP, but ranges between 7% of GDP in Luxembourg to around 11% in Germany, Sweden and France (OECD 2016).

Therefore, the advice and guidance on restructuring the healthcare systems was far more ambiguous and much less determined in terms of how these transformations should proceed (Kornai and McHale 2000). In transition countries, in 2014 the investment in health ranged from little over 5% of GDP in Albania, Latvia and Romania to over 10% in Serbia; in the same year, Macedonia was dedicating 6.5% of its GDP to health expenditures (WHO 2017).

Prior to 1990, systems in most of these countries were financed from general revenues, using historically determined line-budgets for hospitals and fixed salaries for physicians. Healthcare was virtually free to the population and was largely accessible through unnecessarily extensive health infrastructure. With the reforms, healthcare financing was channelled through newly introduced social insurance schemes and its execution transformed to a more performance-based system, mostly as a combination of some of the well-established payment mechanisms of fee-for-service, capitation (payment per patient) and pharmaceutical price regulation (Leive 2010). At the same time, the economic restructuring and decline of the production sector snowballed a reduction in government expenditures for health. This affected access to healthcare, especially in terms of: lapses in availability of care, reductions in supplies of medicines and other materials, lower salaries for healthcare providers and decrease in their motivation, and lowering of patients' confidence and trust in the quality of care (Shkolnikov, 2001; Atun et al 2005; Kunitz 2004; Bartlett et al 2012, pg.4-5). The first in line for reforms was primary care, as the gatekeeper of the system authorising access to specialist and hospital care (Franks et al 1992).

The goals for reforming primary care were relatively similar in all countries: improving efficiency and introducing a stronger gatekeeping role, while ensuring availability and

accessibility as an entry point to the health system (Cernis-Istenic 1998; Nordyke and Peabody 2002). To improve the efficiency of primary care, some countries, as a result of donor-driven initiatives and examples from developed countries (Anell 2011), have opened the market to private initiative (Nordyke and Peabody 2002; Cernic-Istenic 1998) and implemented the privatization model, for example Croatia (Hebrang et al 2003; Dzakula et al 2014), Slovenia (Albrecht and Klazinga 2009; Albrecht 2009) and Macedonia (Nordyke 2000; Milevska Kostova et al 2017).

2.2. Health reform and primary care privatization in Macedonia

2.2.1 Health reform in Macedonia

Prior to gaining independence in 1991, Macedonia had a centrally planned command economy and a well-distributed health care system, free to all at all levels of care (Ivanovska and Ljuma 1999). Similar to other transition economies, Macedonia initiated economic and political changes triggering market-oriented reforms in all (Carvalho et al 2013), including the health sector (Lazarevik et al 2012). The reforms have changed the whole economic and societal fabric, with implications for the health and wellbeing of the population (Ivanovska and Ljuma 1999).

Under the pressure of decreasing resources, the government initiated health sector reforms (Menon 2006). The first decade of reforms was marked with health market liberalization enabling private service provision during the 1990s (Nordyke and Peabody 2002), followed by establishment of a third-party payer system, through establishment of a Health Insurance Fund in 2000 and reintroduction of a social insurance model based on mandatory salary contributions for health insurance (Gjorgev et al 2006; Leive 2010).

In continuation of these reforms, government considered improvement of resource use efficiency, part of which was primary healthcare privatization, initiated in 2005 (Milevska-Kostova 2010).

2.2.2 Privatization of primary healthcare in Macedonia

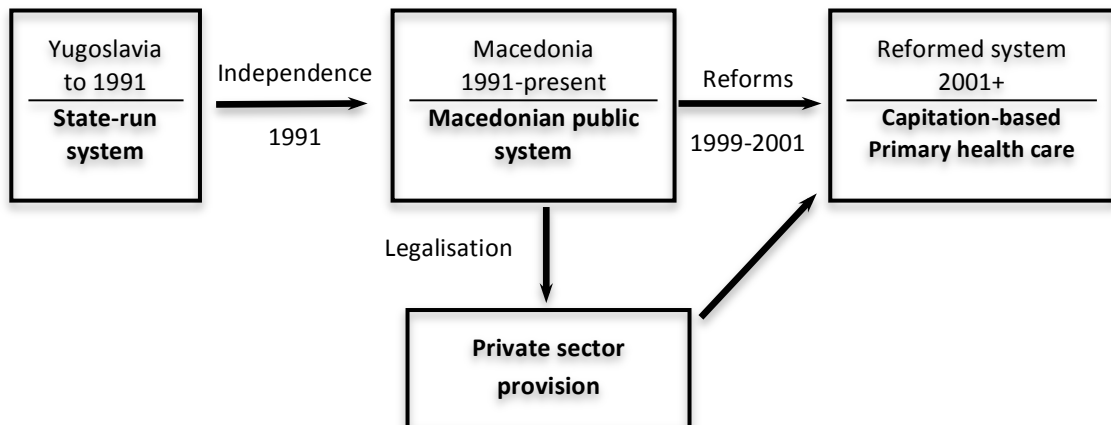
In 2005, the Macedonian government commenced a process of privatization of primary healthcare (PHC), seeking to improve its efficiency and quality, and to strengthen its gatekeeper role in the system (Figure 1) (Nordyke and Peabody 2002). The attempt to capitalize on private investment in the public domain began with the transfer of primary healthcare providers from public to private sector; they then needed to open private practice and set up contracts with the Health Insurance Fund (HIF) for provision of primary care services. This privatisation involved general practitioners, paediatricians, gynaecologists and pharmacists (Gjorgjev et al 2006; Milevska Kostova et al 2017).

Various models of primary care funding were assessed, including fee-for-service, salary and mixed systems (Nordyke 2002). For general practitioners, paediatricians and gynaecologists, the model applied was the blended capitation model, consisting of: payment of a fixed amount for each patient registered in the physician's roster, and a variable amount for delivery of preventive care, i.e. fulfilment of pre-defined preventive goals (Chaix-Couturier et al 2000; Tulevska and Dimkovski 2015), elaborated in more detail in the following paragraphs.

By the end of 2008, a total of 2176 primary care providers were contracted by the Health Insurance Fund (HIF 2009), constituting 95% of all licensed primary care providers (LKM 2009). Within the taxonomy of privatization models, the process of transformation of primary healthcare in Macedonia is closest to the model of franchising

(Savas 1989), as it is mainly concerned with provision of services by private providers through public funding, and does not involve any transfer of assets from the public to the private domain (Poole Jr. 2008).

Figure 1. Development of primary healthcare in Macedonia



(Adapted from: Nordyke and Peabody 2002)

2.2.3 Capitation payment in primary healthcare in Macedonia

The introduced payment model in primary healthcare is a patient-based blended capitation model; contracted physicians receive a defined amount per registered patient (Chaix-Couturier et al 2000; Glazier et al 2009), as well as incentives for rational prescribing and preventive services delivery. In practice, the contract consists of two major payment categories: 70% fixed amount, and 30% conditional amount based on fulfilment of the so-called *preventive goals of the PHC* (Table 1), which are revised each trimester by the Health Insurance Fund. When the system was introduced, the preventive goals and weighted percentage for their fulfilment were: rational prescribing by limiting the number of prescriptions per registered patient (7% of capitation fee),

rational referrals and sick-leaves (4%), and preventive services for early detection of malignancies in adults and health conditions in children (combined 19%) (HIF 2010). In 2009, rational prescribing was defined through a budget ceiling for prescribing.

Table 1. Preventive goals in primary healthcare in Macedonia (2009 and 2014)

Goal	2009		2014	
	Description of activities	% of capitation fee	Description of activities	% of capitation fee
Prescriptions	Rational prescribing based on number of prescriptions per patient	7%	Rational prescribing Prescribing within budget ceiling	6%
Continuous Medical Education	-	-	Undertaking training	2%
Sick leaves and Referrals	Rational referral to higher levels of healthcare	2%	Rational and justified sick leaves and referrals (max. 15 days sick leave)	2%
	Rational and justified referral for sick leave	2%		
Preventive services	Adults: Preventive activities for early detection of cancers and cardiovascular diseases Children: Preventive activities for various conditions, including deformities	19% total	Adults: Preventive activities for cardiovascular diseases, diabetes mellitus and kidney diseases	20%

(Source: adapted from *Preventive Goals in PHC (2010)* and *Tulevska and Dimkovski (2015)*)

The initial preventive goals were later adjusted in accordance with the increasing understanding of population needs and the accumulated experience of purchasing health services from private providers. As shown in Table 1, in 2014, the *preventive goals* were reformulated to: rational prescribing based on defined budget ceiling (6%), rational referrals and sick leaves (2%), undertaking training (2%), and other preventive

services now also including prevention of major non-communicable diseases in the age group 14-65 and deformities in children (20%) (Tulevska and Dimkovski 2015). Based on experience, instead of number of issued prescriptions, rational prescribing was defined and monitored through prescribing budget ceilings. The newly introduced budget ceilings for prescribing were defined for each physician weighted on the characteristics of their patients, in particular age and gender (HIF 2014).

2.3. Prescribing and dispensing in primary healthcare in Macedonia

2.3.1 Overview of prescribing and dispensing policies

Prescribing and dispensing policies in primary healthcare were gradually changed and adapted to address the main issues of: i) rational prescribing and dispensing, i.e. prescribing and dispensing based on medical indication, necessity and known effectiveness of the prescribed medicine or treatment; and ii) cost containment, i.e. reducing costs incurred as a result of excessive and unnecessary prescribing. This section is intended to provide a structured overview of these changes. Table 2 and Figure 2 below summarize the policy changes relating to rational prescribing and dispensing reflected through the following policy changes (PCs):

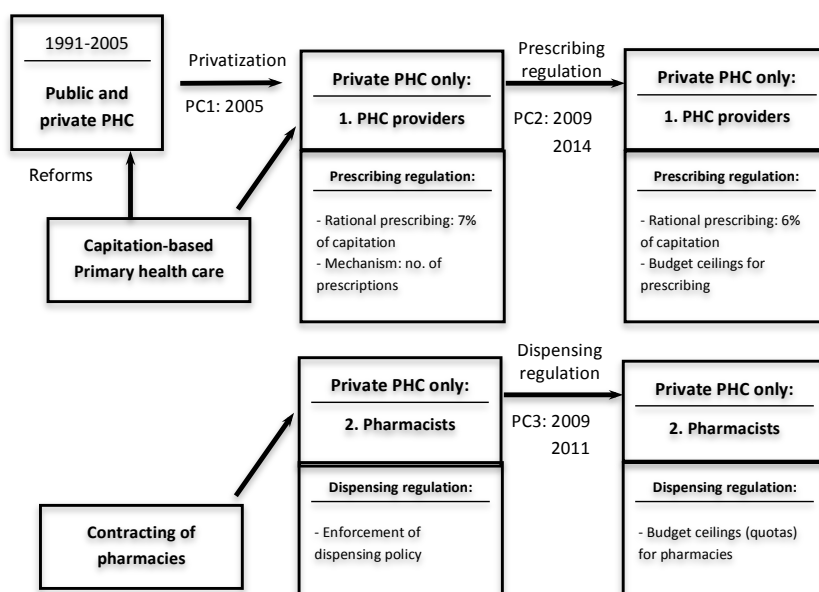
- PC1: Limiting prescriptions per patient per trimester (part of the preventive goals defined for primary care physicians);
- PC2: Budget ceiling for prescribing (part of the preventive goals defined for primary care physicians);
- PC3: Dispensing only upon presentation of valid prescription, and within medicine quotas (part of the enforcement of dispensing in pharmacies).

Table 2. Summary of policy changes in prescribing and dispensing in primary care in Macedonia

Policy change	Year	Mechanism	Indicator	Incentive/ Penalty
Prescribing policy changes				
PC1	2005 (Upon initiation of privatisation)	Part of preventive goals for physicians, measured as number of prescriptions	2 prescriptions per patient per trimester	7% of variable capitation lost/gained
PC2	2009	Part of preventive goals for physicians, measured as number of prescriptions		7% of variable capitation lost/gained
	2014	Part of preventive goals for physicians, measured as budget spent on prescriptions	Budget ceiling, adjusted to number and age/gender of registered patients	6% of variable capitation lost/gained
Dispensing policy changes				
PC3	2009	Enforcement of dispensing policy in pharmacies	Dispensing only upon presentation of valid prescription	Fines in accordance with penal stipulations in the law
	2011	Budget ceilings (quotas) for dispensing under health insurance	Ceiling defined per population coverage and historical records	None

Legend: PC=policy change

Figure 2. Policy changes for rational prescribing in primary healthcare in Macedonia



(Source: own compilation)

As can be seen from the above, prescribing and dispensing were among the areas reformed as part of the primary healthcare reform, and thus, the next sections provide an overview of policies pertaining to this process and relevant to this research.

2.3.2 Prescribing policy changes

With the health system reforms and the aforementioned liberalisation of service delivery and medicine supply markets, a key priority for the governments of transition economies was the regulation of private providers (Petrova 2001; Bartlett et al 2012, p.3). Under the pressure of decreasing resources and with the international community's guidance, the government of Macedonia continued the reform of increasing efficiency, as in other transition economies. The resources did not match the needs and the demand for healthcare (Nordyke 2001); this was particularly true for pharmaceutical expenditures, as the pre-independence policies enabled health insurance coverage of all medicines and medical preparations, including vitamin/mineral supplements. Thus, citizens were used to obtaining their medical supply at no charge, and providers were not bound by any limitation in their prescribing decision-making. Also, there were no policies regulating rational prescribing (Petrova 2002), such as, for example clinical guidelines.

One of the first changes in the early 1990s was removal of over-the-counter medicines from the health insurance package. The next policy action was development of the Positive Medicines List (PML), encompassing essential medicines covered by health insurance. However, there was still no regulation on the quantity of medicines that providers could prescribe or dispense. The overall pharmaceutical expenditure was

controlled through centralized decisions on the procured and distributed quantities of medicines.

It was not until 2005 that the first tangible policy changes for efficiency improvement in prescribing and dispensing were conceptualized and implemented (Lazarevik et al 2012). As explained earlier in this chapter, a transfer of primary care providers (physicians, dentists and pharmacists) from the public to the private domain occurred between 2005-2009 (LKM 2009). Primary care providers were paid for their services via a combined capitation model, where 70% of the capitation amount was fixed (fee per patient) and the remaining 30% was conditioned by implementation and delivery on pre-defined preventive goals, including 'rational prescribing' (HIF 2007; HIF 2014).

The first policy on 'rational prescribing' (Policy Change PC1) involved measuring the appropriateness of prescribing as adherence to an assigned number of prescriptions per patient, unadjusted by any parameter. Physicians were allowed to prescribe a total number of prescriptions calculated as 2 prescriptions per patient quarterly. At this stage, each prescription could be used for any medicine on the PML, irrespective of the cost. Thus, this policy change regulated the habit of prescribing and not the pharmaceutical expenditure. As such, it could not have been expected to contribute much to cost-containment, as it was based on counting (prescriptions) and not on accounting (for their value). It was rather intended to introduce 'discipline' and awareness that medicines are a limited commodity and can come with a 'price tag' (Ernst et al 2000).

Further evolving from this, in 2009, the policy was changed (to PC2) to introduce budget ceiling for prescribing (this time irrespective of the number of prescriptions), with amounts adjusted to reflect the demographic structure of the registered population

with the physician's practice (i.e. age, gender and rural/urban location) (HIF 2010). At first, this still constituted 7% of the variable capitation amount, and was reduced to 6% in 2014 (see Table 2 above). Later on, with the introduction of information technology in the health sector, an e-prescription system was introduced in 2015, as an additional control over pharmaceutical spending in real time (Milevska Kostova et al 2017). This latest policy change is mentioned to illustrate the ever-changing context of prescribing in Macedonia, but it was not analysed within this research, since it was introduced after the data collection for this research was already completed.

While the main focus of the research is on analysing the demand side measures, the interconnectedness with the supply side measures imposes the need to briefly review these, as they potentially correlate with prescribing behaviour and patients' influence on this behaviour. Within the cost-containment strategies, supply side measures were also introduced, such as reference pricing, through capping of medicines' prices to a maximum level of reimbursement by health insurance (Mossialos et al 2004) and promotion of generic substitution, through measures encouraging use of generic medicines (Godman et al 2014; Dauti et al 2015). This triggered expansion of the Positive Medicines List especially for medicines with minimum or no co-payments, which were introduced earlier (in 2003) as a demand side measure for containing costs on medicines covered by health insurance. According to the Health Insurance Fund, by 2013, 76.5% of the medicines on the positive list could be obtained with no additional charge to patients, a major change compared to 2009 when this share was only around 20% (Dauti et al 2015). The effects of this change can be viewed from the perspectives of the two main stakeholders within this research: physicians and patients. Physicians still needed to comply with the prescribing budget ceilings; thus it appears unlikely that

this policy intervention would influence physicians' decision to prescribe more than before or more than they would consider necessary. To patients, the removal of co-payments for a larger share of medicines might resemble the conditions of the past system, and thus encourage increased pressure on physicians for prescription medicines (Leive 2010).

2.3.3 Dispensing policy changes

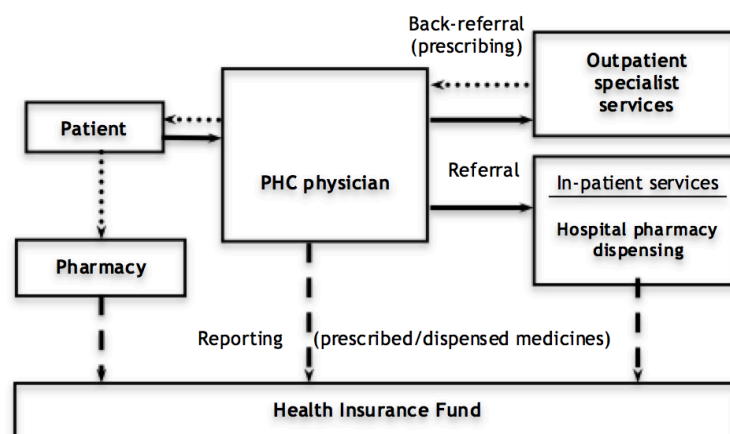
With regards to medicine dispensing, the situation was slightly different, but consistent with the rational prescribing efforts of the government. Privatization of public pharmacies was completed by 2005 and constituted complete transfer to private ownership, including premises. This was accompanied by an obligation for both private and newly privatized pharmacies to sign a contract with the Health Insurance Fund for dispensing medicine under the health insurance scheme. Based on this obligation, the pharmacies were only allowed to dispense medicines upon receipt of a valid prescription (HIF 2004). However, this rule was often not adhered to, with pharmacies regularly selling prescription-only medicines in the absence of a prescription (Rietveld 2006). Starting in 2009, with the third important policy change (PC3), a requirement for a valid prescription was enforced more rigorously (MoH 2008), with on-site inspections and controls over the dispensing of prescription-only medicines.

Further to the above, in 2011 the Health Insurance Fund introduced budget ceilings (quotas) to pharmacies for prescription medicines covered by health insurance. The budget ceilings were determined based on population coverage and historical data of dispensing of particular medicines. This policy was intended to contribute to the rational

prescribing and containment of costs on pharmaceuticals under health insurance. This is categorised within this thesis as part of Policy Change 3 (PC3).

The policy changes described in Table 2 and Figure 2 (section 2.3.1 above) have influenced the regulation of the pharmaceutical market in Macedonia, particularly prescribing and dispensing (shown in Figure 3 below); namely, the primary care providers, represented by physicians and pharmacists, were put under more stringent regulatory control at both the point of prescribing and of dispensing.

Figure 3. Simplified flowchart of prescribing and dispensing in Macedonia



*Legend: solid line = referral; dotted line = back-referral: prescribing; dashed line = reporting
(Source: own compilation)

This new policy setting inevitably influenced and continues to influence the prescribing and dispensing of medicines as the system of incentives has changed for both physicians and pharmacists in primary care. The next section provides an overview of prescribing and dispensing levels in privatized primary healthcare in Macedonia.

2.3.4 Prescribing and dispensing levels in privatized primary health care

In theory, the above elaborated policy changes were expected to have the following effects:

- 1) Move from PC1 (limitation of number of prescriptions) to PC2 (budget ceiling for prescribing) from 2009:
 - a. Physicians in primary healthcare have to: (1) monitor the budget ceiling instead of number of prescriptions; (2) negotiate with patients if there is no obvious need for the prescription medicine; (3) negotiate with the policy makers for the increase of budget ceilings;
 - b. Patients need to: negotiate with the physician the necessity of the prescription medicine, if there is no obvious medical indication for it;
- 2) Amending PC2 (budget ceiling for prescribing) with PC3 (dispensing only upon presentation of valid prescription from 2009, within defined medicine quotas from 2014):
 - a. Pharmacists have to: (1) expect reduced profits from the prescription-only medicines that are dispensed without prescription; (2) engage with patients in explaining why the medicine cannot be dispensed without prescription; (3) handle the dispensing within the defined quotas.
 - b. Patients need to: (1) visit a primary healthcare physician to obtain a valid prescription in order to obtain prescription-only medicines; (2) obtain medicines from the pharmacies where the quota is available.

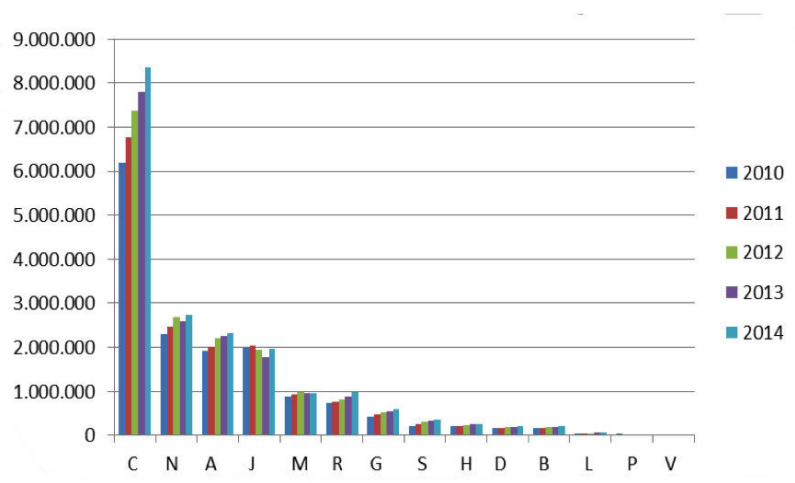
While most of the above theories require testing via a qualitative approach, it is also useful to examine quantitative data from this time period. Table 3 and Figure 4 represent the trends in prescribing in primary healthcare, both in terms of amount of funding and number of prescriptions during the period for which data was available (2008 to 2014).

Table 3. Prescribed and dispensed medicines covered by the Health Insurance Fund, 2008-2014

Year	Number of prescriptions	% increase compared to previous year	Amount spent on prescribed medicines (million MKD)	% increase compared to previous year
2008	10,283,273	-	1,318.9	-
2009	14,959,878	45.5%	1,828.7	38.7%
2010	15,277,792	2.1%	1,778.0	-2.8%
2011	16,332,551	6.9%	1,902.8	7.0%
2012	17,485,146	7.1%	1,993.2	4.8%
2013	17,822,132	1.9%	2,124.0	6.6%
2014	19,385,458	8.8%	2,235.8	5.3%

(Source: own compilation from HIF Annual reports 2008 to 2014)

Figure 4. Prescribed and dispensed medicines by ATC groups covered by the Health Insurance Fund



Anatomical Therapeutic Chemical classification (ATC) codes legend: A - alimentary tract and metabolism; B - blood and blood forming organs; C - cardiovascular system; D - dermatologicals; G - genito-urinary system and sex hormones; H - systemic hormonal preparations, excluding sex hormones and insulins; J - antiinfectives for systemic use; L - antineoplastic and immunomodulating agents; M - musculo-skeletal system; N - nervous system; P - antiparasitic products, insecticides and repellents; R - respiratory system; S - sensory organs; V - various

(Source: own compilation from HIF Annual reports 2010 to 2014)

From the above data, it can be concluded that medicine prescribing and dispensing have generally showed an upward trend, despite the introduced policy changes. It may be argued to be a result of other policy changes, which might act as confounding factors (e.g. the reduction of medicines' prices in 2013). However, these trends in prescribing and dispensing call for additional research, in terms of attitudes, opinions and practices in primary care, which is the main aim of this thesis.

It is noteworthy, that the above data does not represent the totality of medicines consumption in the country. Namely, within the current system, there are two key agencies responsible for pharmaceutical policies and maintaining records of medicines on the pharmaceutical market. The first one is the Health Insurance Fund, responsible for purchasing health services (e.g. physicians, pharmacies) under the health insurance scheme, including insurance-covered medicines. The second is the Agency for Medicines and Medical Devices, responsible for registration of medicines and issuing permits for putting medicines into use, and thus responsible for keeping records of all medicines placed on the market, i.e. including the share of medicines dispensed with prescription issued outside of health insurance or medicines dispensed without prescription. However, no data could be retrieved from the Agency for Medicines and Medical Devices. At the time of data collection for this research, this agency had non-systematized data only in paper format, and was not equipped to analyse the data or to provide any data for this analysis.

In addition, only partial records could be gathered from the Health Insurance Fund, presented above. Due to changes in the methodology of data collection and analysis, detailed information on the number of prescriptions and pharmaceutical expenditures

was also not available from the HIF records prior to 2008. Thus, the picture of medicine consumption as presented is incomplete.

Although incomplete, as mentioned above, the presented data shows a steadily increasing trend in prescribing between the analysed policy changes described in the earlier sections. The data presented in Table 3 and Figure 4 show that the policy change from limitations of prescriptions (PC1, 2005 until 2009) to budget ceiling (PC2, 2009 until present time) did not produce the desired results of reducing prescribing levels, although its predominant aim was to reduce pharmaceutical expenditure (HIF 2009; HIF 2010; HIF 2011).

It has to be noted as well, that the increased number of prescriptions might in part be due to enforcement of the policy for dispensing of prescription-only medicines with prescription only, towards the end of 2009. Since there are no comprehensive analyses and records of the actual enforcement of this policy, this is only a hypothesis.

Due to the limited quantitative data available, a qualitative method was chosen to further explore the impact of policy changes relating to prescribing and dispensing in primary health care in Macedonia.

2.4. Summary of chapter

During the 1990s, transition economies including Macedonia initiated economic and political transformations, including the health sector, primarily for cost containment and increasing resource use efficiency. In Macedonia, prior to the primary healthcare reform, prescription policies were rather liberal and not cost-efficient and new policies were introduced to regulate medicine supply and demand, through rational prescribing

and dispensing in primary care in particular. In prescribing, measures included firstly limitation on number of prescriptions, followed by prescribing budget ceilings. In dispensing, these included reinforcement of the existing policies of dispensing with valid prescription, alongside new policy on dispensing quotas.

Both the reinforcement of the existing and the introduction of the new policies were expected to have relevant influence on prescribing and dispensing, and will be explored in this research. The next chapter provides a review of relevant literature, identifying the gaps in knowledge to be addressed with this research.

CHAPTER 3: Literature review

3.1. Introduction

This chapter provides an overview of the existing knowledge on prescribing medicines, regulation of prescribing and dispensing, and factors influencing them, in particular at primary care level. Further, the literature review touches upon the theories of behaviour that may explain the attitudes and practices and potentially behaviour changes of primary healthcare providers with respect to prescribing and dispensing. This chapter also provides an introduction to the main theoretical framework for the research, drawing upon Habermas' theory of social life, and in particular the interactions of the system and the lifeworld pertaining to decision-making around prescribing. Further in the chapter, the literature on prescribing and dispensing in transition countries is reviewed, with the aim of providing understanding to the reader of the context in which prescribing and dispensing is researched – namely the primary health care reforms and changes in the pharmaceutical policies in Macedonia, which belongs to this cluster of countries. The chapter concludes by summarising the gaps in the literature and the aims of this research in contributing to the existing body of knowledge.

3.2. Literature search strategy

The aim of the literature review was to identify relevant and up-to-date literature on the following key topic areas:

- Regulation of prescribing and dispensing, challenges to regulation, and factors influencing prescribing and dispensing;
- Theories of behaviour which may affect prescribing and dispensing, particularly Habermas' theory;
- Prescribing and dispensing in transition countries, particularly following privatisation and reform of primary healthcare.

3.2.1 Search methods

Within the literature search, systematic principles were used to identify relevant literature on the topic areas above, though not as a full systematic review on a single topic. The initial literature search was conducted between July-December 2014 and updated for new references in March-April 2017. In the process, the following electronic databases were used: PubMed, PubMed Central, Medline, Google Scholar and the Cochrane Database of Systematic Reviews (CDSR).

The literature search used a combination of the following methods:

- Searching of bibliographic databases – as listed above;
- Expert knowledge of the subject area – my expertise and that of my supervisors in different areas of the above topics was used as a source of key articles;
- Reference tracking from key articles – relevant articles to the literature review and research questions cited in the key articles; and
- Iterative searching – further searches of the literature following development of understanding of the wider topic.

3.2.2 Database search strategy

Due to the broad nature of the topic and the different themes covered by the literature review, the databases listed above were searched using combinations of the following terms, which were adapted in further iterative searches as additional useful articles were identified:

- Topic area 1 (regulation of prescribing and dispensing): Terms around the following were used: prescribing, dispensing, regulation, challenges, influences, factors, combined with terms for primary healthcare.

- Topic area 2 (theories of behaviour and Habermas’ theory): Terms around the following were used: theory/theories + behavio(u)r + prescribing, or “Habermas’ theory”
- Topic area 3 (prescribing and dispensing in transition countries): Terms around the following were used: prescribing, dispensing, regulation, transition country/ies, transition economy/ies, privatis(z)ation.

The specific terms and their combination used in the search strategy are shown in Table 4 below. Free text terminology was based on the main concepts and the key issues of research interest to this thesis.

Table 4. Key words used in electronic databases search

Topic area and topics	Search terms
Topic area 1: Prescribing and dispensing	
Prescribing	prescr*; prescription medicines; prescribers; prescribing AND practices; attitudes; behaviour; challenges; influences; factors; AND review AND primary healthcare; primary care
Dispensing	dispens*; dispensing of prescription medicines AND practices; attitudes; behaviour; challenges; influences; factors; AND review AND primary healthcare; primary care
Regulation	regulation AND prescription medicines; prescribing; pharmaceutical policies; pharmaceutical market; challenges; influences; factors; AND review AND primary healthcare; primary care
Topic area 2: Theories of behaviour and Habermas’ theory	
Theories of behaviour	Behaviour AND medicine use; prescribing; dispensing AND review
Habermas’ theory	Habermas’ theory Habermas’ theory AND medic*; medicines; physician-patient relationship; prescribing; health decision making

Topic area and topics	Search terms
Topics area 3: Prescribing and dispensing in transition countries	
Prescribing in transition countries	Transition country/ies; Transition economy/ies AND prescribing AND privatis(z)ation; policies; practices; attitudes; qualitative; influences; factors; AND review AND primary healthcare; primary care
Dispensing in transition countries	Transition country/ies; Transition economy/ies AND dispensing AND policies; pharmaceutical policies; practices; attitudes; qualitative; challenges; influences; factors; AND review AND primary healthcare; primary care

3.2.3 Inclusion and exclusion criteria

Inclusion criteria

The following types of articles were included:

- Key theory articles outlining the main topic areas, including theories around regulation of prescribing and theories of behaviour such as Habermas' theory;
- Review articles on prescribing and dispensing;
- Key empirical studies reporting on the main topic areas, such as regulation of prescribing, challenges to regulation, and factors influencing prescribing, both in primary healthcare generally and within transition countries;
- Key qualitative studies on attitudes and practices in prescribing and dispensing, including physician-patient relationship and patients' expectations;
- Articles published in English, or any of the Slavic languages spoken in the countries in South-Eastern Europe (Bosnian, Bulgarian, Croatian, Macedonian, Montenegrin, and Serbian).

Exclusion criteria

Articles related to the following topics were excluded:

- Prescribing in inpatient facilities (secondary and tertiary care, surgery practice and emergency wards);
- Prescribing associated with specific population groups, such as elderly in care homes, prisoners in prisons and so forth;
- Developing countries that were not classified as transition countries.

3.2.4 Results of literature search

Since the literature search consisted of a series of iterative searches on different topics, plus references identified via expert knowledge and reference tracking from relevant articles, it was not possible to provide a precise figure for the total number of included articles. For the search in the first topic area on prescribing and dispensing, large number of articles were retrieved, which were filtered using the [AND] function for different combinations of two or three search words. The search in the second topic area also retrieved a number of articles and book chapters on theories of behaviour and Habermas' theory in relation to medicine supply. The situation was different with regards to the third topic area, relating to prescribing and dispensing in transition countries. Namely, the search on prescribing or dispensing in primary care in transition countries generated very few articles; the results were similar for the search on privatisation and prescribing or dispensing, and for the use of qualitative methodologies for researching prescribing and dispensing in transition countries. After assessment of their relevance, these articles were analysed and where appropriate were used in the literature review.

3.3. Medicines: An overview

Medicines play a significant role in the curing, management and prevention of diseases (Britten, 2008, p.4) and represent a core element of many healthcare treatments (Harding et al 1985). It is argued that millions of lives have been saved due to the use of medicines (WHO 2002; WHO 2009; Podolsky 2010), and that longer life expectancy can in part be attributed to medicine use (Van Raay 2011).

However, for as long as there have been medicines, alongside benefits, there has been a threat of their harmful and even deadly effects. In the 16th century, Paracelsus (1538) formulated this observation as: *“the dosage makes it [the medicine] either a poison or a remedy”*, explaining the need for knowledge-founded and experience-driven medicine administration, understanding and control of the positive and the adverse effects, the appropriate time to begin and discontinue the administration, the type of administration route and the appropriate dosages. In a broader sense, Paracelsus’ observation can be seen as a precursor of measured and monitored medicine use. Therefore, prescribing was introduced in an attempt to balance the need to provide medicines for improving quality of life while working to prevent the diversion of those substances to their overuse, misuse and abuse (Greene and Watkins 2012, p.5).

As medicines represent a significant element of treatment pathways for many diseases, their common availability and the potential absence of professional supervision raise concerns regarding potential inappropriate use (Oster et al., 1990; Barber, 1993; Blenkinsopp and Bradley, 1996; O’Mahony et al 2015). This has been argued to result in potential iatrogenic harm, misdiagnosis, the masking of more serious conditions and harmful interactions with other medicines taken concurrently (Bissell et al 2001; O’Connor et al 2012; Patterson et al 2012). Thus, providing professional support and

expert knowledge in therapeutic decisions on medicines becomes an intrinsic part of the healthcare system. Prescribing represents one of the core activities for measuring and monitoring the treatments of many medical interventions (Bradley 1991; Britten 2008, p.5). With this in mind, the investigated literature shows that prescribing was of interest to research from many aspects, including clinical, economic and social (Mosiallos and Mrazek 2002). In particular, such interest arises from the complex settings of prescribing itself, taking place at different levels (Cribb and Barber 1997; Opondo et al 2012; Davey et al 2017), and making a decision that involves or is influenced by a wide array of stakeholders, including health professionals, patients (Ryan et al 2014), professional groups, industry and suppliers (Lieb and Scheurich 2014) and the regulatory and payment authorities (Carone et al 2012). In addition, as a result of what is argued to be the asymmetry of information between providers (such as doctors and pharmacists) and patients (Carone et al 2012) additional processes are needed to prevent harm and manage these different perspectives. The regulation of prescribing and dispensing represent key examples of such processes and will be further elaborated in subsequent sections of this thesis.

In most countries, access to and supply of medicines is governed by regulatory frameworks and clinical evidence based on knowledge of benefits and risks of medicines to the population (Barber 1993; Bond 2008; Carone et al 2012). Based on the level of deregulation, literature suggests that access to medicines in general can be divided into three submarkets: over-the-counter (OTC), hospital submarket and prescription submarket (Britten, 2008, p.3). Each of these has been subject to research in terms of effectiveness, risks and so forth (Barber 1993, Bissell et al 2001). While OTC medicines (also referred to as non-prescription medicines or pharmacy medicines) are more

loosely regulated and can be obtained and administered by the general population without physician's prescription, the other two submarkets exhibit different levels of control and management mechanisms, for a number of reasons, including cost containment, but also appropriateness of administration, dosage and duration of treatment (Buetow et al 1997, Spinewine et al 2007, Davey et al 2013, Rashidian et al 2015). In most developed and transition countries medicines at both hospital and primary care level are subject to administration and dispensing based on clinical indication, embedded in evidence-based clinical practice guidelines (Grol and Grimshaw 2003; Carlsen et al 2007; Francke et al 2008; Tonkin-Crine 2012).

Whilst the hospital submarket shares some of the same concerns and challenges with the prescription market (also referred to as primary care level prescribing), the latter involves an additional layer of direct involvement of patients in consultation and therapeutic decision-making, and their knowledge, attitude, and demand in particular influences prescribing practices (Chretien et al 1975; Bauchner et al 1999; Palmer and Bauchner 1997; Vanden Eng et al 2003; Ryan et al 2014; Ofori-Asenso and Agyeman 2016). As will be reviewed later in this chapter, there is an ample body of literature suggesting that diverse factors influence providers' prescribing behaviour (Butler et al 1998; Macfarlane et al 1997; Mangione-Smith et al 1999; Tonkin-Crane 2012).

In addition to the above, and bearing in mind that the prescription market in most developed countries represents 75-85% of total pharmaceuticals expenditures (Tele and Groot 2009), prescribing at primary care level is of particular interest to this thesis, and is elaborated in detail in further sections, from the aspect of regulation and factors influencing decision-making in prescribing. Towards the end of the chapter, prescribing

and dispensing in transition countries is reviewed, with the aim of framing the research questions within the wider available literature.

3.4. Regulating medicines supply and demand

Pharmaceuticals are one of the areas enjoying great attention of governments and their political agendas, in an attempt to secure health policy objectives: protecting public health; guaranteeing patient access to safe and effective medicines; improving the quality of care; and ensuring that pharmaceutical expenditure does not overrun and undermine these and other government objectives (Mossialos et al 2004). As such, one of governments' roles in pharmaceutical policy is to provide the funding and framework that allows the highest attainable quality of care within the available limited resources (Mossialos et al 2004; Carone et al 2012).

Regulation of the pharmaceutical market is a complex process, involving multiple actors, such as government and third-party payers (insurance), prescribing physicians, dispensing pharmacists, patients and patient advocacy groups, manufacturers and wholesale suppliers, and research-based industries (Mossialos et al 2004). And, while the main aims of some groups such as industry and wholesalers are to maximise sales and profits, conversely, the interests of providers and patients are mostly aimed at achieving the best attainable care with little if any consideration of costs and economic efficiency. In trying to balance these interests and achieve effective and efficient use of resources, governments apply different mechanisms in regulating pharmaceutical spending adjusted to their context and circumstances (Permanand et al 2004). In general, these can be divided into regulating the two sides: the supply side and the demand side.

3.4.1 Regulating medicines supply

Governments tend to focus on regulatory measures on the supply side, namely the pharmaceutical industry and wholesale providers. The supply-side strategies for optimising pharmaceutical expenditure are often implemented through regulating pharmaceutical prices and reimbursement levels (Mrazek et al 2004). These so-called cost-containment policies on the supply side are usually implemented through measures such as: direct fixed price controls, profit controls and reference pricing (Mossialos et al 2004). Fixed pricing is aimed at securing pharmaceutical prices that are considered reasonable for a given health system (Mrazek et al 2004), or as defined by the World Health Organisation 'at a price the community can afford.' (WHO 2016). Profit control (currently unique to the UK) is aimed at ensuring that pharmaceutical producers are not making excessive profits on patent-protected products (Department of Health UK, 1999). Reference pricing is a system of setting maximum medicine reimbursement levels per drug that will be paid by the government or health insurance, based on groups of drugs with a similar function (Mrazek et al 2004; Kanavos and Taylor 2007). Yet, the success – or failure – of these policies is discussed in the literature as being difficult to measure as societies are faced with continuing trends of increase in pharmaceutical expenditures (Mossialos et al 2004). The literature notes that in part, this increase in pharmaceutical expenditure is due to growing demand, which is increasingly addressed through demand side measures (Mrazek 2002; Mossialos et al 2004). The following section gives a brief overview of demand-side instruments for regulating the pharmaceutical market.

3.4.2 Regulating medicines demand

Another method of controlling pharmaceutical spending and consumption is through influencing behaviour of groups that generate the demand, namely physicians, pharmacists and patients (Hutton et al 1994). According to the literature, no single strategy could be identified as a 'magic bullet' (Oxman 1995; Tonkin-Crine 2012) and different policy approaches have been designed and implemented to address this issue.

Demand side measures are usually aimed at influencing medicine consumption. This is frequently done through monitoring and influencing physician decision-making and changing the physician-patient relationship (Mossialos et al 2004; Godman et al 2010; Godman et al 2014). One of the most common approaches is standardization of physician decision-making, through enforcement of clinical guidelines. Clinical guidelines have become a common tool for promoting quality and equity of services, and at the same time controlling costs (Carlsen, Glenton and Pope 2007). These evidence-based protocols are intended to improve the standard and consistency of healthcare (Tonkin-Crine 2012, p.8), and to ensure availability of state-of-art knowledge in decision-making. In addition to guidelines, physicians are exposed to the latest scientific developments and practice through their continuous professional development, which in many countries is obligatory. Both of these mechanisms for ensuring standardisation in health care are then monitored by relevant authorities, either from health outcome or expenditure perspectives (Goossens et al 2005; WHO 2009; Zwar et al 1999; Mossialos et al 2004; Godman et al 2014).

Clinical guidelines are also used to standardize decision-making in prescribing, especially since there is a documented trend of overmedicalisation of healthcare (e.g. Chand 2014), stemming from, among other things, inadequate management of diagnostic

uncertainty (Whaley et al 2013), lack of commitment of physicians and patients in shared decision-making (Arnold and Strauss 2005), expressed or perceived patients' expectations (Little et al 2004; Britten and Ukoumunne 1997) and permanent expansion of treatments (Hanslik and Flahault 2016). The next section elaborates more on the literature related to rational prescribing in general, and at the primary level in particular, since as explained earlier, the dominant proportion of prescribing happens at primary care level as in most healthcare systems primary care providers are gatekeepers (Willcox et al 2011) and the first contact of patients with the healthcare system (Shi 2012).

3.5. Prescribing of medicines

Although it has been recognized for some time that prescribing should be necessary, safe and effective (Parish 1973), prescribing approaches are not always standardized (Bateman et al 1996; Buusman et al 2007) or adherent to the relevant clinical guidelines (Metge et al 2004; Carlsen et al 2007; Tonkin-Crine 2012). In support of this statement are studies showing an overall increase in prescribing and antibiotic prescribing in primary care in particular (Butler et al 1998; Holloway et al 2013), despite the global trend of gradual epidemiological shift from communicable to noncommunicable diseases in the past forty years (Omran 2005). The following section provides an overview of what constitutes good and therefore rational prescribing.

3.5.1 Rational prescribing

In order to discuss the factors influencing prescribing and the mechanisms of rational prescribing in the subsequent sections, it is necessary to examine the literature on what constitutes rational prescribing.

Rational prescribing is widely described in the literature as cost-effective prescribing based on clinical indication, for which evidence shows that the prescribed medication will produce benefit or prevent further complications of patients' health conditions. According to the World Health Organisation (WHO), rational use of medicines is a process in which 'patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community' (WHO 1985; WHO 2016). A 2011 report commissioned by the King's Fund, states that within the UK, rational prescribing is cost-efficient therapy proven to be most effective according to evidence-based guidelines (Kings Fund 2011). Clinical guidelines often describe the treatment in full, including medicines to be administered, and any prescribing that does not fit into these guidelines or recommendations is considered inappropriate, irrational or unnecessary (Tonkin-Crine 2012, p.7). This unnecessary prescribing has been extensively researched (e.g. Gallagher et al 2007; Garfield et al 2009; Holloway et al 2013; Ofori-Asenso and Agyeman 2016), identifying for example, wide practice of prescribing antibiotics for viral and self-limiting conditions where antibiotics would contribute either nothing or very little in terms of alleviating the symptoms or improving the health condition (Little et al 2005; Llor and Bjerrum 2014). In a similar way, literature shows that trends in treatment of depression in primary healthcare shifted from under-treatment due to lack of recognition of depressive conditions (Davidson and Meltzer-Brody 1999; Moore et al 2009), toward a concern with over-treatment and over-prescription of antidepressants (Heath 1999; Sirdifield et al 2015) and medicalization of patients with problems of living (Hyde et al 2005, NICE 2004); this resulted in dramatic increase of antidepressants' prescribing over the last three decades although the number of clinical cases of

depression did not follow such a rising trend (Middleton et al 2001). The WHO estimated that globally more than 50% of all medicines are prescribed, dispensed, or sold inappropriately (WHO 2002).

The research interest on prescribing and prescribing behaviours dates from the 1950s, when Dunlop et al (1952) conducted a survey of prescribing of general practitioners in England (Dunlop et al 1952). One of the major findings of most studies conducted since suggests tremendous variations in volume and cost of prescribing between countries (Goossens et al 2005; Ferech et al 2006) and between individual prescribers (Denig et al 1988; Bradley 1991; McGuire et al 1994; Carlsen et al 2007; Buusman et al 2007; Glinz et al 2017). Variations in prescribing have been analysed against both clinical and non-clinical variables (Wilkin 1987; Webb and Lloyd 1994; Bradley 1992; Lewis and Tully 2011) and results show that non-clinical variables, such as the physician's personal characteristics/experience and patients' expectations also play an important role in prescription behaviour (Bradley 1992; Webb and Lloyd 1994; Wilson, 1996; Cockburn and Pit 1997; Lewis and Tully 2011). These will be considered in more detail in subsequent sections.

According to Aronson (2006), good prescribing is one that 'recommends a medicine appropriate to the patient's condition and minimizes the risk of undue harm from it' (Aronson 2006). In his discussion on good prescribing, Barber (1993) argued that the older definition of rational prescribing defined by Parish (1973) as 'appropriate' instils ambiguity and therefore needs to be revisited to reflect the safety and effectiveness of medicine treatment. Barber (1993) argued that rather than defining the outcome of the prescribing, it is worthwhile to consider the process elements that lead to the desired outcome, i.e. defining what prescribers should consider in their prescribing decision. In

his view, prescribers' decisions should be based on the key aspects of safety, effectiveness, economic consideration and respect for patients' choices (Barber 1993). According to this, the complexity of the prescribing decision should allow for a certain level of autonomy of the providers in order to be able to address what constitutes rational prescribing.

In this sense, over the past two decades, irrational prescribing as a result of failure to prescribe in accordance with clinical guidelines has been challenged by the 'patient-centred' approach in which an alternative autonomy of doctors for individualization of prescribing therapy emerges (Armstrong 2002). The following section reviews the literature dealing with prescribing from the perspective of professional autonomy of providers.

3.5.2 Autonomy and prescribing

Autonomy of the medical profession has been subject to research from different perspectives, including economic, political and clinical (Elston 1991). While economic and political autonomy are concerned with doctors' rights to participate in policy making and defining their remuneration, clinical autonomy addresses the professionals' discretion in medical and treatment decision-making (Armstrong 2002).

Prescribing has been of particular interest to clinical autonomy, given that, as mentioned earlier, it represents one of the key elements of treatment pathways (O'Mahony et al 2015) and most frequent decisions taken by physicians at primary care level (Bakker et al 2007). According to Davis (1997), the right to prescribe is a key component of clinical freedom, representing one of the core activities that demarcate the medical profession from other groups (Britten 2001). In the 1990s, the share of

patients attending primary care who received prescriptions was estimated at 68% in Germany (Himmel et al 1997) and 50% in Australia (Cockburn and Pit 1997), with growing trends in recent years (Cadieux et al 2007). Literature links such outcomes to the considerable autonomy of the medical profession over prescribing (Ensor and Duran-Moreno 2004) citing it as an opportunity for increasing the consumption of medicines beyond their '*appropriate use*' (Scott and Shiell 1997) or levels of demand of a well-informed consumer (McGuire et al 1994). Thus, beginning in the 1990s, extensive literature emerged on clinical autonomy and prescribing, reviewed briefly in the subsequent paragraphs.

According to the literature, since the 1990s, autonomy of prescribing has been a focus of governments' attempts to regulate overprescribing and excessive associated costs. Beyond the standardization of decision-making discussed earlier, many governments deregulated the classes of medicines not associated with abuse (Britten 2001), with the aim of reducing the power of doctors and increasing choice for patients (Blenkinsopp and Bradley 1996; Branstad et al. 1994).

Clinical autonomy in prescribing was examined by Freidson (1985) and Elston (1991) from the perspective of the two dominant theses of proletarianisation and deprofessionalisation. The proleterianisation thesis argues that economic forces are increasingly influencing clinical pathways, allowing for dominance of bureaucratic criteria over autonomy (Armstrong 2002; McKinlay and Arches 1985; McKinlay & Stoeckle 1988). The deprofessionalisation thesis, on the other hand, considers the diminishing of dominance of health professionals through changing relations between doctors and patients, emergence of well-informed patients and rise of consumerism (Scambler and Britten 2001). These and other authors (Gabe et al 1994) concluded that both theses

were not particularly applicable to clinical autonomy, given the increasing formalisation through which professions control their own members (Freidson 1985), such as via clinical guidelines discussed earlier.

In the context of transition economies, clinical autonomy has been affected by both bureaucratic criteria and changing relationships between providers and patients. Britten's (2001) arguments on clinical freedom in prescribing being under threat from both regulatory and patient pressures are valid and applicable in the transition context, and will be reviewed under appropriate sections later in this chapter.

Irrational dispensing also occurs as a phenomenon (Ofori-Asenso and Agyeman 2016), mostly as a practice of non-compliance with the policies regulating dispensing of prescription medicines. The following section reviews the literature related to rational dispensing.

3.5.3 Rational prescribing and relationship to changes in behaviour

As discussed earlier, trends for increasing pharmaceutical expenditure are largely related to prescribing levels, which might not always be directly associated with clinical conditions and necessity for therapy. As already mentioned, the main approach in promoting rational prescribing on the demand side is through influencing medicine consumption. In this respect, and of particular interest to this thesis, is the influence of policy changes on change of behaviour in prescribing and dispensing.

Policies and mechanisms for promoting rational prescribing at the least assume change of behaviour, which has been described also in the literature as the most difficult intervention especially at the level of individual interaction (Butler et al 1998; Arnold

and Strauss 2005). So, to be able to influence behaviour it is important to understand the behaviour and its theoretical underpinnings.

Theories of human behaviour emanate from all disciplines of social sciences, conceptualising behaviour in several ways. The largest number of theories comes primarily from within the psychology field, and these focus either on the individual as the locus of behaviour or on behaviour itself, relationships between behaviour, individuals and the social and physical environments in which they occur (Tonkin-Crine 2012).

Physicians' behaviour in decision-making, and in particular in prescribing, has been analysed from the perspective of different theories (Grol et al 2007; Tonkin-Crine 2012), including: social cognitive theory (Bandura 1998); theory of reasoned action and theory of planned behaviour (Ajzen 1991; Ajzen 1998); self-determination theory (Ryan and Deci 2000); operant learning theory (Blackman 1974); self-regulation theory (Leventhal et al 1998) and so forth. The aim of such analysis was to understand physicians' behaviours and identify attitudes and beliefs that have an effect on their motivation to prescribe, which would potentially be used for formulating policies and interventions to change these behaviours (Walker et al 2001). Conclusions emerging from these studies show that, empirical evidence of the effectiveness and feasibility of most theoretical approaches promoting behaviour change is limited (Grol et al 2007). This implies that drawing conclusions and proposing specific interventions needs to be based on the specificities of the different economic, political, and organizational contexts (Godin et al 2008; Goodwin 2012), bearing in mind their complexities and the behaviour intended to be changed (Walker et al 2007; Goossens et al 2005; Ferech et al 2006). An illustrative example is an international comparative study in 13 countries showing major

differences between physicians in the decision of whether or not to prescribe, from twice as likely to four times less likely, compared to the overall mean (Butler et al 2009).

Bearing in mind the above, policies have been designed to embed different contextualized mechanisms to address prescribing behaviour among physicians. These mechanisms in medicolegal terms can be divided into preventive and curative, where preventive implies that physicians are educated in theory and advised in their place of practice on good prescribing based on clinical guidelines and prescribing protocols, and curative is based on incentive and punishment systems. In most cases, a combination of the two types of mechanisms is used. In the UK and most EU countries there are both interventions for providing information through guidelines and continuous professional development, as well as through audit and feedback - based on the monitoring of prescribing at the primary care practice level over a certain period of time, and providing feedback that potentially would initiate behaviour change (Tonkin-Crine 2012). In addition to these preventive mechanisms, as mentioned above, countries have also established curative actions; most EU countries are monitoring physicians' prescription patterns, and in cases of large divergence from the predefined benchmark, the physicians are advised, asked to explain and may be fined or undergo legal action, including waiving of their prescribing right if no explanation is provided (Carone 2012). These interventions have been shown to have positive effect on changing behaviour towards reducing unnecessary prescribing and on higher adherence to clinical guidelines (Zwar et al 1999; Munck et al 1999; Davey et al 2013). An elaborate review of all studies published during 1990-2006, produced by the World Health Organisation (WHO), showed trends of some improvement in rational prescribing over the 25-year period based on the interventions assessed in these studies. The review concludes that the

most frequent types of interventions used for improving appropriateness of prescribing have been educational programmes for health providers alone or in combination with educational programmes and health information for patients (WHO 2009); however, increasing numbers of interventions consisting of enhanced supervision and routine monitoring of prescribing have also been observed. The review concludes that multi-faceted interventions directed at both providers and patients have tended to be more effective than those that employ one strategy only (WHO 2009).

Thus, interventions aimed at change in behaviour can have significant influence on appropriate prescribing and rational use of medicines. However, at the same time, as argued by Britten (2001), 'the acts of prescribing and dispensing define social relationships between patients, doctors, nurses, pharmacists and others' (Britten 2001), and behaviour is determined by these interactions, which are in turn influenced by a number of factors. The next section provides an overview of factors influencing prescribing with a focus on primary healthcare, representing a focal point of contact between physicians and patients.

3.6. Overview of factors influencing prescribing in primary healthcare

As already described, prescribing medicines is one of the most frequent therapeutic decisions made in primary healthcare (Bakker et al 2007) and is used as one of the indicators of quality of care (Glinz et al 2017). As elaborated earlier, one of the major findings of most studies on factors influencing prescribing suggests considerable variations, identifying both clinical and non-clinical reasons (Goossens et al 2005; Ferech et al 2006; Denig et al 1988; Bradley 1991; McGuire et al 1994; Carlsen et al 2007; Buusman et al 2007; Teixeira et al 2013; Glinz et al 2017). In this sense, there is a

continuous research interest in factors influencing prescribing. A recent review of qualitative studies on physician prescribing behaviour divided the influencing factors into two main groups: intrinsic and extrinsic (Rodrigues et al 2013). Among the intrinsic factors conclusive evidence is drawn on the physicians' experience (Paredes et al 1996; Schouten et al 2007; Paluck et al 2001; Kumar et al 2003; Denig and Haaijer-Ruskamp 1995) and level of education (Liabsuetrakul et al 2003; Paluck et al 2001; Kumar et al 2003). Among the extrinsic factors found to influence prescribing, the most prominent are those pertaining to the regulatory mechanisms and patients (Björnsdóttir et al 2010; Kotwani et al 2010; Rodrigues et al 2013).

All of the above reflect the complexity of the prescribing process and highlight the need to understand the influence of these factors (Rodrigues et al 2013) on prescribing and dispensing. These are elaborated in detail in the following sections, reviewed through three perspectives: providers' experience, regulatory mechanisms, and social factors pertaining to the patients and physician-patient interaction.

3.6.1. Providers' experience factors

With regards to providers' experience, several dimensions have been explored in the literature. The majority of studies highlight professional and personal experience of physicians as the most influential factor that dictates prescribing decisions (Wood-Mitchell et al 2008; Schwartz et al. 1989; Tichelaar et al. 2010; Vallano 2004). The predominance of this factor is reported to even influence prescribing when scientific evidence contradicts the professional experience of the physicians (Schwartz et al 1989).

The influence of others' prescribing on the physician's decision-making has been assessed in the literature, and there is evidence that such influence is recognized and

acknowledged in the physicians' perceptions. Research on the attitudes of physicians regarding the influence of other physicians shows that further to their own experience, physicians value the experience of colleagues and peers, even though this is more widely researched and established as a finding among clinicians at hospital level. A few studies have found physicians' decisions on prescribing in primary healthcare to be influenced by specialists or the physicians in higher levels of care, i.e. hospitals (Buusman et al 2007; Eccles et al 1996). For example, several studies have concluded that physicians at primary care level feel reluctant to discontinue the prescription from a higher level of care, i.e. specialist or hospital clinicians (Armstrong and Ogden 2006; Buusman et al. 2007; Cantrill et al. 2000).

The research on attitudes of physicians towards influence of peers on their prescribing shows that physicians in primary care also value the experience and opinion of their peers, but due to lack of possibilities to interact (physically per se) on a daily basis, they exchange their expertise mainly in scientific meetings (Prosser et al. 2003; Wood et al. 2007). Yet, other studies depict that such interaction is not valued or practiced among general practitioners, due to confidence in their own prescribing ability and fear of criticism (Carthy et al 2000).

Related to the confidence in their own prescribing, physicians disclosed it as sometimes being subject to the influence of informal rules (Bishop et al 2011; Cavazos et al 2008), which are not always evidence-based (Ljungberg et al. 2007; Fontana et al 2000; Wood et al 2007). Kumar et al (2003) found that physicians sometimes prescribed without medical indication to prevent complications, and felt comfortable with such decisions (Kumar et al 2003). Further literature suggests that doctors' decision making is altered by patient, time and workload pressures (Petursson 2005; Greenhalgh and Gill 1997;

Miller et al 1999; Welschen et al 2004) - all influenced by the policies regulating health systems. The regulatory factors influencing prescribing are elaborated in further detail in the next section.

3.6.2. Regulatory factors and system's influence on prescribing

There is a long list of regulatory factors influencing prescribing that have been researched in the literature. This review provides insights into those that are of relevance to the research questions, and to the situation in the analysed context.

Cost as a factor for decision-making in prescribing has not been extensively researched, although it was considered in part in several studies. The examined literature distinguishes the costs as those arising for the system, and the costs that are born by the patient. When it comes to costs of prescribing, physicians are rarely aware (Ernst et al 2000; Coenen et al 2006) or concerned (Coenen et al 2006), although in some studies costs to the system were considered in decision making (Greenfield et al. 2005; Jacoby et al 2003; Little and Williamson 1995), as well as costs to the patients (Hassel et al 2003). However, other factors are sometimes viewed as more important than costs (Ljungberg et al 2007; Prosser and Willey 2006; Coenen et al 2006), and while taken into consideration, physicians are not ready to accept or make entirely cost-oriented decisions in prescribing (Maddox 2011).

One of the most researched topics on regulatory factors is the relationship between prescribing and attitudes and practices related to clinical guideline existence and adherence (e.g. Sun et al 2015; Grol and Grimshaw 2003). It can be argued from the literature that guidelines have significant influence on the prescribing decisions of physicians at both primary (Wood et al 2005) and other levels of care (Higgins and Tully

2005; Ljungberg et al 2007). Furthermore, targeted educational efforts at the practice level (Coenen et al 2005) and monitoring of prescribing (Tonkin-Crine 2013) have significant influence in changing prescribing behaviour. However, there are studies showing that guidelines might not always have predominance in influencing decision-making (Wathen and Dean 2004; Butler et al 1998; Coenen et al 2006), and that other factors can override the 'written rules' when they differ from the experience (Schwartz et al 1989), from other guidelines (Wathen and Dean 2004) or from the best interest of the patient (Wood et al. 2007). These other factors include professional experience as mentioned earlier (Wood-Mitchell et al 2008; Schwartz et al. 1989; Tichelaar et al. 2010; Vallano 2004), maintaining a good relationship with the patient (Butler et al 1998; Coenen et al 2006), patient satisfaction (Himmel et al 1997) and so forth.

In this respect, influencing factors related to patients and patient-physician relationship are elaborated further in the next section.

3.6.3. Patients' influence and physician-patient relationship

The third type of influence on prescribing considered in this research is the group of factors pertaining to patients and the physician-patient relationship.

Prescribing is inevitably influenced by patients and the physician-patient relationship, considered by physicians as one of the main elements in decision-making for prescribing (Mossialos et al 2004), alongside the symptoms and condition of the patient (Butler et al 1998; Rodrigues et al 2013).

The past two decades have seen continuous attention within the research community on the role of patients in shaping prescribing behaviour and practices of healthcare providers (Cockburn and Pit 1997; Davey 2002; Vanden Eng 2003; Ashworth 2016). A

number of studies have found that physicians tend to prescribe under patient pressure, despite the imbalance of professional expertise and information between the two parties. With the expansion of the Internet and easier access to information outlets and educational resources, this pressure is likely to become even greater in the future (Gardiner 2008). Literature shows that patients come to the physician with certain expectations, stemming from their somatic symptoms, previous experience, perceived vulnerability, and so forth (Kravitz et al 1996); but also that physicians are to some extent aware of the patients' expectations (Rao et al 2000; Butler et al 1998). The literature review by Rao et al (2000) on the visit-specific expectations of patients underlines that, while there are studies showing no significant influence or that are inconclusive on such influences, there are studies concluding that unmet expectations of patients – for prescription in particular - led to either repeated visits for the same symptoms (Mcfarlane et al 1997) or obtaining the medicine without prescription (Rapoport 1979). These expectations, from a theoretical perspective, play an important role in physician-patient interactions, as will be reviewed in more detail in the following paragraphs.

There is ample evidence in the literature that the physician-patient interaction plays a significant role in decision-making (Britten 2008, Ch. 3) and has a large contribution to excessive and unnecessary prescribing (Cribb and Barber 1997; Butler et al 1998; Arnold and Strauss 2005; Rodrigues 2013). While describing it as the most uncomfortable decision about prescribing that they make (Bradley 1991; Bradley 1992), physicians often incline towards clinically inappropriate prescribing for reasons involving patients' expectations or perceived expectations to have medicines prescribed (Arnold and Straus 2005; Kotwani et al 2010; Hornberger et al 1997; Himmel et al 1997).

As described by Butler et al (1998), for example, ‘general practitioners attempted to sense patients’ flexibility and prescribe antibiotics as soon as they perceived resistance to a non-antibiotic approach’ (Butler et al 1998). When patients expect antibiotics they are more likely to be prescribed (Vinson and Lutz 1993; Kravitz et al 2002) and when physicians perceive that patients expect antibiotics they are 10 times more likely to be prescribed (Cockburn and Pit 1997; Little et al 2004; Toiviainen et al 2005). In this sense, irrespective of the potential non-adherence to the clinical guidelines or rationalization policies, studies have shown that physicians’ decisions on prescribing can often be driven by the motivation of preserving a good physician-patient relationship (Carlsen et al 2007) even if it means fulfilling patients’ wishes without evidence-based justification (Miller et al 1999). Maintaining a good physician-patient relationship (Coenen et al 2006) and impact on the therapeutic power of the physician-patient relationship (Butler et al 1998) were seen by some physicians as more important than prescribing based on medical indication. It can thus be concluded that the physician-patient relationship and interaction during a patient’s visit contribute to the prescribing decision.

3.7. Rational dispensing and challenges to legal supply

The previous sections provided an overview of prescribing and associated influences and also how policy has been used to regulate the supply of medicines but there is an emerging literature that indicates such regulation is not always effective. In particular, there have been several studies - drawing on ethnographic methods in transition countries - that have explored the supply of prescription medicines through practices and settings that are not considered either legal or authorised. These have been helpfully summarised by Whyte, Van der Geest and Hardon (2002) who have identified a

phenomenon of '*pharmacists as doctors*' wherein pharmacists provided an extensive range of medicines without the need for patients to consult a physician. Although stressing the socio-cultural significance of such research, they identified studies particularly in Latin America where pharmacists were engaged in '*quasi-legal and shadowy practices*' (Whyte, Van der Geest and Hardon, 2002). For some communities, this has been argued to arise due to logistical problems in seeking medical advice (Ferguson 1988). In others, however, there appeared to be a more overt intention to subvert recognised laws and, indeed, some health professionals appeared to recognise the problematic nature of such supplies (Wolffers 1987). Van der Geest (1982) framed this phenomenon in terms of two key questions: how are such practices possible and why do patients use such sources of medicines. He argued that there are economic and commercial drivers which can influence pharmacists to make such supplies and further questioned if this is a consequence of *laisse faire* capitalist economies and whether it would happen in socialist countries (Van der Geest 1982 p.211). The desire for patients to make such purchases is argued to arise for complex reasons relating not only to more obvious economic factors, but also complex social factors.

Such issues are not restricted only to Latin America and Smith (2009) provided a review of pharmacy services and highlighted many such practices in settings such as Vietnam (Duong et al 1997), Nepal (Wachter et al 1999), Nigeria (Oladipo and Lamikanra 2002), Brazil (Volpato et al 2005), Zimbabwe (Nyazema et al 2007), Thailand (Apisarnthanarak et al 2008), and Zambia (Kalungia et al 2016). Most of these studies pointed to socio-cultural factors dominating the decision to dispense and obtain medicines without prescription, justified as lack of access to physicians' prescription, but also as perceived sufficient professional knowledge of pharmacists to prescribe.

Literature shows that such practices are present in Europe as well; studies describing self-medication and home keeping of medicines - antimicrobial medicines in particular - in Spain (Orero et al 1997; Gonzalez Nunez et al 1998), Greece (Contopoulos-Ioannidis et al 2001; Mitsi et al 2005), Russia (Stratchounski et al 2003), and Malta (Borg and Scicluna 2002) also suggested considerable use of these medicines without consulting a physician. Obtaining medicines from pharmacies without prescription is also described in the literature as a frequent practice in eastern European countries (Grigoryan et al 2006; Versporten et al 2014). Recent research findings regarding the association between inappropriate use of medicines and antimicrobial resistance (Goossens et al 2005) continue to keep rational prescribing (Aronson 2004; Aronson 2006; Wallerstedt et al 2014; Reeve et al 2015) and legal medicine supply high on the research agenda (Goff et al 2002, Iruka et al 2005).

Other studies found that not only antimicrobials, but other classes of medicines are dispensed without prescription. A study in northwest Spain found that nearly two thirds of pharmacist respondents admitted to dispensing medicines without prescription, including angiotensin-converting enzyme inhibitors, benzodiazepines and oral contraceptives (Caamano et al 2005); Guinovart et al (2015) confirmed this finding and discovered that the practice continued with upward trend for antibiotics. Several studies were looking into determinants of quality of dispensing, indicating a wide range of influences, such as social and demographic factors, educational background and workload (Caamano et al 2004), as well as pharmacists' opinions about their role, especially pertaining to underestimation of physicians qualifications and overestimation of their own qualifications to prescribe (Caamano et al 2005; Beney et al 2000).

This section provided a brief overview of a relatively neglected aspect of medicine supply (Van der Geest 1982). Lack of existing literature and scarce emphasis put on dispensing and rational dispensing by scholars who have researched medicine supply *in extenso*, further confirms the necessity for additional research in the area. For example, Britten in her book *Medicines and Society* (2008) looks into dispensing but is not dedicating substantive attention as part of the medicine supply.

So far, the literature surrounding the supply of medicines has been presented in terms of mainly empirical research relating to various influences upon prescribing and dispensing and associated rationality and autonomy. In the remainder of this chapter, a theoretical approach to considering not only the supply of medicines will be provided (Britten 2008), but also how this relates uniquely to transition countries.

3.8. Medicine supply and Habermas' System and Lifeworld

Several attempts have been made to offer a more sociological account of medicine supply. Whyte, Van der Geest and Hardon (2002) argued that there was a socially grounded nature of medicines and what they termed the '*social lives of medicines*' as evidenced through numerous ethnographic accounts. In addition, Britten (2001) has argued that '*the acts of prescribing and dispensing define social relationships between patients, doctors, nurses, pharmacists and others*' (Britten 2001). Britten went on to explore the conceptualization of medicines and their role and function in society from a more specific theoretical perspective. To do so, she argued that Habermas' social theory of system and lifeworld could be applied to different aspects of medicines – in their development, prescribing and consumption – and that this theory offered an explanation for trends within medicine supply. In the following sections, Habermas'

theory of system and lifeworld will be described and particularly in relation to medicine supply and the respective roles of prescribers and patients.

3.8.1 Habermas' theory of communicative action and healthcare

Before considering medicine supply specifically in this theoretical sense, it is necessary to describe the basic concepts of Habermas' theory of social life and communicative action (Habermas 1987). In his theory, and of particular relevance to this thesis, Habermas provided arguments for the two distinct spheres of social life: the system and the lifeworld (Barry et al, 2001; Finlayson, 2005; Britten, 2008), with each of these two spheres governed by different rationality; the system being largely a subject of instrumental rationality – orientated towards structure, systematisation and successful outputs; whilst the lifeworld is the depiction of the communicative rationality – orientated towards reasoning, interpretation, exchange and achieving mutual understanding (Stanford Encyclopaedia of Philosophy, 2015). System and lifeworld represent just one aspect, however, of a more complex and broader social theory, which focuses on the significance of communicative acts and rationality, and through important mechanisms such as discourse ethics. Although a more detailed discussion of these concepts is beyond the scope of this thesis – particularly in terms of Habermas' political and philosophical aims – the enduring normativity of his work in relation to system and lifeworld are argued to be highly relevant to this thesis, and as will be shown, have been used by several writers to contextualise and understand different aspects of health (Mischler 1984; Barry et al 2001; Scambler and Britten 2001; Britten 2008; Thompson 2009). These have offered important insights into topics as varied as doctor and patient interactions, the role of medicines in society and the involvement of patients in research networks.

Essentially, the lifeworld as explained by Habermas refers to the sphere of social life and through its '*communicative action*' plays an essential role as one of the basic interests of modern society (Habermas 1987), as central to human relationships (Cuff et al 2006, p.292), and through which all cultural, experiential and knowledge exchanges occur (Britten, 2008; Habermas, 1987). Within the lifeworld, communication and exchanges have intrinsic value and aim to achieve common understanding without any dominance or power imbalance between individuals (Barry et al 2001). In other words:

'If communicative action is taken as the most basic form of human action, then, it opens up the possibility of a society in which social relations are conducted on the basis of mutual recognition of one another as free and independent beings.' Cuff et al (2006, p.292)

Habermas' system-world stems from Marx's interpretations of society and the Parsonian conception of the social system (Cuff et al 2006, p. 323). It is concerned predominantly with the material exchanges of the society and structuralism, whereby all means, including human beings are utilized for the successful production of actions and outputs (Finlayson, 2005, Cuff et al 2006, p. 293). This uses rationality again, but instead of communicative rationality, it values scientific rationality and objective measurements (Britten 2008, p.18). In the context of healthcare and prescribing, Britten (2008, p. 19) explaining this divergence as:

'...the lifeworld/system distinction points out the tension between the experiences, needs and concerns of lay people, patients and carers on one hand and, on the other, the need to make profit in a capitalist society (pharmaceutical companies) and the role in enacting government policies (health professionals)...Individuals who become ill not only find themselves as members of the familiar lifeworld but also members of an unfamiliar healthcare system with different rules and modes of behaviour' (Britten 2008, p.19)

A further important aspect of Habermas' theory is what he termed the colonisation of the lifeworld by the system. This is argued to arise in modern societies and it involves increasing systematisation of particular areas of the lifeworld, leading to deviation from or stagnation of the original purpose of the lifeworld and its communicative action (Barry et al 2001). In terms of the physician-patient encounter exemplifying the system/lifeworld interaction such systematisation and superimposition could be illustrated through, for example, pressure of the system on the physician to see more patients, manifest as increasingly limited times for consultation and thorough examination (Butler et al 1998). Physicians, or health providers in general are expected to maximise their output in minimum time, as a prerequisite for being part of the system and its presupposed efficiency (Cuff et al 2006). In turn, this leads to limited space for communicative rationality, producing patient dissatisfaction and unmet expectations (Kravitz et al 1996; Rao et al 2000) that represents a failure to reach the common understanding.

But however different the system and lifeworld rationalities are, they remain interdependent and in continuous interaction (Habermas 1987; Cuff et al 2006, p.296). The actual type of interaction between the two spheres – in this case the patient and the physician – is what determines the product and the outcome of such interaction. Barry et al (2001) in their research identify four types of interaction, summarized in Table 5 below.

Table 5. The four types of engaged interaction between system and lifeworld and the outcomes summarized by Barry et al (2001)

Interaction between system and lifeworld	Outcome
When doctor and patient both used the voice of medicine exclusively (acute physical complaints) this worked for simple unitary problems	<i>Strictly Medicine</i>
When both doctor and patient engaged with the lifeworld, more of the agenda was voiced and patients were recognised as unique human beings	<i>Mutual Lifeworld</i>
Patients use the voice of the lifeworld but were ignored as physicians use the voice of medicine	<i>Lifeworld Ignored</i>
Patients use the voice of lifeworld but are blocked as physicians use of the voice of medicine	<i>Lifeworld Blocked</i>

Their analysis supports the premise that prioritising the lifeworld would contribute to better outcomes and more humane treatment of patients as unique human beings (Barry et al 2001), but would also contribute to higher compliance with the recommendations and medical advice given to them (Roter 1977; Kaplan et al 1989). At the same time, and as Britten (2008) noted, this emphasis on the individualised choice resonates with the work of Giddens (1991) and the work on ‘individualisation’ of Beck (2002) who postulated that contemporary society can be characterised by the way in which individuals choose the kind of life they want to live, with a reflexivity to every aspect of their lives so as to increase the possibility of making *‘the right’* choices.

Following the above theoretical explanations of Habermas’ theory, it can be concluded that the lifeworld has a significant role to play in prescribing, reviewed in the next section.

3.8.2 The Lifeworld: patients' role in prescribing and dispensing

The role of patients in medical decision making, and in particular in prescribing and dispensing, is not to be neglected and needs to be viewed through its perspective of complex, contextualized and meaningful interaction with the physician and the health system in general. As Scambler and Britten (2001) argue, analysing the physician-patient relationship as '*an autonomous and self-contained unit of analysis*' raises the concern of neglecting the broader sociological circumstances that influence it. The theoretical underpinning of this role has initially been reviewed by Mishler (1984) through Habermas' theory of communicative action applied to medical encounters, later researched and elaborated by other scholars (Frank 1997, p.143; Barry et al 2001; Britten 2008).

Patients' influence on decision-making was explained by Mishler (1984) through medical encounters: 'the voice of the lifeworld refers to the patient's contextually-grounded experiences of events and problems in her life.' (Mishler 1984, p.104). Stewart et al (2003) consider that the patient's contribution to the healing process includes 'the patient's personal and subjective experience of sickness; the feelings, thoughts and altered behaviour of someone who feels sick' (Stewart et al 2003, p.35). Therefore, behaviour and thus the influence of patients and their relationship with providers is inevitably bound to the 'complex whole which includes knowledge, belief, art, morals, law, custom and any other capabilities and habits acquired by man as a member of society' (Taylor 1871). Patients' behaviour represents the totality of a person's learned, accumulated experience, which is socially transmitted through communication. In this sense, the personal identity as conceived by Mead (1972) and Durkheim (1984) arises as a structure that results from taking over socially generalized expectations, and 'an

organized set of attitudes that one takes over from one's reference persons' (Habermas 1989, p.58). Habermas refers to culture, society and personality as structural components of the lifeworld, where individuality is expressed through the heightened claims to autonomy and self-realization (Habermas 1989, p.107). Thus, beyond the specialised knowledge and system realities, individuality plays a significant role in shaping the communicative action and outcomes of a medical encounter, including modifying prescribing behaviour (Britten 2008, p. 50). Habermas's communicative action in medical encounters was described by Lazare et al (1975) as a process of negotiation between the physician and the patient:

'Patients are conceived of as appearing with one or more requests... It is the clinician's task to elicit the request, collect the relevant clinical data, and enter into a negotiation that should foster a relationship of mutual influence between patient and clinician.' (Lazare et al 1975)

Increasing access to information, reducing the knowledge gap between providers and patients and deprofessionalisation of medicine (Scambler and Britten 2001) become enablers for the empowered patient's negotiation and influence on decision-making, as part of the resistance to the colonization of the lifeworld by either the state or market forces (Williams and Popay 2002). Such influence is additionally induced by doctors' attempts to 'balance between the task of understanding the disease (the 'science of medicine') and that of understanding the patient (the 'art of medicine')' (Butalid 2014, p.8). Physicians have a dual role to play, representing the system in the physician-patient interaction, and at the same time being themselves part of the lifeworld; thus it is arguable that their behaviour is affected by the exchanges made through this interaction. And, indeed, there is extensive literature not only on such interactions, but

also on their impact on prescribing outcomes, describing a shift from the traditional supply-induced care into a more demand-induced care (Brink-Muinen et al 2006).

However, as already mentioned, these interactions do not happen in a vacuum, and have to be analysed also vis-à-vis the influences of a wider societal and economic context. Cribb and Barber (1997) talk about the context of choice of prescribing as being one of the key factors shaping prescribing decisions (Cribb and Barber 1997). Britten's (2008) further analysis confirmed that prescribing and dispensing is more than a technical issue, and is influenced by a range of social and contextual factors (Britten 2008, p.115). As they are of particular interest to this thesis, the following sections review the literature on prescribing and dispensing in transition countries.

3.9. Prescribing and dispensing in transition countries

Since primary care is continuously evolving, the doctor-patient interaction is influenced by the prevailing context of a particular point in time (Butalid 2014, p.8). It is thus of immense importance to provide an overview of primary care and its changes in the transition countries, as the context in which prescribing and dispensing is of interest to this thesis.

3.9.1 Primary care and system/lifeworld interactions

As explained earlier, primary care represents the first point of contact with patients, and the physician-patient relationship has been widely researched with regards to it (Bakker et al 1997; Bradley 1992). As the focus of this thesis is prescribing and dispensing at primary care level, in order to understand the transition economy context in which these are researched, it is necessary to provide background information on the context

in which primary care is set, functioning and evolving. This section provides an overview of the different engagement mechanisms of providers in primary care through the perspective of the Habermas' theory.

Salaried primary healthcare is closest to and most resembles financing in the health system under the socialist system of command economy (Mandel 1986). Salaries in healthcare incentivise provision of care at the discretion of the provider that is not based on any performance indicators and encourages referrals and prescribing, as these are often not financially confined. If viewing this through the perspective of the system/lifeworld, in the salaried model, physicians have more time and space for interaction with their patients, and a common understanding is much more likely to be reached. Such a common understanding is likely to be unfavourable from the system's perspective, as a result of disguised dissociation of doctors from the system, through lack of performance indicators (characteristic of purposive rationality) and enormous clinical autonomy (supportive of value rationality).

The fee-for-service (FFS) model, on the other hand, is based on the concept of efficient use of allocated resources, incentivising physicians to provide fewer unnecessary (and sometimes necessary) services. It can be argued that with the fee-for-service model, the time for the consultation, i.e. communicative rationality and reaching a common understanding are severely affected, as the system usually sets strict efficiency requirements over the physician for obtaining the reward for the work delivered. Thus, in this model, the system instrumentalizes providers in fulfilling its goals, explicitly superimposing itself onto the lifeworld.

The third major reimbursement method used in primary care, the capitation model – and its modified alternatives, as already described in previous sections - is based on payment of a set amount ex-ante for each registered patient, adding a proportionality dimension to the income relative to the number of patients. In addition, the capitation model also addresses some of the issues of the financing of additional services, such as medicines. The capitation model thus encourages the communicative rationality between the system and the lifeworld, but still can arguably somewhat limit the possibilities for reaching a common understanding, especially with regards to the limitations set for prescribing or referrals.

Following this review of the main features of different models of primary care, the following section reviews primary care in the context of the transition countries.

3.9.2 Primary care in transition countries

Although there were some experimentations with models, by the mid-2000s transition economies have almost all introduced capitation models for payment among primary care doctors (e.g. Albania, Bulgaria, Czech Republic, Hungary, Macedonia), or capitation combined with fee-for-service (Croatia, Poland, Romania) (Ciumas and Vaidean 2008), while some introduced modified versions of partial or full reimbursement through fee-for-service for preventive care or minor surgery (Leive 2010). Policies and mechanisms of capitation are similar in the broadest sense; capitation amount per patient is set based on varied criteria, generally accounting for specific adjustments for the registered patients in terms of their expected health needs, dependent on age, gender, rural/urban location and so forth (Leive 2010). Most of the countries adopting the capitation model have a policy of limitation on the number of patients that can be registered under a single provider (Kornai and Eggleston 2001); however in some systems the limit set is

only to represent the cut-off point beyond which, for additionally registered patients, physicians would receive a lower capitation amount (Milevska-Kostova et al 2017, p.24). This is aimed at dis-incentivising physicians to register more patients than optimally possible to interact with, and thus ensuring equality of access, through, for example, time dedicated to each patient. In other words, such a limitation was aiming at securing time and resources for communicative action and reaching mutual understanding, given that medical consultations are central to health care and primary care in particular (Butalid 2014, p.9). From the perspective of the system/lifeworld, this can be argued as somewhat paradoxical, since it means that the system is diverging itself to the lifeworld, by attempting to enable sufficient time for communicative rationality, as opposed to confining itself to efficiency and objective measurements of the outputs; in other words stimulating more services for less time and resources.

As described at the beginning of this section, the previous dominant model in socialist transition countries was the salary-based one (Mandel 1986). Thus, primary care reform was a major change in the health systems of transition countries, which have previously focused their resource allocation and system development at the hospital level and secondary and tertiary care provision (Leive 2010). Further to the change of reimbursement model, some countries have also employed more radical measures for improving efficiency and effectiveness of resource use, through privatisation of primary care (Hebrang 2003; Menon 2006; Albrecht and Klazinga 2009), mirroring the experience of some developed countries (Pollock 2004; Anell 2011). The following subsection reviews the relevant literature on privatisation of primary care.

3.9.3 Privatisation of primary care in transition countries

Following the principles of the Alma Ata Declaration (Alma Ata 1978) where an emphasis is put on prevention and basic care as an affordable and much needed approach for developing countries, as explained earlier, the transition economies have embraced the idea of having a stronger role of primary healthcare. This, in conjunction with the already notorious perception of unresponsiveness and demotivated providers in the public domain that deliver poor quality of care (Lewis et al 2004), led to privatisation of primary healthcare in many transition countries. Alongside democratization and decentralisation, it was considered one of the main outcomes of the overall societal and economic reform (Baillie et al 1998). The expectations were a better line of responsibility and coordination, more effective use of resources and stronger accountability for public spending on health (Golinowska 2007; Wagstaff and Moreno-Serra 2009). As a result, many of the transition countries, gaining confidence from privatisation in the other economic and production sectors (Trupiano 1993; Tirole 1991), have embarked on the process of privatisation of primary care. The model, with various differences, generally consists of transfer of primary care providers to the private sector, while retaining their function of providing services for public funding, through contracting either with the local and regional self-government or with mandatory health insurance institutions (Golinowska 2007). This reform applied to all physicians, pharmacists and dentists at primary care level (Kornai and Eggleston 2001). The model envisaged establishment of their own practices by doctors through self-employment or working as a group of practices of several physicians (Croatia, Macedonia). Pharmacists opened private pharmacies that could operate freely on the market, but were contracted by the respective insurance institutions for the share of medicines covered

by the mandatory health insurance scheme in the country. By 2005, the transformation and transfer of primary care to the private sector was completed or near completion in most countries; Slovakia reported 94% of primary healthcare 'privatized' (Hlavacka et al 2004; Szalay et al 2011), the Czech Republic 95% (Rokosova et al 2005), and Poland, Hungary and the Baltic States around 80% (Golinowska 2007). In Croatia, the process began in 1997 when half of primary care was privatised and was completed several years later (Hebrang et al 2003). With a slight delay to the above, Macedonia embarked on the process in 2005, and by 2009 had completed the privatisation of 95%, with 2010 being the year of complete transfer of primary care into private ownership (Milevska-Kostova et al 2017, p.24). In some countries, like Russia, however, privatisation was not considered an option for transformation of primary care (Sheiman 1991).

To what extent this transformation of primary care has achieved the desired goals of strengthening its gatekeeper role and improving efficiency of resource use has been the subject of a number of studies (e.g. Kornai and Eggleston 2001; Hebrang et al 2003; Golinowska 2007). Existing literature points to, for example, increased levels of fragmentation of services following the reform (e.g. Chernichovsky and Potapchik 1997) and changes in the number of referrals to higher levels of care (Leive 2010). Responsiveness and adaptability of physicians to the new conditions was also assessed (Hebrang et al 2003), showing improved accountability and competition for ensuring improved quality of care (Leive 2010).

However, a common theme concluded by all the studies reviewed is the apparent change of behaviour in one way or another, of both providers and patients. For example, physicians were triggered by these reforms to further specialise (Golinowska 2007), or provide a wider range of services, including, for example some minor surgeries

and telephone counselling after working hours (Kornai and Eggleston 2001; Hebrang et al 2003). On the other hand, findings also show that in many cases, patients continued to visit primary care physician dominantly for obtaining referral to higher levels of care, bringing into question the actual implementation of the reform with regards to primary care's gatekeeping role (Golinowska 2007). In addition, these and other literature sources (WHO 2009; Kaae et al 2016) note the lack of qualitative research in this area, in particular pertaining to the changes in beliefs, attitudes and practices as a result of primary care reform. Furthermore, no studies were identified which specifically assess prescribing and dispensing in transition countries using qualitative methodology, despite the wide behavioural research literature available for developed countries. The next section provides an overview of prescribing and dispensing in transition economies, with the intention of explaining the social, economic and cultural contexts in which the research questions are based.

3.9.4 Prescribing and dispensing in primary care in transition countries: system and lifeworld perspective

The overall health reform and primary care transformation also affected medicine supply. Before the reform period, most transition countries had expanded limit-free pharmaceutical policies, without any limitations on prescribing or dispensing, which were available free of charge to all patients. The pharmaceutical list was one of a utopian health system, where everything, including vitamins and supplements, was prescribed and dispensed free of charge at the point of delivery, within the possibilities of the rather confined reality of command economies (Joncheere and Paal 2002).

Health reform also changed the services provision landscape, including medicine supply through privatisation of domestic and penetration of foreign pharmaceutical production

and distribution companies. Countries liberalised markets for provision of services, including medicines (Nordyke and Peabody 2002), as a complementary reform to privatisation (Goodhue et al 1998). The liberalisation was quickly embraced by both the public and private sectors; for the former it was seen as a possibility to encourage competition and lower prices while expanding medicines availability for the benefit of the citizens. The latter saw it as an opportunity for expanding markets and generating welfare (Granville and Leonard 2003). In its own right, this enabled competition in the supply side, bringing indeed wider availability of medicines, which consequently affected the demand side in which the consumers, i.e. patients became empowered to recognize the variations in the scope and quality of services and medicines provided (Hebrang et al 2003). The changes had drawbacks too; a study on access to medicines in Russia by Perlman and Balabanova (2011) showed that between the early 1990s and 2000s the availability of prescription medicines in pharmacies improved, but at the same time the percentage of patients unable to obtain prescriptions rose sharply. Similar situations were reported in Armenia, Moldova, Ukraine and Kyrgyzstan (Falkingam et al 2010; Jakab and Kutzin 2009; Balabanova et al 2012) where still in 2010 over half of the respondents reported lack of access to medicines (Footman et al 2014).

Returning to the issue of interest, models in which the transition economies have regulated the pharmaceutical market did not differ much from the models explained earlier in this thesis; countries introduced both supply side and demand side measures adapted to the given health system. Without reiterating the details of the pharmaceutical market regulation explained earlier in this chapter, I will briefly explain the demand side measures introduced, as these are of particular interest to the research questions.

Regulation of the pharmaceutical market did not necessarily come with the expertise of the public sector to deal with the new public-private interaction. In the first years, the public sector, still under the old paradigm of health being 'the most valuable public good' that needs to be undisputedly funded, was producing policies that were not too successful in pharmaceutical cost containment. Just as an illustration, in the late 1990s, the transition economies still spent between 16-26% of health expenditures on medicines, whereas in the EU countries this share was between 7-11% (Joncheere and Paal 2002). A further difficulty was posed by the necessity for mind shift in terms of explaining to voters that the new '*better*' society would actually provide '*less*' of what was available before. Thus, with predominantly political motivation, as well as to maintain social stability (Markota et al 1999), governments considered introducing incremental changes in cost containment policies.

At first, in transition countries adopting the capitation model (e.g. Croatia, Macedonia) there was a limitation on the number of prescriptions (and referrals) that primary healthcare physicians could prescribe for their pool of registered patients. This policy intervention intended to '*train*' physicians to plan and rationalize their decisions for prescribing (Hebrang et al 2003). At the same time, a health insurance-covered list of medicines was introduced, as another measure to confine the previously soaring use of medicines and high pharmaceutical spending (Joncheere and Paal 2002). In parallel with these policy interventions, many transition countries have introduced evidence-based clinical guidelines for the recommended pathways of treatment, most of them taking and adapting the procedures from developed countries, mainly the UK (Kanavos 1999). At this point, the policies still did not have a sufficient effect, keeping costs high and quality of care at '*there is room for improvement*' levels. Further policy changes were

considered, and countries introduced fixed prescribing budgets in primary care (e.g. Croatia, Macedonia) or substitution of brand-name with generic medicines (e.g. Czech Republic, Romania, Slovakia). In addition, patients' co-payments for prescription medicines with varying rates between 10 and 50% were introduced as a measure for preventing overprescribing and overdispensing (e.g. Croatia, Czech Republic, Macedonia). The applied combination of changes depended on many factors (Hlavacka et al 2004; Rokosova et al 2005; Golinowska 2007; Gjorgjev et al 2006), mainly driven by overall higher levels of prescribing compared to western countries. At this point, countries also introduced reference pricing and related policies, but as those are supply side mechanisms, for clarity of the text these are not elaborated further in this thesis.

Yet, in some countries (e.g. Slovakia) even after pharmaceutical reform, the share of medicines remained as high as 28% (in 2008) of the total health expenditures (Golinowska 2007). In Macedonia, too, as already elaborated in the previous chapter, the number of prescriptions and pharmaceutical expenditure show a steady increase over the years, despite the introduced policy changes.

With the above in mind, it can be argued that other factors – stemming from and related to the lifeworld and its interactions with the system – are influencing prescribing and dispensing levels. This is confirmed in the literature from the aspects already discussed above. However, although some findings might be universal to the physician-patient relationship, their communication and outcomes of their communicative action, still their specific effects within the context of transition countries requires further attention.

3.10. Research questions

As shown throughout the literature review, there is a lack of qualitative research on prescribing and dispensing in transition countries, which might provide insights into the possible reasons for increasing levels of medicine use despite measures to contain such trends.

The research presented in this thesis is concerned with two major issues:

- What impact do policy changes for regulating prescribing and dispensing have on: (1) the prescribing practices in primary care settings and (2) the dispensing practices in pharmacies?
- What are the experiences, attitudes and opinions of patients, primary care physicians, pharmacists and other stakeholders (policy/decision makers, professional associations/chambers, academia) regarding the policy changes, relevant to their practice and behaviour in the new circumstances?

In exploring these two questions, further secondary questions also arose, concerning:

- a. What are the issues of concern with the policy changes?
- b. What are the benefits and barriers arising from the policy changes?
- c. Are there ethical issues arising from the policy changes or from efforts to overcome barriers?

3.11. Summary of chapter

The aim of this chapter was to review the available literature and identify gaps in knowledge leading to development of research questions on the impact of policy changes on attitudes and practices of prescribing and dispensing. In addition, its intention was to provide an overview of the research context by summarising the past and ongoing changes to primary health care organisation in transition countries, so as to

inform the reader of the societal context in which prescribing and dispensing of medicines is being considered and studied in this thesis.

The literature review showed that prescribing and dispensing are not solely based on clinical indication and medical knowledge. Other factors also influence prescribing and dispensing – such as regulatory factors (related to the system) and societal factors (related to patients and the lifeworld). Literature suggested that individual attitudes, beliefs and behaviour have significant impact on prescribing and dispensing. Physicians have a dual role to play, representing the system in the physician-patient interaction, and at the same time being a conduit between the patient's lifeworld and system world. The literature additionally highlights the fact that context-specific circumstances play a key role in physician-patient interactions, prescribing behaviour and prescribing and dispensing outcomes. These findings have been confirmed across different contexts; however the literature on transition countries is rather scarce. Therefore, this thesis is aimed at reducing these gaps in knowledge.

This chapter also provided an overview of transition countries' intensive health reforms, where pharmaceutical expenditure control was significantly considered in an attempt to increase efficiency and effectiveness of health systems, and primary care in particular. (Nurdyke and Peabody 2002, Cernis-Istenic 1998). Some countries have seen great improvements in efficiency (Franco et al 2004), while others have not been subject to research to evaluate the economic and social benefits of the reforms.

Despite the large interest in analysing the impact of health policies and health reforms in transition economies (Leive 2010), a very small body of evidence exists from these countries in terms of qualitative health research. The WHO review of medicines' use in

primary care in developing and transitional countries noted that in addition to the small number of studies, the research topics and approaches were rather fragmented (WHO 2009). The same review emphasised that many topics remain virtually unexplored, especially using qualitative approaches.

The status of empirical research has also been considered, as an insight into the current body of knowledge on the researched topic. While extensive qualitative literature was found relating to prescribing in general, very few studies have been identified on transition economies (e.g. Petrusavska et al 2015; Vucemilo et al 2013). Of the available studies, some are concerned with the attitudes and perceptions of particular groups, such as physicians (Petrusavska et al 2015) or of patients and their carers (Ilievska 2010). A significant gap in the literature was identified regarding the perceptions, views and experiences related to prescribing or dispensing in these countries. Furthermore, a gap was also identified in terms of theoretical explanations; neither Habermas' theory nor any other theories of behaviour change were used as theoretical underpinnings in any of the identified empirical studies. Drawing in particular on Britten's (2008) use of Habermas' system and lifeworld in the context of medicines in society more generally, it is proposed to study Macedonian policy changes and regulation of prescribing and dispensing in primary care using such a social theory. As will be considered in the next chapter, theory did not explicitly inform the analysis, as an inductive approach was sought, but the discussion chapter will seek to locate the findings of this study not only in the extant empirical literature described in this chapter, but also Habermas' concepts of system and lifeworld.

From a research point of view, it is intriguing to explore the effects of policy changes in transition economies on the views and experiences of different actors involved in

prescribing and dispensing, and if, why and how these, in turn have affected prescribing and dispensing practices in Macedonia, as a case study. Given the similarities of transition societies elaborated earlier, hopefully this research would also contribute to understanding of prescribing and dispensing in the context of other similar countries.

The next chapter, *Methodology*, elaborates on the available methods, their advantages and disadvantages, and justifies the choice of the most appropriate methods for this research, alongside instruments used, sampling and other methodological issues.

CHAPTER 4: Methodology

4.1. Introduction

The aim of this chapter is to present and describe the research strategy and specific methods chosen to answer the questions that have emerged from the previous chapters, namely: what are the effects of prescription policy changes in primary healthcare on firstly, prescribing and dispensing practices and, secondly, the involved stakeholders' perceptions and attitudes towards changes in the prescribing and dispensing policies. As will be elaborated later in this chapter, in this thesis, the involved stakeholders that were invited to share their opinions and attitudes were primary care physicians and pharmacists, patients, and elites, including policy makers, representatives of professional associations and academia.

In addition, this chapter will describe in detail the data collection methods and consider specific issues relating to sampling, data collection and analysis, as well as concerns relating to research ethics, and practical and logistical issues of conducting the research. A reflexive approach to the research is presented, demonstrating also an on-going and active understanding of my role in the research process.

The next sections will provide the rationale for the appropriateness of the methodology and methods chosen for this research. Further, a description of the actual research, including the above mentioned stages, as a common requirement of the scientific research methodology (Silverman 2005, Seale 1999).

4.2. Choice of qualitative methodology

As summarised in previous chapters, the relevant healthcare reforms and the effects these reforms have had on the Macedonian health system have been mainly explored using quantitative research. These have been typified by the use of dependent variables such as the number of outpatient visits, or the volume of prescribed and dispensed medicines. These represent indicators of success as the most appropriate units of comparison and are arguably appropriate for a hypothetico-deductive epistemological perspective on policy change and its impact. This is not unexpected and it is recognised that common research approaches for assessing health reforms and their impact utilise numerical and measurable data, relating to resources (inputs) (Fox-Rushby and Cairns 2005, p.67), process and outputs (Olsen 2009, p. 18). Similarly, the policies are often changed based on evidence that provides causal relationship between the policy change and the effects of that change (Dunn 2004, p.34). Such approaches are predicated on a positivistic epistemology, privileging scientific knowledge about the social world to be amenable to causal inference. The research questions argued to be relevant to this study seek to explore policy change from a very different perspective and value the subjective meaning attributed to such changes and their impact. Furthermore, they encourage the exploration of the depth and potential variety of experience and as such, it is argued that qualitative methodologies are appropriate.

In addition, as elaborated in the previous chapter, the prescribing and dispensing acts are complex endeavours of system and lifeworld, largely influenced by the interpersonal interaction between physician and patient. In this sense, research dealing with the underlying causality of prescribing and dispensing should not be strictly confined to the formal properties of the process, such as examining the statistical or quantitative data to

identify the impact of policy changes on the outcomes. This may neglect the more subtle elements of the dynamics of these processes, including an understanding of the micro level interactions and decision-making taking place on an individual level that inevitably influence outcomes on the macro level.

Qualitative research methodologies vary but are broadly associated with attempts to gain subjective and highly situated emic (as opposed to objective etic) accounts of social phenomena. In the context of these research questions, it is argued that such methodologies will value the subjective and variable nature of the impact of policy change for a range of stakeholders and, as will be shown, through specific methods associated with a qualitative methodology, permit the solicitation of rich, in-depth individual accounts.

4.2.1 Epistemological position

In this research, as will be shown in later sections, different methodological approaches were considered. For addressing the research questions posed in this thesis, I considered the use of both quantitative and qualitative methodology. After doing thorough reading on methodologies, I reasoned that quantitative methodologies could provide responses to questions involving association of policy changes with policy outcomes in terms of levels of prescribing and dispensing – which I covered as descriptive analysis in chapter two. However, I further considered that the responses to questions such as ‘what happened’ would be beneficial in knowing the outcomes of policy changes and to assess if those outcomes are desirable or sufficient. But, those responses would not be sufficient to understand more in-depth ‘how’ and ‘why’ the policy changes arrived at such outcomes. Further methodological readings revealed to me that qualitative methods are more suited to responding to my chosen research

questions, which are substantially grounded in the social world and its interactions. Therefore, choosing qualitative methodology was considered valuable from the perspective of richness of data that it could provide, while bearing in mind that the accounts themselves do not necessarily represent 'the truth' but rather the 'subtle realism' of the respondents through their views, opinions, experience and attitudes. While these should be regarded as respondents' interpretations of the reality, they are also my interpretations as a researcher, of what their views, experiences and attitudes are.

Thus, I further reasoned which epistemological approach to take. Based on reading and my further understanding of the research methodologies, I rejected the positivist approach as not appropriate, given that this approach is grounded on the postulates of objectivity, which in qualitative research, as discussed in following paragraphs is not possible to achieve.

The epistemological foundation of the research is based on assumptions that the data collected are subject to various possible interpretations and these are dependent on myself as the researcher. Acknowledging that we bring to research ourselves complete with what we know or think highlights the impossibility of separating *myself* from the research. I inevitably, through my background as pharmacist and role of researcher of health policies and health reform in Macedonia in the past fifteen years (described in more detail in Chapter One, section 1.3 on page 20), brought pre-understandings to the research process, as my thoughts and ideas were not something I considered I could abstract from, or according to Husserlian phenomenology, 'bracket' (Gearing, 2004). Freshwater and Avis (2004) also disputed the concept of findings just 'emerging' from qualitative research. In a much earlier work, Gadamer (1976) considered pre-

understandings as prejudices, justifying their existence and arguing that they should not be eliminated, but rather properly acknowledged in the process (Gadamer 1976, p.9).

In other words, pre-understandings are not necessarily misperceptions or distortions of truth but should be understood and accepted as conditions by which we encounter the world as we experience something. We bring these pre-understandings into the research process and they influence how we understand things or phenomena. Thus, pre-understandings and even biases are something we cannot simply avoid or 'bracket', which is reinforced by Finlay (2003):

"We should no longer work towards abolishing the presence of the researcher; instead subjectivity in research is transformed from a problem to an opportunity" (Finlay, 2003 p.5).

It is therefore understandable that the epistemological position taken in this research is one where the research process is inextricably bound up in the researcher and that construction of knowledge occurs jointly with the participant (Freshwater and Avis 2004).

I also attempted to have a critical view of my professional background and previous knowledge of the context, alongside that of the respondents. As part of that process, I attempted to reflect on my role in the interviews, and the influence my own experience had on the collected data. Inevitably, I had influence on the respondents, at least on those in the elite stakeholders' and providers' groups, given my work and exposure in the professional community. As such, and upon advice from the supervisors, I decided to use the method of keeping a reflexive journal (elaborated in details under section 4.3.6 Reflecting on interviewing and data collection process) that helped me keep a continuous reflection process, in terms of both my feelings and experiences, and how I

influenced the encounters in the interviews. As an important part of qualitative research, this process of reflexivity is elaborated in further detail under the section describing the data collection process, later in this chapter.

Having argued that a qualitative approach would be most appropriate for answering the research questions posed, in the next section I elaborate the main qualitative methods available for doing such research, the choice of method and justification for such choice.

4.2.2 Rationale for choice of semi-structured interview method

A variety of qualitative methods are available (Silverman 2005; Mason 2002), including observational approaches, focus groups, one-to-one interviews of varying types and also documentary or content analysis. In this section, the justification for the use of a single method of data collection – semi-structured one-to-one interviews – will be presented. However, in order to demonstrate a transparent and reflexive approach, the alternative methods considered are described, together with reasons why they were not regarded as appropriate to answer the research questions.

Focus group discussions were initially considered as a possible method as these represent an empirically well-established method (Kitzinger 1995, Morgan 1998; Hedges 1985) and have been used in policy related research. These involve a group of people being asked about their perceptions, opinions, beliefs and attitudes towards a product, service, concept or idea (Henderson and Naomi 2009). Focus groups are valuable for obtaining data that emerges from group discussions and debate, and this can be with similar or different types of participants. I decided, however, that focus groups were not an appropriate method for several reasons: firstly, the aim was to consider individual experiences in depth and the use of focus groups is less suited to this than, for example, individual interviews; secondly, there was a concern that some participants such as

primary care providers might feel unable to speak openly in a group environment about some ethical aspects of the policy changes for the fear of repercussions; finally primary care privatisation imposed competition among providers, which was considered another factor that could influence the complete honesty and openness of the respondents.

Also considered were observational methods, which represent another commonly used approach in qualitative research (e.g. Smith 1998b). Such methods involve systematically observing people and events to explore behaviours and interactions in natural settings (Mays 1995). Related to this study, it was considered whether observing different participants may be of value but as with focus groups, this was rejected for several reasons. The choice of research method or technique may vary depending upon the nature of the social phenomena under investigation and upon what one wants to understand about those phenomena (Cooper 2006). Observational methods would arguably not provide insights into the second research question about the views and perceptions of stakeholders but could have offered insights into the first research question concerning the impact of policy change. However, a key concern was that this research related to social phenomena relating to policy changes that occurred over some time and as such observational methods would not be able to capture the impact of *past* policy change and events. A final concern was that some stakeholders such as primary care providers for example, may have not given consent to have their professional activities observed; as will become apparent in the following chapter, the identification of examples of un-professional practice may have been easier to solicit from interviews as retrospective accounts, than to have directly observed.

The chosen method of qualitative data collection involved the use of semi-structured interviews. Interviews are considered a '*conversation with a purpose*' (Erlandson et al

1993) allowing for reflection, introspection and in-depth discussion, and involving reasoning processes that may not be apparent through observation (Bryman 2008, p. 329). Of the available approaches in interviewing, a semi-structured interview was chosen, as it allows both participant and researcher to influence the direction of the conversation, whilst permitting the former the opportunity to express their reasoning in their own language and in a way that they find most appropriate. I considered this method the most appropriate since it would allow me to explore the research questions in depth, encouraging detailed responses and also enabling me to probe and challenge responses where appropriate. Further to that, this method allows for issues and ideas arising out of early interviews to be used to inform subsequent interviews. By adopting such an interpretative approach, interviews would also allow the respondents to reflect upon issues or to raise new ones themselves that they encountered in their practice, but which I have not anticipated in the questionnaire guide, and so could be asked of subsequent respondents. The use of unstructured or narrative interviews (Squire 2008) was also considered but given the aim of capturing accounts from a potentially wide range of stakeholders, it was felt that a balance was needed - between the depth of data and the need to capture diverse accounts. The free association narrative interviews (Holloway and Jefferson 2000), based on free associations made by the interviewee, were also considered but rejected for the same reasons. The next section provides a more detailed account of the data collection and in particular the choice and methods of recruiting different participant stakeholders.

4.3. Data collection

4.3.1 Sampling

After choosing semi-structured interviews as the most suitable method to inform the research questions, the next step in my research approach was to identify respondents for each of the groups of interest as described above and begin the recruitment process for the fieldwork. The aim was to use a range of different stakeholders based on their relationship to the various policy changes: physicians (as prescribers of medicines), pharmacists (as suppliers of medicines), patients (as consumers and users of medicines) and various elite stakeholders (selected due to their involvement in or analysis of policy itself). Although sampling for these groups was ultimately the same and involved purposive sampling, the identification and recruitment process varied.

Elite stakeholders

This participant group was identified based on the literature review and also through my experiences and networks. As a researcher in the health sector for over a decade, I had attended different meetings and events, and participated in a number of studies and research projects involving many professionals belonging to the groups of research interest. Through these endeavours, I had the chance to hear their elaborations and expertise on a variety of issues related to health and the health system in the country, which I considered appropriate to use for the purposive sampling approach that I had chosen to apply. Firstly, for sampling within the group of elites, as will be shown later on, I considered those involved in health policy formulation, including health authorities, academia and professional associations and chambers to be particularly relevant. Given the size of the country, all of these institutions are represented with headquarters in the

capital, and some (not all) have executive branches, which are not involved in the policy planning or formulation happening at central level. Having identified these key associations or bodies, the next stage was to identify individuals or representatives. Although I personally know some of them, I used formal invitation and introduction for all recruited participants in this group.

Physicians and Pharmacists

In the initial stages, I considered a sampling strategy to identify the participants for these two professional subgroups, by using the list of registered physicians and pharmacies publicly available on the Health Insurance Fund's official website. There were a number of issues identified with this approach; firstly, the list did not always contain the contact data for the registered entries, and secondly the lists comprised names of registered offices, in which one or more physicians or pharmacists worked. In this context, given that qualitative research does not require for the sample to be random or quantitatively representative of the population because '*representativeness is not a prime requirement when the objective is to understand social processes*' (Mays and Pope 1995), I have undertaken a purposive sampling approach with these two groups, using relevant categories such as different ages, to allow different generational perspectives on the policy changes; administratively and geographically different places were also used to inform the sample, as I anticipated there might be differences in attitudes and practices between larger and smaller communities, i.e. between urban and rural areas. Reflexively, this approach to identifying and sampling also required consideration particularly with regards to my prior knowledge of the context and some

people from both groups; however, I felt that the benefits such insights offered were ultimately an advantage for the sampling.

Patients

For the final participant group – the patients – I undertook a slightly different purposive sampling approach, by selecting from the patients who visited the office of the interviewed physician or pharmacist. The purposefulness of this sampling approach can be argued in the sense that patients who visit the particular physician or pharmacy are more likely to have similar attitudes, as they are not assigned to the practice or pharmacy by some specific criteria, other than the choice of the patient. A concern in utilising this kind of sampling was seen in the possibility that some dimensions of their interaction might not be available to capture, for example, radically different attitudes within the group. However, at this stage, I hoped that within the sampled patients there would be some with experience of changing their chosen physician, and certainly those that obtain medicines in different pharmacies, that would allow for exploring this aspect as well. A purposive approach was used, however, in selecting patients based also on factors such as different gender, age and geographical location. This included, as much as applicable in the given circumstances, choosing patients from both genders and different ages across all visited physicians' offices and pharmacies. Once I had decided on the sampling strategy, the next stage involved defining the sample size.

4.3.2 Sample size

Sample size calculations are not very commonly used in qualitative research (Sandelowski 1995) and it can often be difficult to predict how many interviews will be undertaken. Theoretical saturation was used as a criterion to define the sample size which was understood as being when: *“no additional data being found whereby [the...] researcher becomes empirically confident that a category is saturated”* (Glaser and Strauss 1967). Although this criterion has originally been developed and used in theory development (Glaser and Strauss 1967), it has become an important approach by which purposive sample sizes are determined in health science research (Guest et al 2006). So, although a definitive sample size was not possible to calculate initially, to manage the logistical aspects of the research, approximately fifteen participants in each of the respondent groups were anticipated. The actual samples have shown that the estimated number of interviews, with the exception of the physicians’ group, was sufficient to achieve data saturation for detailed analysis, as the literature suggests that up to twelve interviews are usually sufficient if the aim is to understand common perceptions and experiences among a group of relatively homogeneous individuals (Guest et al 2006).

The final sample and associated characteristics of the participants in each of the groups are presented in Tables 6-10 below.

Table 6. Sampling rationale for interviewees – Elite stakeholders

		N=12
Representative area	Rationale for inclusion	
Ministry of Health (2 participants)	To learn about how the policies regulating prescription and dispensing have been designed, envisaged to be implemented and are implemented;	
Health Insurance Fund (3 participants)	To learn how Health Insurance Fund has transferred these policies into their practice and what are the implications from these policy changes on the overall pharmaceuticals prescription and on the prescription reimbursements;	
Agency for Drugs and Medical Devices (2 participants)	To learn how the Agency for Drugs and Medical Devices has transferred these policies into their practice and what are the implications from these policy changes on the overall pharmaceutical market;	
Professional associations and chambers (3 participants)	To learn what is the professional standpoint of the medical community in regard to the medicine prescribing policies and how it affects the practices and attitudes of health professionals; how the prescription policies overall have affected the work and income of the pharmacists, if there are complaints or other forms of dissatisfaction from the changes. Specific focus was put on the: - Macedonian Medical Association, as an umbrella organisation of all professional associations; and - Association of private doctors in primary care.	
Academic staff working in the fields of economics and social medicine (2 participants)	To learn how these legislative and policy changes are intended to influence the overall prescription regulation, and what are the forecasts of their long-term effects in the Macedonian healthcare system; to obtain academic views on the policies with regard to international and European Union practices in the field.	

Table 7. Interviewees' characteristics – Elites (educational background)

Elite stakeholders		N= 12
Gender	Female	6
	Male	6
Educational background	Medical doctor	7
	Pharmacist	4
	Economist	1
Position	Policy maker	7
	Professional association representative	3
	Academia representative	2

Table 8. Interviewees' characteristics – Primary care physicians

Physicians in primary care		N= 17
Gender	Female	9
	Male	8
Geographical location	Capital	5
	Small town or city	10
	Rural	2

Table 9. Interviewees' characteristics – Pharmacists

Pharmacists in primary care		N= 12
Gender	Female	9
	Male	3
Geographical location	Capital	3
	Small town or city	8
	Rural	1
Status	Owner	2
	Employee	10

Table 10. Interviewees' characteristics – Patients

Patients		N= 14
Gender	Female	6
	Male	8
Geographical location	Capital	5
	Small town or city	7
	Rural	2

4.3.3 Research instruments

Four different topic guides for semi-structured interviews were developed, one for each of the groups of interest to reflect the different experiences, perspectives and relative knowledge of each. While all guides comprised common themes to inform the research

question, they differed to reflect the specific position and role of each of the groups. The initial content of the topic guide was informed by the literature, identifying a broad agenda of topics and themes to explore (Ritchie and Lewis 2003, p. 115). These were then discussed with the supervisors, who provided critical review and substantial comments that helped me structure the guide and reformulate questions. A key aim was to maintain 'neutrality' in how questions were developed and to avoid leading the respondents (Ritchie and Lewis 2003, p.160). Following this, I undertook pilot interviews with one representative from each group, to ensure questions were not only understood, but also comprehensive so that they permitted sufficient scope and depth of data to be obtained (Ritchie and Lewis 2003, p. 135). Piloting was also helpful as it provided me with some experience of using the guides, mostly with regards to maintaining neutrality during the conversations, which could have been jeopardized as a result of my knowledge and involvement in the content and context of the country of interest (Bryman 2008, p. 247). Following piloting, minor changes were introduced to the guides, so the data from the pilot interviews was used to inform the research questions, as suggested by Ritchie and Lewis (2003, p. 135). The research instruments are provided in Appendices D to G.

4.3.4 Incentives for participants

Given the national economic and societal context and the necessity to recruit physicians and pharmacists who are part of the private sector, it became apparent that there might be some reluctance to participate for the reasons of interviews being a time-consuming exercise. It was as a result of these assumptions that I decided to offer some form of remuneration to participants, as suggested by Seidman (2012 p.73) to ensure uninterrupted time for getting an in-depth interview. The funds for this remuneration

were to be secured from the organization in which I work in the capacity of executive director – Centre for Regional Policy Research and Cooperation “Studiorum”, a non-governmental research think-tank that does research on a daily basis and is familiar with such concepts as compensation for loss of time or earnings. In practice, this meant that every invited and participating interviewee was offered a small monetary sum in exchange for the value of the time they were asked to spend in the interview. However, in practice, almost all participants declined the offered remuneration, with the exception of four patient respondents. It could therefore, be concluded that the participants agreed to the interview and shared their opinions, views and experiences without expectation of any direct benefit.

4.3.5 Interviewing

This section describes the process of approaching and informing the respondents and the interview itself, including issues related to the location.

Firstly, prospective participants were approached by telephone or in person with a brief explanation of the study inviting them to participate. Once they agreed and as required by the research ethics standards, prior to the interview, the respondents were informed in further detail of the purpose of the study and its outcome, both verbally and through a study information sheet (given in Appendix B). A signed consent form (sample given in Appendix C) was a requirement from all respondents for participating in the interview. The respondent was given all relevant information, the right to voluntarily participate and the right to withdraw at any given time without giving explanation about the reasons. The information sheet and the consent form were provided to the participants in both English and Macedonian languages. Participants were asked to sign the consent form in both languages.

For securing anonymity, the consent form contains a line where the coding number of the interview was written. The audio recordings, as will be described later, contained only the coding number and the date of the interview. Consent forms and audio files were kept separately in locked cabinets.

The majority of interviews lasted between 40 minutes and an hour, but a small number were significantly longer in duration. These included two physicians, one pharmacist and two respondents in the elite stakeholders' group. Regarding time the interviews were conducted, all respondents from physicians' and pharmacists' groups preferred to be interviewed outside of their working hours, most of them requesting a time period immediately after working hours, while three physicians and two pharmacists agreed to meet at the weekend when they were free from professional duties. In the elites group, with the exception of three persons, all respondents insisted the interview be conducted during their office hours. In the group of patients, interviews were scheduled on a different day than the day when they were initially recruited from the physician's office or pharmacy. In most cases – with exception to the retired persons – the interviews were scheduled after their own working hours.

Respondents were encouraged to choose a location they preferred, to encourage their engagement and participation in research (Mauthner 1997, Gallagher 2005) so they could speak freely, comfortably and in confidence. Most of the interviews with physicians and pharmacists took place at their office, or in the pharmacy where they worked (specifically, in the dispensary, so to be uninterrupted by incoming customers), and some were conducted at the common room at their workplace (usually the tea kitchen or similar place). Four interviews were conducted at the office where I work (three with the elites and one with a physician), as their preferred option of location,

since they found it convenient or considered it would allow for uninterrupted interview time. For the patients several options were offered, including their home, cafeteria or office where I work. With the exception of two, who chose to be interviewed at a quiet cafeteria, all patients considered their home to be most appropriate for the interview.

The participants were also given the choice of whether to conduct the interview in either English or Macedonian language, as interviews conducted in a native language may yield much richer data than if conducted in English as a second language (Wallin and Ahlstrom 2006); all of them chose their native language. There are many advantages to conducting interviews in native language, such as there are no language barriers and it avoids the use of interpreters, which has been shown to reduce validity (Kaae et al 2016).

As the interview guide was exactly that – a guide that could provide structure for systematically covering the relevant issues, while allowing flexibility to pursue details salient to each individual respondent (Ritchie and Lewis 2003, p.115) – it was not used in a rigid manner and additional questions were posed in response to particular responses and some questions were occasionally omitted. However, throughout the interview, wherever possible, respondents were asked to reflect on their views of current or potential problems, and were encouraged to discuss ideas for overcoming any of the obstacles or issues they found to be relevant and important in their view. For example, one of the participants, as will be reviewed in the later chapters, opened a discussion on the ‘chosen pharmacy’ concept that at the time of the interviews was a policy option considered by the government; another participant elaborated *in extenso* a policy alternative that was considered prior to introducing the budget ceilings, but was not adopted, yet it was important to understand the process from the perspective of policy

formulation. A pharmacist from a rural settlement picked up on a topic that was in the media during the period of the interviews, and related to the rural 'pharmacies on wheels', which was considered as issue of concern from the pharmacists' perspective. The intention was, as stated earlier in this chapter, to identify what the respondents in their view and from their daily practice and experience considered to be problematic, if any, and to gain new perspectives on why they perceived these to be problematic, mostly in relation to their subsequently declared attitudes and behaviour in the given circumstances. Vignette questions were used several times, to probe with respondents who have been extremely categorical about a certain topic, however, not in the sense of controlling what the respondent had to say or to divert their opinion on the issue, but rather to test if the categorical attitude was indeed intrinsic or was used as a theoretical answer to the question posed. Such hypothetical situations were asked for example regarding the prescribing of medicine without medical indication to a close friend or family member; dispensing medicine without prescription to a vulnerable patient coming into the pharmacy, or what would be the policy response if physicians prescribed so little as to jeopardize the access to medicines to preserve their prescribing budget. Prompting as a technique was not used.

4.3.6 Reflecting on interviewing and data collection process

As part of reflexive practice (Jupp 2006), what is also termed 'benign introspection' (Davies 2002, p.7), keeping a reflexive journal of notes has been considered as another source of information, as the researcher needs to fully recognize the role of reflexivity with acceptance so that in social research 'the specificity and individuality of the observer are ever present and must therefore be acknowledged, explored and put to creative use' (Okely 1996, p.28). Reflexivity encompasses the continuous evaluation of

subjective responses and the research process itself and involves a shift in understanding data as something objective to the active construction of knowledge (Finlay 2002).

Throughout my research I have been conscious of my relationship with the context and some of the respondents and thus decided to keep a reflexive journal, including personal observations and progress during the course of the qualitative data collection and analysis to facilitate reflection on each aspect of the research. Through this process, I was able to identify ways in which my findings may have been shaped by the co-construction of accounts and, where possible, I challenged myself as principal researcher in relation to these co-constructions. As the interviews were conducted in the Macedonian language, the reflective journal was kept in the same language, for uninterrupted reflexive process. As mentioned by Davies (2002, p.8), there are concerns of the interference from subjectivity of the interviewer's observations, and these are acknowledged throughout the thesis, where relevant.

In line with the above, throughout the data collection, analysis and interpretation processes, I was reflecting a lot on my relationship with the research context and some of the respondents. With my background and previous experience, it was inevitable to anticipate that some of the respondents who were familiar with my previous work – especially policy makers – would have pre-understanding of my knowledge, and thus this was very important to acknowledge in the interviewing process. Thus, I decided to undertake piloting of research instruments, which was to serve a dual purpose: to clarify and further refine the questions, but as well to observe my interaction with the respondents in terms of keeping neutrality as much as possible when asking questions. Beyond the piloting phase, I kept this process of understanding the influence of my

knowledge and relationship with some respondents throughout the entire data collection, improving the approach to asking questions in each subsequent interview. The issue of knowing my previous work was not significant for the other two respondent groups – providers and patients. However, with these groups I kept reflecting on how my personal pre-understandings would affect the interviews, and continued to observe ways in which I could be as neutral as possible when asking the questions.

With all of the above, I have described particular instances of my reflexive practice and sensitivity about how my experiences and relationship with the research context and previous acquaintance with some of the respondents could influence the data collection and analysis. The next section describes the process of recording, transcribing and translation of data.

4.3.7 Recording, transcribing and translation

The majority of interviews were recorded using a digital audio recorder so that later transcription could be undertaken. The recordings were made on a digital recording device (Dictaphone), allowing convenient and prompt data transfer into a computer that was used for listening to the recordings while transcribing. As the interviews were conducted in Macedonian as the native language (Kaae et al 2016), the use of personal computer dictation software was not considered, as no technical possibilities were yet developed for this language on the required professional level at the time of conducting the data analysis. Each recorded file was labelled with the date and the coding number assigned onto the consent form, as a reference to protect the anonymity of data. After each interview, brief notes were made about the overall impression from the interview, mainly regarding how much the respondent felt comfortable with the questions, if there were significant interruptions and so forth. These, as described under a separate

section, were kept in a reflective journal. One physician and four patients preferred not to be recorded and in these cases, extensive notes were taken during the interview and follow-up notes also made summarising key points in the interview.

I undertook transcription as soon as possible after each interview. This approach was chosen as there is an advantage of this very time-consuming process (Bryman 2008, p. 456), over the professional transcription service, as it allows for closer familiarisation with the data and identification of key themes at a very early stage, which contributed to identifying emerging issues that were incorporated into the subsequent interviews. Through this process, it was much easier for me to become aware of similarities and differences between the accounts of different respondents, and to capture some nuances that could be noted only from the recording and not from the written account itself. For example, a long pause of hesitation, a tone of voice or specific sound of agreement or disapproval; these gave me valuable insights into the feelings of the participant about the particular issue that was not verbally expressed.

There are conflicting views in the literature about who should undertake translation. Some literature suggests that combining the role of researcher and translator may influence the objectivity of the knowledge claims (Temple 2005). In contrast, it has also been argued that a joint approach provides the possibility for checking the validity of interpretations (Young and Ackerman, 2001), and offers the researcher significant opportunities for close attention to cross-cultural meanings and interpretations and potentially brings the researcher close to the problems of the equivalence of the meaning within the research process (Temple and Young 2004). The latter arguments coupled with my familiarity with the local language, and also my understanding of the subject itself, led me to undertake the translation process myself. The use of third party

translation might not have enabled this, and the associated requirement to provide contextual meaning in qualitative research (Esposito 2001). To address the threat to validity posed in the literature by the subjective presentation of accounts from a researcher's own social position (Temple 2005) the technique of back translation was used (Pham and Harris 2001, Twinn 1998). Back translation was used on the pilot interviews and involved me translating the full Macedonian language transcripts of the pilot interview into English language firstly. Then these English translations were given to a professional translator for back translation into the Macedonian language. The final stage involved comparing the original Macedonian transcript with that produced through the back translation and checking for any differences. No significant discrepancies were found in the use of specific terminology between the two document types. As a result, I was confident that the analysis of transcripts could be done in the original language and that only the selected quotes relevant to the identified themes would be translated and used in the data interpretation of this thesis.

4.4. Data analysis

4.4.1 Description of thematic analysis

Analysis of the data in this research was undertaken using thematic analysis (Braun and Clarke 2006). This approach to analysis was selected as it represents a well recognised, transparent, and methodical approach which can be applied to this research topic and is compatible with all qualitative methods (Boyatzis 1998). This type of analysis enables researchers to create the '*big picture*' about experiences and events as participants understand them or act upon them (Chambliss and Schutt 2010, p.339).

Although it has been interpreted differently, thematic analysis is usually understood as ‘a method for identifying, analysing and reporting patterns (themes) within data’ (Braun and Clarke, 2006). The most influential and thorough approach to thematic analysis is that of Braun and Clarke (2006) who identify six phases (as illustrated in Table 11).

Table 11. The six phases of thematic analysis

Phase of analysis	Description of the analytic process
1. Familiarizing yourself with the data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic ‘map’ of the analysis.
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back from the analysis to the research question and literature, producing a scholarly report of the analysis.

(Reproduced from Braun and Clarke, 2006)

The sections that follow offer a more situated account of the stages as they related to this research, giving relevant examples and insights that contribute to a transparent approach to research.

4.4.2 Data familiarization

The first step in data analysis, as suggested by Braun and Clarke (2006) is to familiarize oneself with the data. This involved reading the transcripts, listening to audio files and

being immersed in each respondent's account. In addition, I went back to the reflective journal and tried to understand if my own pre-understandings emerged during the interview process, and how they might have affected the respondents. Understanding that my personal horizons would evolve throughout the research, I undertook this step as the first attempt to understand the topic from a broader perspective. In this sense, Gadamer (1996, p.360) helped me through his emphasis on the essence of the right questions, further stating that there is no understanding without the activity of questioning.

Reflecting upon potential bases of interpretation of the respondents' accounts, I posed myself several additional questions, which aimed to provide a greater context to the fusing of horizons between the texts and the researcher:

- Why is the past system frequently mentioned and what is the significance of its influence on current practices?
- What value do providers and patients place on prescribing and dispensing?
- What value do elite stakeholders place on prescribing and dispensing?
- How are decisions made by providers regarding prescribing and dispensing?
- Are those decisions always based on medical indication and clinical knowledge?
- What is the influence of communication between the providers and the policy makers on implementation?
- What is the influence of communication between providers and patients on prescribing and dispensing?

I personally transcribed the interviews as soon as possible after conducting each interview, so as to maximise familiarity with the data. The transcribed and already anonymised text was set out in Microsoft Word as plain text that was later reorganized into table format while generating initial codes, as described in the next section.

4.4.3. Generating initial codes

In qualitative research, collected data can be quite large even if collected from few cases or respondents (Chambliss and Schutt 2010, p.324). It is therefore necessary to employ a data management process, so to enable analysis of its meaningful parts that could inform the research questions. I used coding, as this is the most often used data management method in qualitative research, as conceived by Glaser and Strauss in grounded theory (1967). Coding is a process in which the data are broken down into their component parts that are related to a similar concept or issue, and are analysed based on their common characterisation (Braun and Clarke 2006). Coding is thus essential as it 'provides the link between data and the conceptualization' (Bryman and Burgess 2002, p. 5).

For coding, software packages have been developed, such as NVivo and similar. I have familiarized myself with NVivo in one of the courses taken as part of the graduate research requirements, but realized that it could not be used for the Macedonian language. Thus, I had to take a manual rather than software-assisted approach to data analysis, in line with Ritchie and Lewis's (2003) suggestion that software packages such as these should not be a replacement for the researcher and/or rigorous analysis. The next step of data analysis involved making notes of initial ideas, interesting features and messages from respondents' accounts.

Since thematic analysis is a flexible method, the size of data chunks identified for analysis was variable. In some cases, I identified a broad code to one component of an interview and then within it further identified several others. As I gradually completed more transcripts, the earlier identified codes were revisited and refined. For example, I

might have read an excerpt from an account and interpreted it as an example of a specific phenomenon, when, if I looked at it within the context of the account and data as a whole, I would then see it as more complex, and continued to analyse into further more specific codes. The process of initial coding is illustrated in Table 12 below.

Table 12. An example of analysis conducted on a section of transcript, together with the resolved interpretation in the final column

Respondent	Transcribed text	First analysis attempt	Second analysis attempt	Interpretation
PCP4	<i>The list of medicines was satisfactory. And there were no limitations, we had freedom of prescribing. Let's say, I as a practitioner believe that certain illness should be treated with certain medications and I was free to prescribe them. Things are different today. Nowadays, I cannot prescribe certain medications although I am an experienced pediatrician. I face limitations and I am obliged to ask for the opinion of different institution from a less-experienced medical practitioner. It doesn't make any sense to me.</i>	Emphasis put on freedom to prescribe and professional knowledge and experience valuation in the past system compared with the current policy changes	Previous system had no limitations and Professional knowledge and experience were more valued in the past	There is obvious attachment and association with the previous system Professional autonomy is affected by policy changes

The coding is necessary for categorizing and sorting data (Charmaz 1984, p.111), and it precedes the identification of themes (Bryman 2008, p.554), which are essentially recurring motifs in the interviews used at later stages to analyse the data against. In following sections I describe the process of searching for themes, reviewing and subsequently refining them.

4.4.4. Development of themes

As explained in the previous section, with initial coding I extracted the data chunks from the transcripts and divided each into codes, i.e. units of meaning, identifying interesting features and choosing codes to capture the meaning in the accounts.

The next step of development of themes was performed using a manual approach of identifying the common patterns in the data chunks to form potential themes and sub-themes, searching for the presence or absence of illustrative data extracts relating to these themes from each participant in each of the groups. I have repeated this process several times; an apparent 'absence' of data from a participant that was highlighted in other participants' accounts triggered a review of their transcript to ensure the related data had not been missed. A good example from my analysis relates to the theme 'Nostalgia for the past' which although not initially planned in the interview guides, has strongly emerged in many accounts in all respondents' groups. Although interview guides included questions related to the past system, the strength of responses was such that I felt it should stand as a theme in its own right.

At the same time, I was conscious of the issue of 'importance' of data that was not dominant in all accounts, and therefore paid additional attention to data that was raising interesting issues but was only present in some accounts, considering these as deviant or negative cases. From my initial coding I started to get a sense for themes existing within the transcripts, and continued to reflect on the identified themes, reviewing and refining them into the finally defined themes and sub-themes. These steps are elaborated in the next section.

4.4.5. Reviewing and refining of themes

The next step in thematic analysis was reviewing and refining the themes. This involved reading and interpreting texts as a whole, and repeated coming back to the supplementary questions developed at the stage of familiarizing myself with the data in a process of deepening my understanding. As I was getting more immersed in the transcripts and the extracted data, I continuously worked on refining the specifics of each theme, the overall story of the analysis, and finally generating clear descriptors for the themes.

In detail, firstly I checked the themes against the data extracts and explored whether the themes work in relationship to the data. Checking if the themes ‘worked’ in relation to the entire dataset was undertaken as an iterative process using the following questions taken from Braun and Clarke (2006) to guide my decisions:

- Is this a theme?
- What is the quality of the theme and does it tell us something useful about my dataset and research questions?
- Is there enough meaningful data to support this theme?

The main themes and sub-themes were further refined through continuation of the iterative process, until I felt that optimal understanding of the transcripts had been achieved. As an outcome of this process, I identified three themes each with several sub-themes, elaborated in detail in the next chapter on findings.

4.4.6 Presenting the data findings and write-up

The final step of the thematic analysis, as suggested by Braun and Clarke (2006) is writing up the findings and relating them back to the research aims and literature. This section describes this process in further detail and particularly in relation to the use of quotations. This involved several aspects such as the level of detail from the individual accounts to be presented and the presentation of deviant cases. It was considered important to present not only quotations supporting the main themes, but also to capture alternative and contrasting accounts, particularly from the perspective of deviant cases (Emigh 1997). As noted by Anderson (2010):

'It is also important to present outlying or negative/deviant cases that did not fit with the central interpretation.' (Anderson 2010)

However, as the data were collected in a language different from the one in which this thesis is written, additional attention was dedicated to the process of translation, as already elaborated in the section on data collection.

In summary, to present the findings of the present research, predominantly verbatim fragments from personal interviewees' accounts were used, and where necessary, although to a minimal extent, interpretations of interview data were employed, mainly in an attempt to avoid duplicated presentation of very similar accounts, which contribute to arriving at a given finding or conclusion. In addition, deviant cases were treated with utmost sincerity and openness, so to avoid reducing the data richness in the convenience of fitting the themes into existing theories.

The entire process of data collection and analysis should be subjected to scrutiny of quality and credibility issues, which are elaborated on in the next section.

4.5. Quality and credibility of this research

The positivist approach in research utilises concepts of validity and reliability. Validity refers to how well the research assesses what it is attempting to assess and if generalisation of the results could be inferred, whereas reliability is concerned with the degree to which the research process produces stable and consistent results (Bale 2011). These definitions are not entirely applicable to the qualitative interpretative approach, as argued by Ritchie and Lewis (2003) due to:

“the very different epistemological basis of qualitative research, there are real concerns about whether the same concepts have any value in determining the quality or sustainability of qualitative evidence.” (Ritchie and Lewis 2003 p.270)

Although the need for achieving rigour in qualitative health research is well recognised, there is no agreement on specific criteria for demonstrating the robustness of evidence derived from qualitative inquiries into health practice issues (Bale 2011). However, among the most commonly used criteria for achieving the required scientific rigour are quality and credibility of the research. In the next paragraphs I address these in the context of my research.

To evidence the quality of the research, I considered the categories of reflexivity and reliability. Under the section on data collection, I have already described my reflexive practice and how my experiences and viewpoints could influence the data collection and analysis, and how I have addressed this potential influence in the process.

Assessment of reliability of qualitative research is complicated by a number of issues, related to the possibility for and the extent to which the current study can be replicated

in terms of design and sampling. The possibility that others may be able to replicate the study was considered from the perspective taken by LeCompte and Goetz (1982), who argued that the impossibility to 'freeze' the social setting has to be taken into consideration when considering the reliability issues with qualitative research. As such, the standpoints of Ritchie and Lewis (2003) and Mays and Pope (2000) mentioned earlier become the main arguments for reliability, bearing in mind that the process represents a mapping exercise of particular views, experiences and phenomena, and that search for 'subtle realism' rather than 'the truth' is pursued. In this sense, and relevant to this research, I applied a social constructivist approach, as explained by Finlay (2002):

"Meanings are to be seen to be negotiated between researcher and researched within a particular social context so that another researcher in a different relationship will unfold a different story." (Finlay 2002 p.53)

From the point of view that the social setting cannot be 'frozen' (LeCompte and Goetz 1982), and that meanings are bound to a '*particular social context*' (Finlay 2002), I have considered the credibility of the research as another technique to ensuring scientific rigour of my work. Evidence to this end is presentations and papers produced during the course of this research. As presented in the beginning of this thesis, I have written and published several publications related to the broader topic of health policy, primary health care and policy changes in primary health care, which were written with or consulted with other academics in the field. In addition, as I myself have conducted the research within this thesis, this raised the concern of lack of an additional perspective from another researcher in terms of sampling, data gathering or data analysis. In this sense, a general process of peer review (LeCompte and Goetz 1982) was pursued

through discussions with my supervisors in relation to the data, interpretations and the overall thesis, as described under relevant sections earlier in this chapter.

Through the above, I believe that I have paid due attention to the issues of quality and credibility throughout this research and that the identified themes and sub-themes, as well as the discussion and conclusions elaborated in the following chapters are a result of a thorough and appropriate approach to the research process.

4.6. Research ethics and confidentiality

In the course of the research, some of the issues discussed during data collection and analysis involved disclosure of information that might incriminate the respondents, such as non-compliance of PHC physicians with the policy for limitation of prescriptions, or non-compliance of pharmacists with the existing dispensing policies. From an ethical standpoint, during the interviews it was inferred that PHC physicians or pharmacists were not always adhering to the prescribing and dispensing policies or in other ways performed practices that were not in full compliance with ethical principles. As the purpose was to research attitudes and practices, the anonymity and protection of the data from misuse or abuse by a third party was essential.

As in any other research involving personal and corporate data, the personal accounts of respondents or data collected and analysed in this study that may in any way incriminate involved parties have been processed according to the principles of protection of such data. As part of the research done under the regulations of the University of Sheffield, the study was subject to University of Sheffield Ethics and Research Governance conditions and approval, including proper information of

respondents, obtaining informed consent and management and protection of personal data gathered in the research process.¹ An application was prepared for the University of Sheffield Ethics and Research Governance Committee, containing all necessary information regarding the research, i.e. the project's aim and objectives; the planned methodology and research approach; types of respondents and sampling strategy; means for ensuring confidentiality and anonymity; and use of a consent form. Ethics approval was obtained in May 2013 (Appendix A). The application was accompanied by an information sheet, consent form and interview guides for each participant group. The information sheet and consent form are given in Appendix B and Appendix C, respectively. The interview guides are given in the subsequent appendices, i.e. for elite stakeholders (Appendix D), primary care providers (Appendix E), pharmacists (Appendix F) and patients (Appendix G).

Further to this, as the primary data collection was done in Macedonia, the research proposal was also submitted for review and approval to the Ethics Committee at the State Medical Faculty at University "Ss. Cyril and Methodius" in Skopje, together with the obtained Ethics approval from the University of Sheffield. This Ethics Committee is authorized by the Ministry of Health to give approval for all medical and bioethical research done on the territory of the country. The Ethics Committee considered that the nature of the research, i.e. qualitative data collection, was not subject to ethical approval in the country, and provided a written notice that the obtained Ethics approval from the University of Sheffield is sufficient to continue the research.

¹ Details of rules and procedures of the University of Sheffield Ethics and research Governance are available at: <http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/routes>; and regulatory requirements for research data management are available at: <https://www.sheffield.ac.uk/library/rdm/requirements> (accessed: 10 September 2017)

All research activities were conducted in line with relevant legal frameworks and guidance related to personal data protection acts applicable in both the country of study (Law on Personal Data Protection, Official Gazette of the Republic of Macedonia, no. 7/05 and 103/08), and country of submission of the study (Data Protection Act 1998 (c 29)). Further to this, the study was conducted and framed within University of Sheffield Guidelines on anonymity, confidentiality and data protection, as stated in the University of Sheffield's Research Ethics Policy Note no. 4: Principles of Anonymity, Confidentiality, and Data Protection.²

No personal data of respondents, such as date or place of birth, or personal identification number were collected; respondents' full names were stored securely: information that identifies them was not stored on a computer. All forms from the research, the interview recordings and transcripts were stored securely in a locked cabinet, separately so as to ensure that no respondent could be identified by persons other than myself. All participants were assigned a coding number that was used in this thesis in order to protect their identity. However, given their specific role, the elite stakeholders were asked if they want to be identified in the study. All of them expressed a wish to be anonymous, so they too were assigned a coding number.

As the rigid scientific rules require, written consent (Appendix C) was obtained from all respondents who agreed to participate. Respondents received an information sheet (Appendix B), explaining their rights in relation to confidentiality and personal data safeguarding policy. The protection of the identity of participants and their accounts was

² Research Ethics Policy Note no. 4: Principles of Anonymity, Confidentiality, and Data Protection, available at: <http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/confidentiality-anonymity-data-protection>

secured by providing a consent form signed by the participants with the following content:

“Any information you supply will be kept confidential. However, if you tell me something that makes me think you are in danger of being harmed, I will tell you so and advise you to seek assistance from appropriate institutions and authorities”.

Participants were made aware, in writing and in person that participation in the research was entirely voluntary, that they could withdraw at any time without stating the reason and that they would not be affected in any way by withdrawal.

4.7. Dissemination of findings

Although the main purpose of my research was to prepare and defend this thesis, I intend also to further elaborate and report the findings of the research to specific audiences. Among these is the academic community in Macedonia, in particular the teaching and research staff at the State Medical Faculty at the University “Ss. Cyril and Methodius” in Skopje and the University American College Skopje where I am also engaged as a visiting researcher. As my intention is to continue working in this field, the expanded research will continuously be presented in papers, academic conferences and policy meetings. As I also work on formulation of national policies in Europe, I hope that the knowledge acquired through this research will have applied value for prescribing and dispensing policies in my country and other transition countries with similar economic and societal contexts.

4.8. Summary of chapter

The primary aim of this chapter was to defend and describe the choice of the most appropriate research methodology and methods to answer the research questions of this research. A further aim was to reflect critically upon different aspects of the chosen method and overall research process. Qualitative semi-structured interviews were chosen, as they would provide important insights into the perspectives, attitudes and practices of diverse stakeholders regarding the changes of policy environment. The stakeholders' groups identified and interviewed in this research were: physicians, pharmacists, patients and elite stakeholders. The researched changes in policy environment were the primary care reform and accompanying prescribing and dispensing policy changes, and their impact on prescribing and dispensing practices and behaviours. The chapter also described the data collection process, including sampling, research instruments, interview process and reflexive practice. I described my reflexive practice and elaborated how I viewed my experiences and relationship with the research context and how it might have influenced the data collection and analysis. I also described the methods of recording, transcribing and translation, which I considered particularly important given the use of language different from the one in which I have written this thesis.

Further, the chapter explained the data analysis. The chosen analytical method was thematic analysis, and I followed the approach proposed by Braun and Clarke (2006), as this appeared most appropriate to analyse similar concepts from different sources of information – in this case different groups of respondents who represent different sides in the prescribing process. Towards the end of the chapter, I addressed the issues of

ensuring scientific rigour, through concepts of quality and credibility of this research, as well as the process for observing ethics in research.

The following chapters are dedicated to presentation of the collected data pertinent to the research questions and its relevance to the wider body of knowledge from the perspective of the chosen theoretical framework. Beyond the data presentation in the next chapter, the subsequent chapters are dedicated to discussion of findings, and linking them to the context and the wider social theory, leading into conclusions and recommendations intended to feed future policy making processes.

CHAPTER 5: Findings

5.1. Introduction

5.1.1 Overview of chapter

This chapter describes the identified themes and associated attitudes and opinions of physicians, pharmacists, patients and elite stakeholders in relation to the various policy changes described in chapter 2. The aim in this chapter is to offer descriptions of these identified themes, with illustrative extracts from interviews. It is left to the next chapter, to consider these findings in relation to the literature described in chapter 3 and in particular to Habermas' conception of system and lifeworld. Before elaborating on the findings, it is important to offer a brief reminder of the rationale and context of the study, and also explain the approach taken to the presentation of collected data and emerging themes.

Since its independence, Macedonia embarked on large economic and social reforms that affected the health system (Ivanovska and Ljuma 1999; Lazarevik et al 2012). Prior to reforms, the system provided universal health coverage, free to all at every point of delivery, including health services, rehabilitation treatment, prescription and over-the-counter medicines. A lack of resources imposed a need for rationalisation and increased efficiency of the use of such health services and medicines. Policy changes were introduced to reduce pharmaceutical expenditures through rationalisation to a list of essential medicines, and existing policies were reinforced to dispensing of prescription medicines only with a prescription issued by a physician.

The adoption of new and the reinforcement of existing policies were anticipated to bring a new period of rules and discipline in prescribing and dispensing. However, as described in the second chapter, both pharmaceutical costs and number of prescriptions have continued to increase. This chapter presents a range of accounts relating to these changes, from very different stakeholder perspectives based, as will be shown, on differing values, beliefs and needs.

5.1.2. Approaches to data presentation

The complexity of policy changes of interest and the diversity of interviewed groups raised the issue of the most suitable approach to presentation of collected data. One of the approaches considered was to have a straightforward data presentation, in which the identified themes from each of the respondents' groups would be presented in separate sections. This approach would be beneficial in allowing for an in-depth consideration of the understanding, experiences and practices of each of the *groups* in relation to all analysed policy changes, and only then to comparatively interpret them in the subsequent chapters. This approach, though, while seeming more appropriate from the perspective of the different roles played by each group, was rejected as it was considered a threat to illustrating the relevance of, and relationship between, emerging themes. Trying to offer differing perspectives so overtly as a structure may also result in the danger that Mason terms 'mutivocality', and it is important:

"[...] that we get to grips with different and often diverging perspectives in our arguments, and with different ways of expressing those [...] but I think we should be cautious in assuming that we can absent ourselves and in so doing create a genuinely democratic multivocality." (Mason 2002 p.185)

As such, organising the findings in terms of identified themes, illustrated using participant quotations, is argued to be most beneficial. Such an approach was chosen as it best represented how analysis was undertaken but also as it would still allow the variety of opinions and views of the interviewed stakeholders to be represented. As will be shown, three main overarching themes were identified but within these many sub-themes were also apparent and these are considered in turn. It should also be noted that whilst these represent summary themes and sub-themes, they did not reflect consensus and it will be shown where contrasting or minority views and experiences were also identified.

This chapter presents only the emerging themes and sub-themes and quotations from the interviews with participants; it is left to the following chapter to provide a further development of the findings, in terms of how they are related to the theoretical framework – Habermas’ system and lifeworld – and how themes relate to existing literature.

5.1.3. Summary of key themes

Interviews revealed differing perspectives between stakeholder groups. Using thematic analysis, key findings were clustered into three key themes, briefly summarized in the following paragraphs, and elaborated in more details in the subsequent sections (see Table 13 below).

Table 13. Summary of key themes and sub-themes and relationship to participants

Theme	Sub-theme	Group	Sub-theme	Sub-theme	
Past and present policies	Nostalgia for the past system	Providers	Autonomy in prescribing	Clinical experience & patient need With the system	
		Elites	Better relationship	With the patients – more patient-centred system	
			Some nostalgia for previous system but not sustainable		
		Patients	Availability of medicines	Freedom to obtain medicines (no need to negotiate)	
	Reflections on recent policies	Providers	Qualified acknowledgement of need for policies' cost containment		
		Elites	Necessity for change – efficiency, cost limitation, inappropriate prescribing		
		Patients	Not aware of policies or what the changes are bringing		
	Lack of providers' involvement in policy			Exclusion from policy making	
				Pressure to implement policies	
			Lack of support in implementation, detachment from system		
Providers		Reduced autonomy in prescribing due to policies			
		Inability to prescribe where clinically appropriate due to budget ceilings			
Elites		Acknowledgement	Lessened provider autonomy		
			Poor enforcement of policies		
			Lack of willingness to share responsibility for implementation		
Pressures in practice		Providers	Dis-empowerment	Pressure from patients – cannot get medicines they previously could	
				Non-prudent prescribing and dispensing under patient pressure	
	Denial of irrational prescribing				
	Perception of patients playing an unenforced system				
	Elites	Acknowledgement	Increased power of patients qua rights		
			Aware of prescribing under pressure and dispensing without prescription		
			Perceived requirement for patient education on appropriate medications		
	Patients	Expectation	Perceived requirement for better physician knowledge of clinical guidelines		
			Lack of willingness to share responsibility for policy enforcement		
Patients	New Demands	Reduced possibility for obtaining medicines (patients' disempowerment)			
		Negotiating medicine supply	Response to system changes		
			Justification		

One of the key identified themes related to the stakeholders' perceptions of the past and present policies. The narratives of providers revealed nostalgia for the past system, which brought comparisons with current practice, regarding professional autonomy and appreciation of their profession in the society. Similar to providers, patients also felt the past system to be more beneficial to their health needs, and the current one as disempowering when it came to negotiating the necessity to obtain medicines. Many of the respondents in the elite stakeholders' group referred to the benefits in the past, and conversely the lack of sustainability of such a system, justifying the need for policy changes.

The second key theme that emerged from analysis of the data related to pharmacist and physician providers' perceptions of a lack of their involvement in policy making and a lack of support for them in implementing new policies. The providers felt detached from the system for policy development and implementation, which for both physicians and pharmacists meant they had to find other ways of dealing with the arising problems, some of which were beyond their competences and authorisation. In a similar way, patients, whilst not appearing very familiar with specific policies or their aims, were explicit about their own disempowerment, which in their view was imposed by the new policy context. While elite stakeholders fully justified the necessity for policy change in terms of implementation, their opinions varied but were generally in agreement that implementation of policies was lacking. It also emerged that this was not effective and patients were still able to obtain medicines without prescription, particularly cheaper ones. In their views, both the reasons and the responsibility for lack of implementation laid with the patients and providers.

The third identified theme, closely linked to the other two above, was related to the pressures in practice, experienced by both providers and patients. Physicians and pharmacists perceived pressures from regulatory and governmental bodies to adopt policies; policies, moreover, that they did not feel sufficiently involved in when being developed. They also perceived or anticipated pressure from patients in terms of their expectations and demands for medicines, with a related negative impact upon them maintaining professional autonomy.

Patients also felt pressures related to the new policies, such as having to negotiate to obtain prescriptions from primary care physicians, and from the now limited opportunity to buy medicines without prescription. Accounts revealed that patients found their autonomy and options for self-medication to be very important. Most of them did not consider out-of-pocket payments for medicines to be a problem as much as was the limitation of their right to purchase medicines at their own discretion. Their response, however, to this new medicine supply situation was a pragmatic one; in their views, the reduced access to medicines offered justification for subterfuge of regular prescribing and dispensing procedures.

Throughout all these accounts, it will be shown that there were diverse views and differing opinions:

- For physicians and pharmacists, this was manifest in being caught between patient demands and expectations and maintaining professional autonomy within a more constraining system in which they felt unsupported and unconsulted about.
- For elite stakeholders, this was articulated as justification for policy changes to contain costs and to reduce inappropriate prescribing, and an admission that implementation was difficult for providers due to patient pressure and other

issues; yet, they shifted the responsibility for implementation onto both providers and patients, suggesting both groups needed a better understanding of the policies and associated drivers.

- For patients, in terms of an awareness of the consequences of policy changes that appeared to restrict their access to prescribed medicines yet having the opportunity to act as new health consumers and obtain medicines beyond the traditional pathway of a physician.

The following sections describe in depth the identified themes emerging from the interviews with different stakeholder groups. In relation to the ordering of themes, this adopts a temporal sequence, with the first to be presented relating to comparisons between past and present policy, followed by reflections on the implementation and finally the subsequent implications of the policy changes.

5.2. Reflections on past and present policies

This theme is constructed from two sub-themes: 'nostalgia for the past system' and 'recent policies: necessity for change and qualified acceptance'. The first sub-theme focuses on what I interpreted as comparisons between the past and present policies, and what effect the experience from the past had on the perception of the new reality. The first sub-theme 'nostalgia for the past system' as it suggests, is concerned with the reflections of participants on the past system in general, and on the specific topics of professional autonomy, raised by providers and availability of medicines, raised by the patients. The second sub-theme 'reflections on recent policies: necessity for change and qualified acceptance' focuses on what I interpreted as respondents' perceptions and acceptance of policy changes.

5.2.1 Nostalgia for the past system

5.2.1.1 Reflections on the past system

In reflecting on their understanding of recent policy changes, all respondent groups made explicit reference to the past system under socialist control and, most tellingly, its benefits. The discourse of nostalgia was strongly present despite the apparent understanding of the necessity for policy change. In most of the interviews, when discussion was initiated on the actual system and respondents' opinions on its characteristics, the current situation was referred to as a compound of changes, and significant emphasis was placed on the comparison with the previous socialist system. Discussions on specific policies (described in earlier chapters as PC1, PC2 and PC3)³ only came later in dialogues, upon explicit reference by the researcher. In the providers' group, accounts varied according to whether they had experience of working in the previous system, while in the elite stakeholders' group, variations were noted according to whether they had experience as providers in primary practice in the past.

In many of the physicians' accounts there appeared to be reminiscence and indeed nostalgia for the past system. It mainly projected through the professional autonomy they seem to have enjoyed with prescribing. Such discourse was articulated in an almost uncritical view on the circumstances at the time and idealization of the system, in which prescribing was the discretionary right and responsibility of doctors:

"We could prescribe anything we wanted. There were no policies... So, for any diagnosis the doctor could prescribe any medicine. I don't know if somebody could have held him responsible for that... before 1990, what

³ The mentioned policy changes are: PC1 - prescribing policy with limitation on number of prescriptions per patient; PC2 – prescribing ceiling policy; PC3 - reinforcement of dispensing policy and introduction of dispensing ceiling policy.

can I say, you could go to the pharmacy and go out carrying five bags of medicines and you wouldn't spend a penny, there was no participation fee or anything..." (PCP2)

"...we were not scrutinized, but we knew what was appropriate, there was no doubt about it..." (PCP12)

What could be noted from the accounts was their perception of the professional freedom they experienced in the past. As illustrated in the quote above, such freedom was associated with a perceived limitless amount of treatment and medicines. The vocabulary physicians used suggested that this freedom and availability of care were some of the features that, in their opinion, were significantly reduced in the current system.

Besides professional autonomy and availability of medicines, elaborated as sub-themes in the following sub-sections, the dialogues on previous policies did not reveal other specific features of association to the past. Interestingly, when asked what the policy was at the time, the majority of physicians could not provide a simple response, as they would for the policy changes of the present time. Rather, they provided elaborations on the outcomes produced by the past policies. They were certain that the policy's aim was care for patient and highest standards of professional practice - even at the expense of the economy. In their view, the system was responsible for providing the necessary care at whatever cost; at the core of healthcare then were patients, and everything else was secondary. Within such a system, providers' sole role was to provide health services without any fiscal responsibility, and thus they were not concerned with the economics of care. In their opinion, this represented a good health system, where everyone got what they needed and no one talked about budgets:

“...we prescribed antibiotics, simply, with no budget limitations, no danger, I think that we used to have a very good health care system...it was a budget-free system...Before everything was budgeted, one couldn't know where exactly the money came from, the medications were produced here, they were cheap, the factory wasn't making any profit...” (PCP13)

The elite stakeholders, more notably those who had working experience in primary care in the past system, shared similar opinions on the previous system's benefits where peoples' welfare was put before profit. For most of them, it was an exceptional achievement that medicines and even medical preparations without active pharmaceutical components, including supplements and vitamins, were paid for through health insurance. One of them described it as an ideal, 'perfect' system:

“I'd have to go back to the socialist system, when all registered drugs were put on the positive list, even multivitamins, supplements.... Meaning that the system was perfect, the state provided complete coverage of the drugs.” (E14)

The noted access to medicines without any limitations was confirmed through accounts of patients, who made similar recollections. Although patients constituted a mixed group, many of them had experience or could recall prescribing and dispensing practices of the previous system. Within this group too, there were reflections on the fairness and suitability of the past, although not as elaborate and eloquent as those of physicians and pharmacists.

When comparing to the previous system, patients mostly reflected on the free access of medicines and the ease of obtaining them. In their recollections, at the time, while medicines could only be obtained on prescription, getting the physician to prescribe, even without medical indication, was not seen as an obstacle. As illustrated with the

following quote, medicines - in this case antibiotics - were obtained without medical indication, yet with physician's agreement:

"Our children were small, so we always had antibiotics with us when we went on holidays. Especially if you're abroad, you don't know any doctors, the language. In case the child got fever, you want to be prepared. Everyone had a home pharmacy; now you can have it too, but you have to pay for it." (Pat12)

Most of the patients considered access to free medicines as an important benefit. In a wider sense, this was articulated as a good physician-patient relationship and their satisfaction with the treatment from the system. One of the patients, however, pointed to the fact that although everything was free, there were still some obstacles to access. As illustrated in the quote below, these obstacles were not associated with prescribing, but with dispensing, and more specifically with the availability of medicines at community pharmacy level:

"Everything was on prescription and it was free...it was not always accessible, pharmacies were getting medicines once per month, but if you had a friend they would stock it for you... It was not so hard, now I think it's more difficult to have your therapy...there are many more patients compared to then, everybody I know is on some therapy..." (Pat5)

Some disagreement with the idealisation of the system also emerged among elites, questioning whether such a situation was realistic, in terms of the actual provision of services and medicines to patients:

"Imagine how all the needs of everyone were covered (smiling)... it [the previous socialist system] suffered from non-efficiency... [in the past] I think not everything was provided in real sense, people received prescriptions, but if medicines were not available at the pharmacy, that prescription was worthless..." (E17)

Broadly, this respondent showed concern about the discrepancy of providers' and patients' perceptions and the reality of medicine supply. In other words, it brought into question the roots of nostalgic feelings which might have been based on (mis)perceptions and idealisation, as already illustrated with earlier quotes. In addition, this quote clearly illustrates elite stakeholders' view on inefficiency of resource use as a concern of sustainability, raising the issue of necessity for change, addressed as the second sub-theme later in this section, after elaboration of the sub-theme on autonomy in prescribing and availability of medicines within the past system.

5.2.1.2 Autonomy in prescribing and obtaining medicines within the past system

Within the reflections on past policies, participants mostly reminisced about aspects they considered to have been negatively affected by the changes, in particular pertaining to their professional role for providers, or personal benefits in medicine supply for patients. Providers, and to some extent elite stakeholders reflected that changes brought reduced autonomy in prescribing. Interviews with patients resonated on the same theme, but were expressed through their perspective of reduced availability of medicines, due to reduced possibility to obtain prescriptions or be dispensed a medicine without a prescription. As described in the previous section, patients talked about their position to obtain medicines even without medical indication, which confirmed their negotiating power and autonomy to take medicine upon their own decision, once it was put at their disposal. With this being said, I have interpreted these two as interlinked, given that the expressed concern of reduced availability of medicines, in a way, could also be interpreted as reduced autonomy of the patients in obtaining medicines.

Both physicians and pharmacists in primary care felt a level of threat to their profession in relation to the curtailing policy changes. This was articulated both in relation to their professional autonomy vis-à-vis the system and professional appreciation in the wider society, which in their view, were both related to the policy changes.

Physicians' accounts revealed that for them the most important feature lost with the policy changes was the '*liberty*' of making decisions in prescribing:

"Back then we had the liberty of prescribing. So we could prescribe medicine with no limits depending on the knowledge and the experience of the general practitioner, on what he [sic] gained in the process of education." (PCP6)

This so-called '*liberty*' was not necessarily considered by all of them as an ultimate freedom – although the wording used by some of the respondents might implicate such perception. The above quote also illustrates physicians' opinion of their knowledge being a very important part of the system. Thus, their concern could rather be linked to the perceived questioning of their knowledge and professionalism:

"I am a physician for over fifteen years, and the least I know is what is the best therapy for the patients..." (PCP10)

"...professional integrity and ethics' are in question..." (PCP12)

Elites, too, agreed that policy changes affected the autonomy of health care providers. In the views of most elite respondents, the autonomy of physicians was somewhat confined to the limitations on prescribing. This reduced their ability to provide the most optimal care, described by one respondent, as being '*creative*' in prescribing:

“When the doctors are prescribing, very often they are concerned with what is going to happen to them. The doctor has to be creative in the prescription of treatment, with untied hands ... isn't health the biggest national treasure?” (E13)

Defending the importance of autonomy in prescribing was found mainly in the accounts of the elites who were practising medicine before moving into their current positions. This was understandable, given the influence past experiences and memories have on personal attitudes and perceptions. Conversely, among elite stakeholders without experience in primary care practice, discussions had a more neutral tone. There was an acknowledgement of reduced autonomy, but they had a different view on what it meant and why it was important to providers:

“They [physicians] would prefer having more freedom when it comes to their expertise, some of them even believe that there shouldn't be any protocols, that they have studied long enough to know it...”(E18)

The above quote also illustrates another issue raised by most elites, pertaining to the existence of, and adherence to, evidence-based guidelines. For them, guidelines were inevitable, despite the desired *'freedom'* and discretion in prescribing. Protocols, as much as exerting rigidity of one's behaviour, were considered to provide certainty in decision-making. In their accounts, there was a strongly expressed association between autonomy as a right and protocol adherence as a responsibility. Along these lines, when asked, participants did not feel competent to define the boundaries of autonomy, but were certain it needed to be confined to evidence-based medicine, and conditioned by a systematic, standardized approach in advancing knowledge and practice:

“The physician should be enabled to treat the patients as he [sic] sees fit, by prescribing therapies that he [sic] thinks would give the best results...but, it [the system] should be upgraded with education of both patients and physicians...” (E16)

In most elites’ accounts when talking about providers, there was an explicit acknowledgement of a frustrating position regarding autonomy. But, the elites’ group provided other reasons for reduced autonomy, which in their view was not intended to undermine primary care physicians’ knowledge or reputation. Rather, it was part of the cost-containment strategy, involving among others, a recommendation for prescribing by a specialist for medicines usually prescribed at primary level. According to one respondent, this resulted in a very cumbersome mechanism of referring patients between levels of care for obtaining confirmation of therapy appropriateness – particularly and only for very expensive medicines:

“I understand the frustration, sometimes they need to send the patient to a specialist for a medicine that is typical for primary care, because the law says it has to be recommended by the specialist...these rules are imposed mainly for medicines that are very expensive... in most cases, the price is the reason for imposing limitations. So there might not be a medical justification, as there wasn’t for the [...] but because it was expensive, you could read on the package that it must be recommended by a specialist although it had nothing to do with that, the medicine is typical for primary care, the same was for [...], it was the same as it was quite expensive... they have to ask permission, if you wish, to prescribe something that is already within their competences.” (E17)

Physicians felt their knowledge and experience were also underappreciated by patients. They were particularly uncomfortable when they had to continue an already taken prescribing decision with which they tended to disagree professionally. In several of the

accounts, providers noted cases of patient's decision for self-medication or requests for medicines for which patients have heard from another person:

"I don't like when the patient already started using antibiotic 'at own hand'⁴ or when 'colleague' who's friend of the patient suggests the antibiotic I should prescribe." (PCP17)

Similar to physicians, pharmacists expressed the feeling of threat to their profession, but more in terms of its appreciation in the society, and particularly by patients. For many of them, one of their crucial roles was making the final check on prescription regarding medicine and its dosage, and making sure that patient understood instructions spoken and hand-written by them on the box. But they felt patients, sometimes questioning their ability to understand the doctor's instructions, undermined this role:

"I dispensed the medicine based on the prescription, which said three times one pill per day...and he [patient] started quarrelling with me that this is his regular therapy, it should be half a pill per day, not one; he said who am I to increase the dosage, and to make him take more... I think he simply didn't remember what the doctor said, and he blamed it on me... we get that every day, it is not nice, but you get used to it..." (Ph11)

The level of details provided by this respondent to describe the event illustrate the apparent discontent of providers – in this case, pharmacists – with the patients' attitude towards their profession, manifested as distrust in their knowledge and qualifications.

Another pharmacist, expressed this discontent in even stronger language, clearly exhibiting a frustration from the attitude of patients who came in without prescriptions, sought medicines but would not listen to the professional advice provided. She

⁴ Idiom describing making a decision based on own judgment and responsibility, not supported by any formal expertise or legal mandate.

explained that her feeling in such moments was as if pharmacists were perceived to be simply delivering an ordered good, like a 'grocer in a grocery store' (Ph9):

"I am not a grocer in a grocery store...it is the kind of attitude of 'I pay for you to give me the medicines I want', like they're buying pears or apples... 'give me 2 capsules of Vibramycin' is not right when I tell them that the full therapy is five days, but they insist, even though the medicine is so cheap, it is not about the money, I think it is about their feeling of being able to get what they want." (Ph9)

Several of the elite stakeholders expressed similar views on lessened appreciation of pharmacists, considering it to be largely due to poor enforcement of the dispensing policy, which enables uncontrolled access to prescription medicines without a valid prescription:

"Very frequently patients are buying [on their own] medicines... Only 40% are covered by the state and for 60% citizens are paying...most of the time without a valid prescription." (E14)

"It is a rather annoying fact that patients can come and get any medicine they ask for. First thing they teach at pharmacy school is that every drug is a poison at the same time and has to be under control, under specific administration...it's irritating...people don't draw blood themselves, so they also shouldn't buy or take medicines as they consider necessary." (E1)

Although most of policy makers' accounts resonated in the tone of support and understanding of the lessened appreciation and profession's standing in society, there were those who disagreed. One of them, critical of his own profession, considered that decreased cognizance was in part the responsibility of the providers and professionalism they exhibited and practiced at their workplace:

"I expect the pharmacist to be more persistent in explaining to the client that taking medicines 'at own hand' is not appropriate. He can offer alternatives, herbal preparations, teas, supplements; he should advise a visit to the doctor at the very least." (E15)

This quote in a rather prescriptive tone, illustrates the standpoint of the majority of elites regarding the health providers' roles in society, but also their responsibilities. As this issue strongly emerged and was discussed at length with all respondent groups, it is elaborated in more details under the second theme, as part of the sub-theme dealing with the willingness to share responsibility for implementation.

Providers held views about their own roles and responsibilities in society. According to them, decreased appreciation of the profession in the society, was undoubtedly associated with the policy changes pertaining to prescribing and dispensing but also with other circumstances, such as strengthening patients' rights. Under these new circumstances, patients were perceived to exert pressure on providers in the process of decision-making in prescribing. This raised the issue of pressure that pharmacists and physicians felt from actual and perceived patients' expectations, which as an emerging theme is elaborated on later in this chapter.

Before going into the elaboration of the other two themes touched upon in the two preceding paragraphs, it is important to describe the reflections of respondents on the recent policies and their differing perspectives on acceptance of policy changes.

5.2.2 Reflections on recent policies: necessity for change and qualified acceptance

Alongside the reminiscence on the past elaborated in previous sections, reflections on recent policies emerged very strongly throughout dialogues with all respondent groups. But, as mentioned earlier, when referring to the *current situation*, participants did not appear to differentiate between various recent policies and these appeared to be considered together; specific policy changes were only discussed when prompted in interviews. As noted in earlier chapters, interviews specifically sought to explore views on limiting the number of prescriptions and prescribing budget ceilings, mandatory dispensing only with prescription and introduction of dispensing budget ceilings. Dialogues were intended to investigate the understanding of current policies and the necessity for their enforcement, as well as attitudes towards their implementation. As will be elaborated upon further in this section, the findings showed diverse accounts around acceptance of the recent policies across respondent groups. For example, policy makers were explicit about the necessity for change and drew upon wider economic concerns, referring to issues such as '*inefficiency*' and '*lack of resources*' in their accounts. Their narratives were also characterised by a measured and considered tone, with objectivity and fairness being evident in their accounts. In contrast, the accounts of providers and patients were more emotional and rich with detailed descriptions of particular events, which they used to illustrate the effects of policy changes. They were less keen to discuss the necessity for change, but exhibited their qualified acceptance of policy interventions.

The majority of elite stakeholders were supportive of policy changes introduced in primary care in Macedonia. In their view, the changes addressed some of the key issues,

one of which was the inefficient resource use present across the entire health system. To illustrate the effects of these changes, one of the respondents proudly used the comparison with secondary and tertiary care, which in his view were far less-well organized and still inefficient:

“Let me tell you, if something good has happened in this country, the best thing is the primary health care. It’s the most organized system...unlike the secondary or the tertiary care, where we invested far more and the situation is still not as good...” (E12)

The efficiency of resource use, touched upon in the above quote was pointed out by several of the respondents as one of the key motivations for changes. In their view, there was a need to introduce efficiency measures, for example through rationalization of the oversupply of medical staff, as illustrated by one participant:

“There was oversupply of medical staff in some places... For example, in a town of 10,000 we had 17 doctors... In the pharmacies we had in some places 5 [pharmaceutical] staff in one shift...” (E17)

To improve efficiency, according to elite stakeholders, several models were considered. While none of the respondents in this group discussed any of the other models specifically, in general they were in agreement that the model of privatisation of primary care chosen in Macedonia was appropriate for the purpose. There was also a common inference that change of the existing fixed salary system was inevitable, to reduce inefficiency and unfair treatment between physicians, as illustrated in the quote below:

“The reform in the primary care was inevitable...overemployment and demotivation were the deciding factors. There were doctors who did nothing but drinking coffee and chatting and got the same salary as those who were examining forty to fifty patients a day.” (E18)

Improving efficiency was linked to the lack of resources, which also emerged in the accounts. As already elaborated above, many of the elites acknowledged various types of benefits of the old system, but when elaborating further also raised concerns about the unsustainability of that system. One of the extensively discussed topics from this point of view involved pharmaceutical expenditure, which, as elaborated before, included both prescription and over-the-counter medicines and was used on a first-come-first-served basis. In the view of the elite stakeholders, changes and restrictions of spending on medicines were inevitable, and as one participant noted:

"[...] the needs and the requests of the health system and the patients are one thing, and what the state can afford is a different thing..."(E14).

Whilst the concept of equity was not explicitly mentioned or discussed, the above quote illustrates the implicit view amongst at least some elites that a fair and just distribution of the limited health resources was important.

Patient participants did not appear to be as well-informed on the changes and reasons for the new policies, as the other two groups, and their views were very much bound to personal experiences with the system, and in some cases – second-hand knowledge acquired through personal conversations with someone engaged as a provider. Only three patients recognized the inefficient resource use, exemplified through widespread stockpiling of medicines at home:

"It's nice to have all at hand, but that's not right... Many people, me too, were having boxes of medicines at home, most of it for 'God forbid' cases and then thrown them away when expired. I used to do the same, but now I see that it makes no sense when you can go to your doctor and get the prescription when you need it." (Pat8)

“My sister in law is a pharmacist, and she’s saying that earlier people would leave [the pharmacy] with whole bags of drugs, especially around holidays. And then, some complained there were not enough medicines in pharmacies; well, the medicines were available only they were in the wrong place...” (Pat4)

Although disclosed through personal examples and without touching upon the system perspective, the above quotes suggest justification for the enactment of the policies, from the perspective of the non-sustainability of earlier practices. Thus, through recognising the importance of efficient resource use, these three patients implicitly acknowledged the necessity for policy change. Furthermore, one of them illustrated this using the Macedonian idiom of *‘stretching your legs as long as your carpet is’*⁵ (Pat4), referring to its common meaning that one can only spend as much as they have and any other practice represents a route into debts and poor reputation. The above quotes also suggest that some patients were aware of, and knowledgeable about, the circumstances and arising changes, from their personal involvement with the system or from conversations with a person who had experience as a provider. However, and as elaborated in following paragraphs, this was not a widespread understanding.

Such justification did not come forward so clearly in the other patients’ accounts, although there was a sense of reluctant acceptance of the changes. Despite the lack of understanding of the policies’ aims and functioning, patients nonetheless were aware of the consequences of policy changes. The following quote is illustrative of the level of awareness about more recent policy changes that characterised the majority of interviewed patients’ accounts:

⁵ Idiom with a meaning of getting only as much as you can afford.

“It was the way it was, now it’s different...To me, the most important thing is to get the therapy I need, and I go to the doctor, she gives me prescriptions...when I go to the pharmacy, for some medicines they say I have to pay participation [co-payment] and for some there is no participation. If they say I have to pay, I pay...I don’t really know how they decide which one goes with participation [i.e. co-payment] and which one without.” (Pat11)

Of note in the final sentence of this quote and typifying many patients’ experiences, was a lack of understanding as to specific details about recent policy and with the exception of the three informed patients discussed earlier, ignorance of recent policy was also bound up in a perception of patients having no options:

“Your question is ridiculous to me, sounds like we have some other choice...we are patients, we have no other alternative but to do as they have decided; if I don’t like the procedures, I can always buy the drugs privately, but why spend money when I can follow the procedure and get it for a lot less?” (Pat 10)

Although according to this participant, the implementation had little to do with patients’ choice, as will be described later in the chapter, there were choices that patients made, especially when it came to negotiating medicine supply and practicing self-medication. Their views on the impact of policies on their behaviour and practices are elaborated under the third theme of pressures in practice.

Thus, I have to note that, specific policies were not deliberated at length with the patients’ group, given their lack of knowledge on policies’ rationale and aim. Rather, the discussions were directed towards opinions on the effects of policy implementation, which is elaborated under the second theme, later in this chapter.

Among physicians there was some understanding of the necessity for change, and qualified acceptance of the new circumstances. Very few of them expressed their understanding in a positive tone, such as the one who used the analogy of a domestic budget:

“Budgets are limited thing, it is not a bottomless well, and we all live in the real world...it’s like the budget you have at home...” (PCP3)

When asked about privatisation, in a number of accounts there was a sense that physicians were not quite aware why the policy change had been introduced. Most of them already felt used to being private providers and recalled the transition from public to private itself to have not been particularly difficult; they continued to perceive themselves as part of the public health service provision, with one participant (PCP 10) commenting that they felt they belonged to the *‘most important and indispensable part of the healthcare system’*. It was apparent, however, that many still questioned the necessity of this transformation overall. However, the prevailing opinion was somewhat dismissive of the policy change; to them, privatisation disrupted the continuity of care, and links to other levels in the health system, as illustrated in the following quote:

“They shouldn’t have privatized the primary care, we were ‘one’ in the health centres and working together with the hospitals, maternities, community nurses...now we are separate worlds...” (PCP11)

Only one participating physician referred to the impact of policy change on the efficiency of resource use and service provision, and even this participant appeared to have gained insights from rather superficial information acquired from the bulletins and reports read out of personal interest:

“It was introduced so as to limit the spending on medicines. In general, practitioners prescribe medicines a lot, with their cap and fist⁶, and I believe that this ministerial policy directly aims to limit that practice...”
(PCP4)

Physicians continued to see privatisation as insufficiently thought-through policy with lots of problems arising in its implementation. Their shared experiences hugely contributed to their views that the previous system was far fairer to both patients and providers. There was apparent justification of the policy changes, although mostly hypothetical, further contrasted with statements of reluctant acceptance. The arising dilemma as to whether the changes were a necessary, logical and inevitable step in reforming the health system was mainly informed by individual examples of daily practice, and those are elaborated under the second theme dealing with the aspects of policy implementation, in the later parts of this chapter.

Pharmacists were also not too familiar with the overall aims of any of the policies they have been asked about. For them, privatisation was not a significant issue and they readily accepted being part of the private sector. They were to a lesser extent questioning the necessity for change compared to physicians. One of the underlying reasons might be that liberalisation of the health market started with private community pharmacy practice, as early as the beginning of the 1990s, whereas the privatisation of primary care came over a decade later. Several of the respondents who shared their opinion about the necessity for change considered it to be for ‘*money saving*’ (Ph7) and monitoring the use of medicines:

⁶ Cap and fist is a local Macedonian idiom which approximates to giving in abundance

"I think it was for the medicine usage, who was taking what and how much...in the previous system we had no control; of course we had prescriptions, but no one was controlling who was taking how much of what..." (Ph2)

However, far more important concerns for pharmacists were the other two policies considered in this research, namely the dispensing ceiling policy (referred to as quotas) and the enforcement of the dispensing policy, which are elaborated later in this section.

Although physicians and pharmacists shared their views on the overall policy circumstances and necessity for change, they were more interested in talking about the current system through recounting involvement with particular policies. They were generally very opinionated about the budget ceilings or limits to prescribing and dispensing, and they did not talk about privatisation specifically, as for most of them these policies were seen as part of the privatisation process. However, while most of the providers justified policy changes, it was apparent that such justification was accepted in theory *qua* policy change but in practice, views differed somewhat and were more equivocal. Their accounts, reflecting quite an opposite opinion, were rich of detailed narrations of specific events shared as experience with implementation of these policies.

With regards to specific policies of interest to this research, understanding and justification was amply offered by policy makers for the introduction of limitation to prescribing. The major thread of arguments was namely around the expenditure on medicines:

"Limiting the prescribing was a very necessary step, with the country being in transition and economically very weak...As you know, everything was covered before and that created huge costs, enormous debts of the health system...We separated from Yugoslavia and some of the companies were

in Slovenia, Croatia, we were not part of the same country anymore, so those debts became real liabilities...” (E11)

This respondent provided explanation for the necessity to introduce limitations to prescribing, referring back to the old system in which everything was covered. Namely, what this respondent is explaining is the historical background of rising debts, generated through unlimited medicine supply, despite the political and economic changes that happened in the country. During the times of Socialist Federative Republic of Yugoslavia, there was one health market with state-owned factories for producing and distributing medicines to state-owned health facilities. After separation from Yugoslavia, Macedonia was still providing its supplies from some of these factories, which were now part of other countries, and which imposed market rules for medicine supply. Thus, under the new political circumstances, debts within the health system very quickly became executable liabilities, demanding restrictions in medicine supply.

Further to improving efficiency, the policy for limitation of number of prescriptions was justified as a measure for standardization of care at primary level. It was widely acknowledged that unlimited medicine supply was encouraging overprescribing, and several of the respondents talked about this as particularly apparent in prescribing of antibiotics. One of the respondents pointed to research conducted in the early years after independence (Spasovski 1996, PhD dissertation), which showed that antibiotics were prescribed widely, to 100% of patients who came in with any symptom that could be mistaken for bacterial infection, including sore throat, running or congested nose:

“...every patient who had some sort of infection was treated with antibiotics... so antibiotics were prescribed 100%... It was striking that antibiotics were generously prescribed for respiratory infections, exclusively upper respiratory ones, and the results were catastrophic. One

could see that even children at the age of 6 were prescribed with aminoglycosides...” (E19)

Thus, the policy of limitation on prescribing, in the policy makers’ view had dual intended outcome: to ensure pharmaceutical costs containment and prudent prescribing. For several of them the policy, however, was not producing the economic saving anticipated, and for some initially it was not intended to. One participant described it as ‘*the first aid*’ policy on dealing with overprescribing; the policy was intended to introduce prescribing discipline with primary care physicians:

“We expected some effects, but not drastic... And there was some lowering of the expenditures. The intention was for physicians to understand that there is a limit, and to make them adhere to it. This, as first aid policy was to limit the number of prescriptions per patient without any value attached to it. So, the physicians could write any medicine from 10 to 1000 denars and it would still count as one prescription...We had no experience where to put the thresholds...” (E112)

Many of the elite stakeholders shared the same view about the first policy change of limiting the number of prescriptions. Another policy maker respondent explained in further detail, as illustrated through the quote below, how limiting the number of prescriptions would potentially contribute to increased pharmaceutical expenditure, since the prescriptions were not accounted for their monetary value:

“Let’s say, a package of diazepam costs 30 denars, so the doctors asks the patient to go and buy this medicine, the patient still needs to pay, if not 30, then 20, so that these kinds of medicines wouldn’t be counted in the total number of prescriptions. The doctor doesn’t want the cheap medicines to be counted in the end so that he could prescribe to any of his patients or relatives a medicine that costs, let’s say, 3000 denars... It’s because the medicine that costs 30 and the other one that costs 3000 denars were counted in the same way.” (E11)

This participant was arguing for justification of subsequent budget ceiling policies for prescribing and dispensing. Many of the elites had only general understanding of how these policies were functioning in practice, and were interpreting them as an advancement of the efficiency-improving agenda. The majority of them considered budget ceilings policy to be a better solution than the previous limitation of number of prescriptions, aimed at a real containment of pharmaceutical expenditure at primary level:

"...Budget ceilings on medicines had to be introduced, a prescription is a monetary instrument and has to have a price tag to it. Over time, we found doctors that prescribed only several very expensive medicines all the time, and that was symptomatic..." (E11)

"...based on the experience with the limits [on number of prescriptions] we were able to define the [budget] ceilings...we are able to provide more [medicines] with the money we have." (E12)

As elaborated earlier, providers did not consider budget ceilings to be an appropriate measure for regulating their relationship with the system. In fact, the majority of them considered this to be a measure of unnecessary control, again reinforcing that it undermines their professional knowledge and ethics in prescribing the most appropriate therapy:

"I don't think there should be a budget because we are aware enough...I don't think there should be a Fund, or a budget or anything. Nobody is that foolish, patients aren't either, nobody would take a medication just to have it; so people really consume those medications." (PCP3)

5.2.3 Summary of policy perceptions

The data presented above illustrates the diversity of views regarding past and current policies, and acceptance of policy changes.

Across the accounts of all respondent groups, there was an explicit positive sense of attachment to the policies of the past. In the narratives, the nostalgic notion was dominantly linked to autonomy in prescribing and dispensing (for providers) and access to medicines (for patients). For providers, the old '*perfect*' and '*budget-free*' system was perceived as posing '*no danger*' to the professional delivery of services. Stories from their experiences were used to provide arguments that the previous system was far fairer for both providers and patients, although there were some contrasting views of its unsustainability. Elites also perceived the previous system as fairer, but, were more objective in their understanding that it was unsustainable. For patients, the past system was better as it represented easy and unlimited access to medicines.

On the current policies, respondent groups also had different opinions. These ranged from justifying the inevitability of changes by the policy makers' group to qualified acceptance by the providers and patients. Policy makers advocated the necessity for change, offering sustained and forthright arguments of justification that related to improving efficiency of resource use and rational prescribing based on protocols. Among providers, there was general lack of understanding of policy changes overall; the accounts were deprived of serious contemplation on the aims of these policies at conceptual level. The most apparent was the dilemma as to whether the changes - privatisation in particular - were a necessary, logical or inevitable step in reforming the health system, which culminated in a reluctant acceptance of the policy changes.

Overall, discussions with regards to current policies were driven by examples of practice and difficulties in implementation and their consequences that will be considered in the following sections of this chapter. Patients were aware that health reforms were happening, but most of them were not aware of specific policy changes. Understandably, their views were mostly informed by their own experiences, which reflected issues of implementation, and patients lacked understanding of specific policy changes. A minority of patients were somewhat more knowledgeable of the on-going processes, mainly as a result of their own experience of working in the system or knowing a provider. They, too, provided justification for policy changes, with argumentation mainly on resource use and availability of medicines.

The above sections described the wider understanding of the policy context in which the present research is investigating the attitudes and practices of the primary care physicians and pharmacists regarding prescribing and dispensing. In the following sections, the other two main identified themes relating to implementation problems and pressures in practice will be presented.

5.3. Policy implementation problems: lack of involvement and support

This section explores the second identified key theme, which related more specifically to the implementation of policy changes, particularly from the perspective of pharmacist and physician providers. Furthermore, this theme was broadly negative and revealed perceptions amongst providers of a lack of being sufficiently included in any of the processes related to their line of work. Notably, they expressed a lack of involvement in policy making, revealing the feeling of not being consulted sufficiently about decisions

made in primary care. They also expressed dissatisfaction with the support provided by institutions in the implementation of imposed policies, and a feeling of being detached from the overall process. Elite stakeholders' accounts mirrored to some extent these perceptions of providers, but in contrast there was more concern about policy implementation deficiencies overall and a perceived failure to observe the full potential of policies. However, they were unwilling to share the responsibility for the lack of implementation, which they considered to be mostly within the domain of the other two groups – patients and providers. They believed that improving health literacy for patients and education for providers could potentially be part of the solution. On the same issue, providers also did not quite readily accept the responsibility; they considered policy makers to be in a position to improve implementation, through fixing the identified flaws for implementation. Physicians and pharmacists were also seeking accountability from the others in the provider group (physicians from pharmacists and vice versa). Their perception of responsibility was always described at individual level, narrowing it down to sporadic and distant cases of lack of adherence to policies. Also, they were calling upon the interrelatedness of prescribing and dispensing but never considered a shared responsibility as a possibility for improved implementation. In addition, providers sought responsibility from patients, bringing to the attention experienced and perceived pressures, which are elaborated under the third theme later in this chapter. But, before arriving at the theme of pressures in practice, in continuation, I elaborate the findings from the second theme of issues with implementation, divided into three sub-themes: lack of involvement in policy making, lack of support to implementation, and willingness to share responsibility for lack of implementation.

5.3.1 Lack of involvement in policy making

An identified sub-theme concerned providers' perceived lack of involvement in the policy development process. In their accounts they emphasised their feeling of exclusion from the processes that directly affected their daily work. Physicians were more emotional about having a chance to participate in the policy making, whereas pharmacists, were not as concerned with their involvement in consultation processes. Several physicians admitted there might be some processes - consultations through their professional association body for example - but most were not aware of when and how these processes had happened, and doubted if they actually existed. Several of the physicians expressed a very sceptical view, with one participant believing that most of the policies had been 'invented' by someone 'who was never a practicing doctor' (PCP5). Overall, there was a perceived lack of communication, which exacerbated the sense of a lack of involvement and a didactic approach:

"I don't think anyone was ever invited to tell our problems...maybe the associations...we are only invited when they [Ministry and HIF] want to inform us of the new rules. Sometimes not even that, they simply send them in an e-mail as instructions." (PCP7)

Providers believed that policies should not be developed without their participation, and were persuaded that officials and policy makers without practicing experience particularly in primary care could not develop appropriate policies:

"I don't think anyone working in the Ministry and not in the primary health care should create a policy; one should have experience in the field." (PCP6)

"...we are forced to sign the contract because if you don't, you'd be out of work, nobody asks if you want to sign it or not, all they [the Health Insurance Fund] do is give us the papers, we don't even read them, why

should we, even if we read and don't agree with everything, we still have to sign them. Otherwise, I'd be out of work, and what patient would come to my private practice? So I accept everything." (PCP3)

Although wanting to be part of the process, providers were not very articulate about how this involvement could be achieved. Only two providers, however, expressed their ideas on how they could be involved, mentioning online consultation and surveys:

"Well, maybe before sending out a plan of activities or measures, they could include us by making surveys on whether we agree on some issue or not..." (PCP6)

Among pharmacists, there were also several who did not feel they were consulted enough. One respondent shared an example of an initiative among small pharmacies to become a relevant voice at the negotiating table, which in her view, as depicted in the first quote below (Ph6), was not adequately recognised. Instead, as illustrated in the second quote, they felt that they simply had to deliver on the decisions, without being asked 'if they can do it' (Ph4):

"Large pharmacy chains like [...] and [...] are very strong, I don't have such position...We [small pharmacies] got organized in the Joint Pharmacies of Macedonia, there were benefits for joint procurement, having one voice, but still the HIF does how they think, we didn't get to change much..." (Ph6)

"We get letters or e-mails with decisions, what, how to do...there is no question in those mails if we can do it...I don't even want to send reply back with a question, as they will see who is sending and maybe they will send me an inspection..." (Ph4)

Lack of involvement in the policy making was expressed also as not being consulted on the list of treatments made available to patients. As noted in the earlier sections, some

of the medicines typically prescribed at primary level were raised at higher level of care and could be prescribed only upon specialist recommendation. The purpose of such decisions was argued by policy makers to relate to controlling consumption of very expensive medicines (as exemplified in the quote by E17 earlier (page 144), under the sub-theme of autonomy), but was interpreted by physicians as a lack of involvement, as they were not consulted on such decision.

"We are limited as [primary health] doctors to treat the patients in accordance with the knowledge we have acquired...if I know a patient is well off, I might suggest to buy the medicine out-of-pocket, if it's better than the one on the insurance" (PCP7)

"I want to be treated as a professional. I am not here to take anything from them, I'm here to do my job, and I deserve to be part [of creation of policies]." (PCP16)

As reflected in this quote, and articulated by other physicians as well, after privatisation, there was a notion of divide - a sense of *them* and *us* - which was interpreted as widening with the introduction of the subsequent policy changes. As a prevailing perception among the providers, this detachment from the system was considered an important finding and interpreted under a separate sub-theme and is described in the next section.

Based on their expressed perception of lack of involvement in policy making, providers were asked to reflect on possible ideas they might have shared if they were invited to participate in policy creation processes. From these discussions and across other parts of interviews, it was apparent that providers found it difficult to identify specific suggestions. So, although having strong feelings of being unrightfully distanced from the processes, providers did not appear to have specific proposals relating to their

involvement. There was, however, a belief among most of the providers – especially physicians – that, if given the chance to exert influence, they would either revert to the previous system or waive some of the restrictions and administrative burden imposed with the changes. The first of these propositions is consistent with the views expressed in section 5.2.1. The second suggested more of a concern around possible bureaucracy and process and did not appear to be related to the main concern about a lack of involvement for providers. However, one respondent did express a view as to how policies should be changed to improve providers' position:

"...as there is a budget ceiling setting the limit we cannot exceed, there should be a lower limit [threshold] that we mustn't go below as well. If somebody doesn't spend the estimated amount of money, he [sic] should be rewarded. There should be rewards as there are sanctions." (PCP3)

It was also interesting to observe that elites, in particular policy makers did not consider it problematic that providers were only informed about policy decisions that they were asked to conform to. In policy makers' accounts, providers were mostly mentioned as part of the implementation process, and policymaking was seen as the work of government institutions including themselves or institutions they represented. In this way, they appeared to implicitly delineate the responsibilities: policy makers – for policymaking, and providers – for implementation. Overall, the issue of involvement of diverse stakeholders in the policy making process was covered rather vaguely in their accounts. Policy makers were unanimous in acknowledging the necessity for involvement, but this appeared to be manifest more in a symbolic rather than actual way; only a few policy makers advocated or actually gave examples of provider involvement in policy development, mostly through providers' associations.

Apart from the involvement in policy-making, participation of providers in development of clinical protocols and evidence-based guidelines was mentioned. Providers' opinions were diversified and at one extreme were those who had no opinion on who should be involved in writing such protocols. In contrast, others considered their non-involvement to be a problematic limit to them expressing their professional knowledge and potential for providing best care to patients. In line with the latter, one policy maker respondent raised the issue, confirming lack of providers' involvement, despite her view that it was critical to ensuring ownership and adherence to such standardized procedures:

"This is exactly what I was talking about earlier. Before it [the guideline] is accepted and finalized by the [Health Insurance] Fund and the Ministry [of Health] as a public document, to make the draft available for discussion and review to the doctors in their Association or on their web site, so they can provide their input and express their thoughts about the guideline. In that case the guidelines will be more acceptable for all of them." (E16)

Other policy makers also considered evidence-based guidelines to be essential for containing costs and providing better quality of care, but as mentioned earlier, they have not made clear connection between guidelines development and providers' involvement. Rather, in the view of the majority, this was the role of academia in collaboration with the Ministry of Health and Health Insurance Fund.

The issue of involvement of providers in policy making has not been explored with the patient group, for obvious reasons and the earlier discussed lack of knowledge within this group on policies and policy processes in which they were developed.

In summary, there was an expressed dissatisfaction by providers with their involvement in policymaking, but a limited knowledge or idea as to how policies should be changed if participation in the processes was granted. Policy makers shared these views to some

extent, ultimately providing a mixed message in arguing that provider involvement was important, but that delineation of responsibilities between policy making and implementation was also necessary. Crucially, it was apparent that elite stakeholders viewed providers as part of the latter in practice. The next section explores crucial consequences related to implementation for providers, manifest as a lack of support and a perception of detachment.

5.3.2 Providers' lack of support and detachment

In addition to the lack of involvement in policy making, in their accounts, providers expressed dissatisfaction about the support they had obtained from institutions in the implementation of the imposed policies. This emerged in relation to newly imposed administrative work and lack of guidance with regards to problems arising in implementation. It also led to increased curative actions (such as inspections) at the expense of preventive ones (such as advice) by the relevant institutions.

The providers' complaints on the lack of support from the system were, among others, related to the additional administrative work imposed. As mentioned earlier, one of the changes physicians would make if they could exert influence was reducing the administrative burden. This lack of support from the system in relation to implementation emerged from many provider accounts and was associated with the view that privatisation had also imposed additional administrative work, which was not their responsibility before, since they were part of large health centres that had dedicated administrative units. With the subsequent policy changes, (i.e. limitation of prescriptions and budget ceilings described earlier), the administrative workload increased, comprising of record filling and frequent reporting to the Health Insurance

Fund. In their view, this clerical work impacted negatively on the main work of treating patients as the following three quotes variously illustrate:

"We are literally buried in admin stuff...paper forms, electronic forms, reports to the Fund, reports to the Ministry...and with only one nurse... I also have patients to see, so, we often stay [with the nurse] afterhours to fill them [records and reports]" (PCP12)

"Lot of administration...we've even become accountants...I am alone with the nurse, and the capitation is not enough to hire an assistant; I give some extra money to the nurse to stay overtime, and myself, I do it within my salary." (PCP15)

"Let's say that according to the Fund, we should give each patient 15 minutes, that that would be the length of the examination in the primary health care, five minutes consultation, and you spend the rest of the time writing everything down, checking if it all corresponds with the health book, with that in the computer, in the chart..." (PCP6)

Physicians did not seem to have willingly accepted the amount of administrative work imposed, as in their accounts they did not express any added value from the files and reports they were preparing and submitting. They understood the epidemiological need for data collection, but nonetheless felt dissatisfaction from the lack of feedback provided to them. Only one of the physician respondents was aware that the Health Insurance Fund was providing feedback through publishing reports online:

"...that information can be found on the Fund's website, you can learn how many antibiotics we have spent, how many, to be more precise, antidepressants, how many antihypertensives, and so on, so they provide a report that we have access to. The information is also divided by cities." (PCP8)

Regardless of the feelings of providers, this quote confirmed the existence of transparency on the part of institutions, at least with regards to information sharing,

and at the same time it raised the issue of providers' wish to be informed, understanding the policies and having meaningful participation in policy making, as discussed earlier.

Another important manifestation of the isolation felt by providers was the lack of support from the responsible authorities in dealing with arising issues during policy implementation. In their view, the problems that occurred should be a concern of and dealt with by the institutions and not made *'their own business'* (Ph3). Examples shared referred mainly to obtaining support for administrative issues, as these two quotes illustrate:

"If you know someone there [at the HIF] you can call and ask. If you call regular numbers you're always transferred or asked for your mail to send you the same unclear information you already got..." (PCP9)

"Clerks [at the Fund] can be nice, but they are not very helpful, they simply don't get it [the problem], they look into the law, or some bylaw and tell you what you already know. I say, 'I know that, but this is different' and they simply smile or nod. They are not interested what is the problem. There are exceptions, for sure, but I have no such experience, unfortunately." (PCP12)

In contrast to the majority of provider respondents sharing the feeling of lack of support, several respondents expressed satisfaction from their relationship, with Health Insurance Fund (HIF). In their opinions, HIF was responsive to questions and arising issues, however, still with limited scope:

"If I send e-mail to the [Health Insurance] Fund, they respond very quickly, especially on [issues of] reporting or e-software...they always refer to their website; all instructions are put there" (PCP8)

Elites held similar views with physicians in some aspects regarding policy implementation. As portrayed in the following quote, elites spoke highly of policies, but they were willing to admit that suitable implementation was not always in place:

“We are good at creating policies and writing laws, we have a very good legal and policy base, but it usually stays on paper...” (E16)

Elites had diverse views on providers’ practices. Whilst the majority disapproved of non-compliance with the policies, some of them appeared to be sympathetic towards providers’ perspectives, which as previously noted, may have been related to the fact that some of the policy makers were having provider experience previously. Illustrating this, several elites argued that there had been unrealistic setting of budget ceilings, especially for the pharmacies:

“No matter how many prescriptions are brought in, they should be issued. Actually, the [Health Insurance] Fund issues prescriptions and I don’t see why the pharmacy should have a limited budget when the doctors already have set ceilings with the Fund, right? All prescriptions from the doctors have to be dispensed by the pharmacies. With the limited budgets this is not possible...it’s dishonest, you issue a prescription under the insurance for a medicine that can’t get covered” (E14)

This view was also shared by pharmacists, who felt that one of the difficulties of implementation was the low threshold of the dispensing ceilings policy. This was dramatically described by one pharmacist in terms of the need to then try and communicate this to patients:

“We had a lot of trouble at first to explain that they cannot get their medicine, that they have to come earlier in the month...it was like ‘first come first served’...sometimes we posted announcements on the window that the medicines are finished for that month...” (Ph2)

However, there were also opposing opinions on the levels of prescribing. In the view of some policy makers, both overprescribing and overdispensing still represented a significant problem, which required further improvement:

“In the beginning we had higher ceilings than we would have expected to be prescribed, and we noticed that our doctors are spending always close to the upper limit; we lowered them and they were again on the upper limit. To me that means that still there is overprescribing, and probably more room for corrections of the budgets.” (E112)

Related to this, physicians’ accounts involved admissions relating to overprescribing, as a result of previous practices and perseverance of some patients, exemplified through the quote below:

“Some pensioners were very used to making stashes of therapy for several months...It was not easy to persuade them to get a prescription only for a month...some were persistent saying it is difficult to come every month...” (PCP5)

This quote raises the issue of provider-patient relationship, and in particular the pressures providers experience or perceive from patients and represented a recurrent theme in many provider accounts that is described in more detail later in this chapter.

Discussions on policy implementation elicited another important finding. Both physician and pharmacist providers, openly and vigorously expressed their feeling of detachment from the system. Physicians felt that prior to the policy changes, within the health system they worked in coordination with other levels of care, whereas under the more recent policy circumstances they considered themselves to be distanced, especially as a result of the privatisation, as illustrated by the following quote:

“They shouldn’t have privatized the primary care, we were ‘one’ in the health centres and working together with the hospitals, maternities, community nurses...now we are separate worlds...” (PCP11)

Echoing this theme, another physician expanded on the consequences of the policy changes in terms of being much less connected to others:

“We got alienated from each other, from the colleagues, from the [Health Insurance] Fund...in the beginning at least we would go there to submit the reports, now we don’t need to go there in person any more, and I don’t know anybody there anymore.” (PCP16)

“Providers are part of the system, we are not enemies...” (PCP11)

The participant in the first quote above further illustrated how these changes to ‘separate worlds’ (PCP11) affected the vertical links between the primary and the other levels of care – as in the following example with preventive services, which in her view should have been re-established, to enable their full potential as professionals:

“When I worked at the health centre, if I had a child coming often with respiratory problems, I would send the community nurse to check their home conditions, maybe the kid lives in a damp place, or they don’t clean the dust; she would advise them to air the room and so forth. Now, I can’t do that, I have no authority to send the nurse. All I can do is ask the family, or visit myself or, if the nurse is a good friend she will go for me...” (PCP11)

These quotes captured a sense of separation and difference and were a recurrent theme in provider accounts. This perception of being isolated was not only felt to be due to changes that had removed previous aspects of health care delivery but also due to a perception that health professionals were actively being treated as if they were not part of the system; there was an emerging feeling of being under unnecessarily strict scrutiny

and an associated dislike for such treatment. In varying accounts, it was apparent that health care professionals believed there was intentionality to this consequence of the policy changes, and an associated level of disquiet from participants:

“...They [Ministry and HIF] cannot simply treat us as if we are other people than we were before...they take now that we are private and that we work for profit, and that we are different, changed; we are the same old folks, that treated patients the same way we were before, just now we have more controls and inspections snooping around...” (PCP4)

This participant highlights another dimension of this feeling – namely, this quote insinuates something that was in other accounts more openly outspoken: that they have been subordinated to authorities and scrutinized in a rather negative way - with numerous controls and inspections, which instead of being advisory in the first instance like the legislation recommends, in most cases ended up with penalty for the physician or the pharmacy:

“Inspection came, they do come a lot...yes, sometimes they inform you and sometimes you don’t know they are coming...when you see the inspector, you know already you will be fined, 500, 1000 euros, depends...usually you’re fined, not advised or warned, like they are doing in the public health [settings]”. (PCP9)

“It didn't really happen to me, but a colleague of mine told me that when the inspector couldn't find anything he simply fined her for not having a proper display of the nameplate [at the practice]. How insane is that...” (PCP4)

One example was given of a penalty being imposed for a clerical error on a prescription, which the participant pharmacist considered to be completely unwarranted and disproportionate. The participant felt that this undermined the relationship between

providers and government and argued that such relationships were important but needed to be based on good will, trust and confidence.

In some other accounts, the dislike of the treatment was articulated as unreturned commitment in the relationship – in which physicians feel they have invested disproportionately more than what they got in return. Some health care professionals have given extreme examples of their attempts to cope with the challenges of the daily work that they have not signed up for. And, yet in their view the system perceives them as just another number:

“My replacement colleague broke her leg and I had to receive all her patients for over a year, and I was using my stamp and I went over the ceilings every trimester...I got penalized for not staying within the limits, but, what could I do... Who, you mean the Fund? They are not interested, for them we are only numbers...” (PCP9)

This quite clearly illustrated how the physicians’ feeling of being left alone materialized in non-protection for unforeseen circumstances, for which they had nowhere to turn.

Similar, although hypothetical, examples were given for maternity leave:

“You simply do not have the luxury to get sick...if I go on a maternity leave, or longer sick leave, there is no coverage for my patients. I am lucky that we are two at the practice, so we can manage, but for those that are alone, I don’t know how they deal...how could we manage? We would use each other’s stamps, we have agreement on that” (PCP13)

From the quotes above, and other examples physicians clearly depict their perception of the response from the Health Insurance Fund per se, as turning a deaf ear for their claims or problems. Another less dramatic case was penalisation for not staying within the limits, which triggered the issue of using only the stick without the carrot:

“I got fined last year for going over the limit with the prescriptions, but it was such a year, many of my patients were sick, the air pollution was very high...I was never rewarded for staying within the budget” (PCP16).

“If we spend under the ceiling, nothing happens (he smiles). On the contrary, we face sanctions.”(PCP9)

The pharmacists felt detachment in a similar way, but obviously in the context of medicine dispensing. For them, the quotas on medicines that can be dispensed under the health insurance were the key stumbling block in their relationship with the system. Their examples illustrated circumstances in which they were surpassing the quota for a certain medicine that was requested from them by a patient. They felt they had no proper interaction with the responsible organisations to solve the issue through the formal channels:

“We asked, but they [HIF] say that quotas are enough, but there are times when we have no quota medicines in stock...we don't want to turn the patient down, so what I do is I go to the neighbouring pharmacy to 'borrow' (showing quotation sign) from their quota if they have left. Then I return it the next month...yes, I do the same for them...” (Ph3).

As explained above, they resorted to finding their own ways of solving such issues, within or outside the legal frameworks. Although not captured in the quote, the shrug of shoulders of the pharmacist made it clear that such behaviour was unlawful and could be subject to penalty. However, she believes that providing medicines to a patient should be the highest priority – as a dedication to the profession.

On the same issue, policy makers had an opposing opinion. In their accounts, some of them provided examples of irregularities to illustrate how pharmacists used the policy's loopholes in their practice:

“It is not forbidden to get prescription medicine with a private prescription so long as it has a valid stamp, but you pay for it privately [out-of-pocket]. In some pharmacies inspectors found empty pink [private] prescriptions under the counter, stamped and ready to be used to cover for such privately bought medicines.” (E12)

“The current system enables us to oversee all activities at primary level; in pharmacies though, we can only see the medicines from the quota, and not the other supplies they would have. But you can expect that if the quota is finished by the 10th of the month, the rest is sold privately...whether all dispensed medicines are issued with a valid prescription can only be detected by inspection on the spot.” (E14)

Another example was shared by one of the pharmacist respondents, regarding the disregard of the system for the investments – both material and professional – made by the providers. Namely, with privatisation, providers were expected to invest their own resources for opening a practice or pharmacy. At first, licensing of practices and pharmacies was done in a non-systematic manner, with all applications that fulfilled general technical conditions were approved. As the market reached saturation, institutions, namely HIF, submitted to rationalisation of contracts, but without consideration of the already invested resources. One respondent was agitatedly explaining the frustration from the situation she was put in, where despite discussions and negotiations with the HIF to continue the contract for a village pharmacy, without prior notice the HIF has not signed an extension, explaining that village didn't have enough patients and the nearby town was close:

“They didn't explain anything, they simply discontinued the collaboration when the contract expired...no prior notice, no nothing. I went several times to ask, but got no answer, just that I can file a claim, that's it... there is no other pharmacy in the village, the nearest one is in the town some 20 kilometres away. I had really invested a lot, and it's not a car or a TV [i.e. movable item] to move it to a different place...” (Ph6)

As noted above, policy implementation and its appropriateness were also discussed with policy makers, as they were seen as particularly knowledgeable through their position to overview, monitor and control the implementation. Additional issues of concern related to implementation for them were the continuing trends of overprescribing and non-compliance with the dispensing policy.

The issue with overprescribing, according to the policy makers is still a serious concern not only from a fiscal perspective, but more so for its public health consequences. In their view, it had its highest levels during the policy of limited number of prescriptions per patient, for which reason the fiscal discipline measures of prescribing ceilings were introduced:

“Doctors were prescribing generously, because the policy was that for each patient two prescriptions were counted, without any earmarking or amount. There was a case of one doctor who prescribed 200 scatulas to a single patient in one month...it was suspicious so we sent the inspection; he was fined but we never found out what actually happened... He could’ve sold those medicines or provided them to uninsured persons under the name of a registered patient.” (E14)

From the patients’ accounts, the issues evidently of most concern were the access to medicines and the impact new policies had on obtaining them; further and related to the above, an important theme identified from their accounts was on the self-medication and providing justification for it. They openly admitted non-adherence and using loopholes when possible, which they interpreted as a response to the curtailing policy changes. Patients thought that information asymmetry is used for the interests and material gains of the providers, but also used it as an argument in justifying their

self-medication practices; to them, self-medication and circumventing procedures for legal medicine supply were a consequence of the policy changes. As this finding came strongly in patients' accounts and was linked to the pressures felt by providers, it is elaborated under the separate theme of pressures in practice, later in this chapter.

Through all of the above, the appropriateness of policy implementation was implicitly linked to responsibility for policy implementation, analysed below as a separate sub-theme.

5.3.3 Unwillingness to share responsibility

The experiences and opinions described above suggested that among respondents there was a pronounced belief that policy implementation was lacking in certain aspects. Policy makers considered overprescribing and non-adherence to dispensing policy to be the most critical issues; for providers, lack of implementation was linked to lack of support from the system and pressures from patients – the latter described under the third theme further in this chapter. Patients on the other hand, considered failure of the policies to be mainly related to reduced access to medicines, and increased need to negotiate their medicines' supply. These findings triggered discussions regarding responsibility for implementation.

Policy makers were very forthright in their opinions about the responsibility for policy implementation; in their view the system was doing as much as it could, with the limited resources for control and inspection being available, and it was felt that governmental efforts related to implementation were sufficient. Their accounts very clearly placed the responsibility with providers and patients, and the policy makers' role was perceived to involve ensuring policies were in place rather than implementing them. Specific

examples were given on the dispensing policy enforcement, which as described earlier was considered by policy makers as one of the remaining implementation issues:

“These [dispensing with prescription only] policies are not new; they have been endorsed long time ago. The medicine that has an R on it, even if it’s an ointment, mustn’t be dispensed by a pharmacist [without prescription]. But they do it regularly, the authorities didn’t fine them nor did they think of doing anything like that. This was the practice up until 2009 when they decided that each medicine must be prescribed [so to be dispensed].” (E13)

This quote illustrates the opinion of policy makers that responsibility lay with pharmacists but also implicitly with patients too, since the unlawful act committed by pharmacists was initiated by demand from the patients. Also of particular note in this quote was reference to ‘prescribing and dispensing by a pharmacist’ and whilst there is no legal authority given to pharmacists to prescribe medicines in Macedonia, in the accounts of several policy makers this practice was described. Namely, upon enforcement of the dispensing policy in 2009, the pressure to dispense without prescription was still felt to be considerable – both from patients to obtain their medicines, as well as from owners of pharmacies interested in maximizing their sales. According to elites, subterfuge was used to create a procedure that deviated from the dispensing policy, in which pharmacies kept blank non-reimbursable prescriptions under their desk and filled them when a patient without a prescription came in:

“They [prescriptions] could be from the [Health Insurance] Fund, empty like this one [showing a prescription], the only difference is that there isn’t anything in the upper corner, no name and surname, so they aren’t counted by the Fund in the quota...A doctor would, let’s say, leave a bunch of stamped prescriptions, and they [pharmacists] would write the medicine down, the pharmacist would write it himself.” (E11)

This sought to make the subsequent dispensing legal, but also involved obvious illegality in the actual writing of the prescription. Furthermore, elites argued that such practices encouraged self-medication through unprofessional means. Hence, many of the elites not only considered providers responsible for the lack of implementation, but they also viewed them to be primarily responsible for the diminished appreciation of the medical profession, elaborated in more details under section 5.2.1.2.

It was not just in elite interviews that unprofessional practice emerged; some of the pharmacist respondents described similar examples of dispensing without prescription. However, their interpretation of such practices was very different, placing responsibility with policy makers, who it was argued, have allowed variable implementation in primary care, and also were not checking on and recognising such practices. According to one pharmacist, although such ambiguous enforcement was perceived to be common knowledge, it was regarded as a:

"[...] public secret that there are pharmacies issuing medicines without prescription. I know which those are; I don't want to mention names...patients use it as an argument when they come without prescription. I tell them to go there if they can get it elsewhere" (Ph9)

The pharmacist believed that there were few or no repercussions for those who did not adhere to prudent policy implementation, and were alleged to be abused by those 'having connections' (Ph9).

It was not just pharmacists but physicians who also engaged in non-standard practices that did not follow the new policy:

“If I know a patient is well off, I might suggest to buy the medicine out-of-pocket, if it’s better than the one on insurance...I issue the prescription, but it is not counted in my medicines’ budget.” (PCP7)

As illustrated in the above quote, most providers perceived their own behaviour to be justified, and distanced themselves from any responsibility or blame in relation to the perceived problems of policy implementation. Rather, their opinions cast aspersions towards other groups – namely policy makers or patients. According to them, their responsibility was minimized with the increased regulation that marginalised them and their professional autonomy to make independent decisions about prescribing and dispensing medicines. Among physicians, there was an apparent distancing from responsibility that emerged in their accounts, illustrated through the quotes below:

“Doctors cannot be responsible if there are not enough medicines...I sometimes go over the limits, but cannot do it too much and too often, I get less money, which is not patients’ business but I have to care about it...’don’t kill the messenger’, you know...I am only doing as told, and they [patients] can go claim it above [to the authorities]...” (PCP17)

“...you do your job and it is not our fault that there are patients who got used to consuming certain quantity of medications; the fault is with completely other factor.” (PCP1)

“When they were writing them [laws and bylaws] they hopefully had an idea how they would work in practice. I don’t know if they are happy with this, but you know what hurts most? If I don’t pass the ceiling I risk losing patients, and if I go above, I lose the capitation. It’s like the snake and the donkey choice⁷ (laughs). I’m like ‘from all sides Gorgi surrounded’⁸” (PCP6)

Again, similar narratives emerged between the two provider groups, and pharmacists also felt that they were not responsible and levelled concerns of policy makers:

⁷ Idiom referring to having to choose between one of two poor options.

⁸ Further Macedonian idiom that implies having no options.

“Officials [i.e. policy makers] should be responsible, they probably had in mind how to execute them when they were writing...And it’s their responsibility to enforce, to inspect, all...if I get a valid prescription, I don’t think I have any responsibility but to dispense it. I cannot tell doctors that antibiotics are not for viral infections, let’s say, they learnt it in the medical school” (Ph10)

The above quotes suggest that as well as policy makers, providers also consider patients to bear a large share of the responsibility, based on perceptions of their demands in relation to medicines, as the following quotes explicate:

“...I mean self-treatment is the problem. You come to the pharmacy and you take antibiotics, you take tuberculostatic, antiviral medicine...” (Ph3)

“The other day, a patient came to ask for diazepam, he was obviously disturbed; he said his daughter had an accident at school, but, he didn’t seem to me like he had a daughter of school age. I tried to explain when to use, when not to use, but I think he knew already, he seemed like a user...” (Ph8)

The accountability of patients was also referred to by policy makers, who considered patients’ behaviour of seeking ways to perpetuate self-medication practices:

“I personally think that the doctors prescribe drugs rationally, there is no dilemma. The patients spend irrationally when they decide to buy drugs on their own.” (E15)

“Unless we raise people’s awareness that they cannot simply go to the pharmacy and buy medicines as if they were in a grocery store, nothing will change.” (E11)

However, of note was that a minority of providers admitted that some responsibility was with providers as already illustrated in a quote of one pharmacist who admitted to the practice of other colleagues ‘issuing medicines without prescription’ (Ph9). This reflected

a minority view, however, and most provider participants believed that the responsibility of providers rested with the other provider. Physicians readily transferred the obligation for improving implementation to pharmacists:

“Pharmacists shouldn’t dispense without prescription. If I didn’t think it was necessary, why should they think otherwise? It is for their benefit only, not for the patient’s...” (PCP10)

Pharmacists too, considered that physicians could improve their practices to contribute to better implementation:

“Sometimes patients do ask for antibiotics without prescription but I always suggest them to first consult a physician...I’m not competent for establishing diagnosis which is why I advise them [patients] to go and see a physician. I do the same myself.” (Ph5)

Patients’ narratives disclosed interesting views on responsibility for implementation. They were mainly concerned with the satisfaction of providing for their real or perceived needs for medicines. Most patients were vaguely interested in the overall policy implementation or responsibility but admitted to having managed to establish regular practices of obtaining medicines – sometimes outside legal procedures. Several of the respondents, acknowledged that dispensing without a prescription was not appropriate practice, but this was accepted as a necessity due to a lack of other opportunities:

“...if you can’t afford to buy medicines privately, you have to find a way...” (Pat2)

Although patients were aware that they are not always adhering to the regular practices, they did not consider themselves directly responsible for lack of policy

implementation. On the contrary, they used their feeling of subordination as a good ground for justifying their practices and established routines, explained at length in the third theme of pressures in practice.

5.3.4 Summary of theme findings

In summary, the views of policy makers on the policy changes reflected a forthright justification for the necessity of changes, although it was admitted that implementation had not been complete and therefore a success. Their understanding of the sometimes unfavourable position of providers suggested a good degree of insight although, ultimately, they placed the responsibility for the lack of successful implementation with providers and not themselves. While distancing themselves from responsibility for policy implementation, they also found patients to be responsible for implementation problems, through perpetuating practices of self-medication and requesting medicines without prescription.

Patients' standpoint depicted a feeling of lack of care and focus on their problems and concerns when it came to medicines – quite contrary to the perceptions of policy makers (as the later part of this chapter will show) and providers about the supremacy of the patient, safeguarded by the system. To respond to this situation, they had managed to develop their own ways of handling the new situation of limited access and need to negotiate medical supply. They disclosed a set of justifying arguments for the non-adherence and subterfuge of the regular prescribing and dispensing procedures, and did not accept any responsibility for that.

Providers considered the lack of implementation to be associated with additional administrative workload imposed in their work, as well as with lack of support from the

system. This brought about the feeling of isolation and detachment from the system. In their view, lack of implementation was vaguely associated with themselves, and mostly with the providers outside of their own group. Still they placed the greatest share of responsibility with policy makers and patients.

Overall, it was apparent from all groups that there was lack of willingness to accept responsibility for the failure of implementation. All groups, with exception of several respondents, considered the responsibility to be with others, despite some of the examples clearly pointing to shared responsibility for actions of all stakeholders and finally resulting in policy failure of overprescribing, subterfuge of dispensing policy and encouraging self-medication.

5.4. Pressures in practice

This section presents the final group of findings, which are related to another perspective of implementation, namely the diverse pressures experienced by providers and patients in relation to medicine supply. Presenting them as a separate overarching theme relating to pressures in practice was justified given how important these issues were for the two groups. It also emerged, although to a lesser extent, in the interviews with elite stakeholders who also recognised it was of importance. This third main theme is further divided into two sub-themes that are framed around the different insights from providers and patients: one related to providers' perceived pressures from the system and from patients, and the second related to patients' perceived pressures for negotiating medicine supply.

5.4.1 Providers' professional disempowerment

Many providers' accounts revealed a key emerging theme related to pressures felt in their daily work. One of the pressures pertained to the system, and was largely linked to the previously elaborated sub-theme of a lack of support in implementation and detachment from the system. In addition, though, providers described a perceived pressure from patients in relation to medicine supply, describing it as a lack of understanding and empathy from patients about the circumstances imposed on the providers. In a broader sense, providers' feelings could be summarized as loneliness in handling the situation, in which they had to respond to requirements and deliver on demands of both sides they interacted with – the system and the patients. Or, as already illustrated in the previous section, they described their situation as unfavourable of being *'from all sides Gorgi surrounded'*⁹ (PCP6). With this and similar quotes, it appeared that providers considered pressures from the system and patients to be interlinked – in their view, the system was encouraging patients' empowerment, while not equally supporting providers, as part of the system. As the following quote illustrates, this notion came from the endorsement of patients' rights, at the expense of the rights of providers:

"Everyone talks about those patients' rights, nobody says a thing about the doctors' rights, we haven't read those anywhere, it hasn't been promoted yet...patients should know that we, too, have rights..." (PCP6)

This quote captures providers' perception of increased pressure from patients, but it also suggests an implicit pressure from the system, by not taking actions to protect

⁹ Further Macedonian idiom that implies having no options.

providers' rights and interests. These perceptions were articulated in different examples linked to all analysed policy changes. Namely, as described in the quote below, the enforcement of prescribing ceiling policy also brought two types of pressure – one from the system to change providers' prescribing behaviour, and the other one from patients, whose behaviour providers were expected to influence, regarding medicine demand:

“Patients are not interested if I have no budget to prescribe, they feel they have the right to their medicines, they have paid for their health insurance...” (PCP3)

“Some pensioners were very used to making stashes of therapy for several months, because during the transition years, there were periods of deficiency of medicines. It was not easy to persuade them to get a prescription only for a month...some were persistent saying it is difficult to come in every month...” (PCP5)

In their view, physicians' position was pressurised from the current policies but also from past conduct. The second quote above exemplifies these pressures, arising from their dual role of acting on behalf of the system in safeguarding it, and being patients' agents in delivering good quality care and professional advice.

Pharmacists felt similarly regarding pressures from the system and patients. In their view, the system did not appropriately communicate the new circumstances of dispensing ceiling policy to the wider public, causing misperception and distrust in the profession:

“We had a lot of trouble at first to explain that they cannot get their medicine, that they have to come earlier in the month...it was like ‘first come first served’...sometimes we posted announcements on the window that the medicines are finished for that month...” (Ph2)

Related to this, the following short quote, illustrates pharmacists' perception of patients' negativity and suspicion related to the new policies and specifically quotas:

"I know that some people think we are hiding the quota so to be able to sell them the medicines..." (Ph8)

Providers expressed their reluctance to prescribe under pressure, but also admitted a sense of defeat, describing it as 'indulging' patients in their requests:

"It is difficult to explain to a patient, when you can see it in their eyes, they would not go away without antibiotic...I would otherwise not indulge, but I decide to give those the antibiotic...I think it would do no good, but I prescribe anyway" (PCP14)

"I tell young mothers that antibiotics are not always needed, but it is our mentality, an advice from other mothers, they even suggest what to prescribe...I really don't like when the sentence starts with: 'a friend of mine told me...' I have a desire to say 'go to your friend'..." (PCP10)

While being descriptive of the pressures felt from patients, this last quote also illustrates the undermining of professional autonomy by providers themselves. When asked, providers justified such behaviour again through the lack of support from the system, describing it through examples of loose policy implementation allowing patients to still pursue their desired goal:

"Our people get easily petty and they could say 'OK, I don't need that prescription from you, I'll get it from another physician'... So you prescribe, what can you do..." (PCP14)

In the pharmacists' accounts, this submission to pressure was also articulated through variable implementation and ambiguous enforcement of policy regulating dispensing only with prescription. Many of the pharmacist respondents articulated the pressure in

terms of it being the persistence of patients obtaining medicines for their own self-medication plan. In addition, concerns emerged in relation to how to respond to patient pressures when they ask that rules be not observed. Some of the pharmacist respondents tried to justify the dispensing without prescription, through specific situation, which not necessarily could be associated with the discussed policy changes:

“Sometimes a patient comes without a prescription, but we live in a small town, everybody knows everybody. I ask him who is his doctor and dispense the medicine. Later I call the doctor to ask for a prescription and I go fetch it later, so that I have the dispensed medicine covered.” (Ph7).

Such accounts reflected a duality and this pharmacist appeared to convey two interpretations of such occurrences: firstly, that they reflected pressure and this diminished the professional autonomy of providers, but secondly and more positively, that this was perceived as an attempt to assist and serve the patient in need. The majority of pharmacists held the opinion that uneven implementation of policies was a far more important factor enabling patients to exert pressures to obtain medicines without prescription:

“...if I didn't [give patient the medicine without prescription], he'd have gone to the pharmacy next door, we are three in a row if you look out the window...” (Ph8)

The above quotes from both the pharmacist and the physician respondent PCP14 earlier (page 188), suggest importantly that to providers, simply keeping the patient as client to the pharmacy or as registered patient in the physician's roster (and the associated capitation) was sometimes more important than professional knowledge and integrity.

It was not only in provider accounts that such pressures were perceived, and as shown in the following quote, it also emerged in the accounts of elite stakeholders. It was apparent that they also understood and predicted some pressure and perceived expectations from patients, which possibly affected providers' attitudes and practices, motivated by maintaining a good physician-patient relationship:

"...they prescribe, because they are expected to prescribe... it would make them look foolish if they don't, the patient would go to see the neighbour[ing doctor] if he must..." (E110)

Elites also agreed with providers that patients were excessively demanding medicines and that such behaviour was one of the most challenging aspects of the policy implementation. Elites' accounts revealed that the greatest influence on prescribing and dispensing was that exerted by patients, and that this could be traced back to the past when medicines were fully accessible. This legacy was, in their view, additionally and unintentionally reinforced by the recent policies on patient empowerment:

"Those I call the 'informed patients' (laughs). They read off the internet or talk to friends and neighbours, and they all know what is wrong with them, then also know the best therapy... or they would not like the therapy that the specialist prescribed, before they even took it, because it wasn't what they'd expected, so they ask for referral to go to another one...and this is all covered with the insurance, the first opinion, the second opinion...We introduced this in 2008 in the law on protection of patients' rights but the intention was not to enable abuse, rather to give wider access..." (E110)

In their view, such practices continued to exist, in a form of overprescribing and dispensing without prescription, both of which were viewed as unethical:

“The electronic system has a real time information on the so-called patient pathways; that means where and at what time the patients are with their papers...We see a lot of antibiotics there...individually I am not convinced that all those prescriptions were really necessary.” (E113)

One of the elites stakeholders described patients’ exerted pressure as one supported by the ‘aura’ of supremacy of the patient, which was also reflected in their behaviour towards the system and responsible institutions for handling the claims, as illustrated in the next quote:

“There is this aura that the system exists for the patients ...in their understanding there shouldn’t be any hesitation to giving them the best available treatment, be it diagnostics, treatments, medicines, medical aids...We get complaints from patients which are not always grounded, and when we reject them they go to the second instance [higher authority level]...” (E11)

As noted above, elites considered such behaviour and a feeling of supremacy to be reinforced by the recently endorsed policies that promoted patient empowerment. Among other impacts, according to them, these policies enabled a high degree of freedom of the patient to make choices that could be single-handedly decided upon, but had implications for physician’s practice and even income:

“Patients can change their physician as many times as they want, and there were lot of requests at first, so we limited it to two times per year...in the beginning, it was required to state the reason for changing, now not any more... They don’t even have to inform the doctor that they have chosen a different one, all there is to do is to go to the new one and sign in, the system automatically removes them from the doctor’s listing, no questions asked...the capitation will be deducted for the removed patient.” (E113)

This view was consistent with the providers' concerns about the diminution of their autonomy and respect for their profession, discussed earlier in this chapter. However, policy makers perceived this reduction in autonomy and respect to also come from providers themselves, and believed that more should be invested in the continuous professional development and communication skills of providers in primary care. For policy makers, the role of education and continuing professional development was argued to be key; in their view, the physicians had sufficient clinical knowledge, but they lacked awareness of clinical guidelines. In addition, many of them felt that introducing training on communication with patients would be beneficial, for both physicians and pharmacists, which was in a way confirmed by the providers themselves:

“Many trainings we had [on rational prescribing] with foreign consultants... we used to ask doctors what would they prescribe given the diagnosis. We would give them the example, I'd ask, this was the medicine prescribed in one country, what would you have prescribed? ...they said that it was easier to answer theoretical questions or to raise the color-coded card [with correct answers], rather than telling to the patient...”
(E19)

In summary, this section has presented a varied and complex account of the experiences and views of physicians and pharmacists in primary care in Macedonia in relation to one particular aspect of implementation, articulated as pressures in practice. It has been shown that they appear to be in a difficult position due to dual pressures – upwards from patients' pressure and expectations and downwards from new policy frameworks. These, in their view, are exacerbated by a perceived lack of support or guidance in relation to policy changes, elaborated in the previous sections. Similar accounts were provided by policy makers, though their views also included proposed solutions for reducing these pressures through continued professional development and providing

training for communication with patients. The next section goes on to explore the experiences and views of patients, with regards to their perceived pressures from the new policy circumstances.

5.4.2 Patients' negotiation of medicine supply

The second sub-theme related to pressures in practice following policy change involves patients' felt pressures under the new policy circumstances. As elaborated earlier, patients related closely to the past system, and shared experiences of several negative consequences related to policy changes. In the new policy setting of limited prescribing and dispensing, patients no longer had unlimited access to medicines and supplements, and in their view perceived themselves to be pressured into engaging in negotiation over medicine supply. As will become clear, this was manifest in terms of pressure being exercised by patients over physicians in relation to prescribing decisions, and also over pharmacists in relation to dispensing medicines without prescription.

Although a range of patients and ages were purposively sampled in this study, many of the respondents had experience of, and could recollect, the prescribing and dispensing practices in the previous system. Although there was explicit acknowledgement of the necessity of limitations and cost containment (as noted in section 5.2.2 *Reflections on recent policies: necessity for change and qualified acceptance*), patients were critical when considering the personal impact of such policy changes. Their understanding appeared to be informed by their own personal needs in relation to medicines. There was a sense that for many, they did not represent a burden to the system, and as a result there was a certain entitlement or expectation in relation to medicines and

therapies. This was justified in terms of the view that they had contributed sufficiently to health insurance through fringe benefits, as one patient argued:

"...I worked for 35 years, was strong as a horse, never got sick, so I think I am entitled to the healthcare to enable me to enjoy my retirement for as long as I would be around...I take a very common therapy for high blood pressure, I also take prevention for blood clotting... those are all regular stuff, half of the nation is taking them, I think they are not as expensive as cancer treatment for example..." (Pat12)

In their view, access to medicines should be guaranteed, and they found it rather novel that in some instances they needed to negotiate or argue with physicians or pharmacists to obtain the medical therapy. Of note was that most of the examples given were about anti-microbial treatment, usually in smaller children. As the following quote illustrates:

"Several times the paediatrician suggested we try without antibiotics, but I know my child, she is very weak on her throat, and if we don't react quickly it goes straight down to the lungs...I tried once and it didn't work, we ended up with pneumonia in Kozle [lung disease hospital for children]...I know my child and if I think antibiotics are needed, they usually are...I am not in favour of medications, but when it's needed, it can't be helped..." (Pat9)

To many of the interviewed patients this need to negotiate for medicines represented a new dimension of their relationship with the system, and this was not just related to examples like the one above about controversial antibiotic prescribing, but also medicines for well-recognised long-term conditions. For those who were on long-term therapies, the main issue raised was the very real possibility of not being able to obtain necessary therapies for longer periods in advance. One patient felt it was a futile exercise that was not only an inefficient use of time, but was also undermining the expertise by a specialist:

“I’m a heart patient for 20 years; I know all medicines, I’ve taken them all; I can even tell you which companies’ have better effect... enalapril, for example, from [...] company is not effective, at least not for me, so I stay with [...] company...I go to the cardiologist once a year, so I tell my doctor, if the cardiologist thinks that I can go with the therapy that long, why can’t I get the prescriptions at once?” (Pat12)

What then emerges from the perspective of patients, is a threat to their previous ability to obtain any medicine through prescribing, and a current process whereby physicians appeared to be restricting patients’ access to certain medicines. Although, as noted, not framed in an explicit understanding or awareness of the three key policies themselves, patients nonetheless were aware of the changes and the negative consequences and need to negotiate more.

Two other patients, referring to the impact that new policies’ limited access to medicines had on their routines, considered alternative solutions to obtaining the required medicines:

“I have a holiday apartment in Ohrid and I go there for three-four months during summer...so, I ask the doctor to give me the medicines for the whole period but it is not possible...up to three months, yes but after that I have to come back to Skopje to get the prescription, because I can’t get it from a doctor in Ohrid...sometimes I decide to buy privately as it is less bothering to pay than to go back in the heat just for the prescription...sometimes, I ask someone to go to my doctor for the prescription and then anyone traveling to Ohrid will bring it for me...” (Pat1)

“My daughter lives in Serbia, and I spend the winter with her to help with the children...but it is most difficult with the medicines, they have different ones and also I don’t have insurance there. So, when I have to make larger stock, and it’s not easy...some of the medicines are the same as my husband’s, so I take prescriptions some on my name and some on his to get enough of the medicines I need. I leave with him some, and he can get additional packs while I’m away...he does the same to get the medicines,

some on my name and some on his...if you can't afford to buy medicines privately, you have to find a way..." (Pat2)

In the second quote above, the patient is describing a rather complex scheme of trying to circumvent current policies in order to be able to continue the established practice of providing sufficient medicine supply that was possible in the past. For the described situation not covered by the policies, the patient needs a medicine supply for a period longer than the allowed maximum, so she combined prescriptions with another patient - in this case her partner - to make an advance supply in another name, that will later be covered by the prescriptions in her name for the supply of the other patient.

These quotes illustrate two of the non-standard alternative routes to medicine supply faced by patients within the current prescribing and dispensing policies, to either fund the supply of medicines themselves privately, or to use subterfuge to obtain supplies.

For some of the patients the wearying nature of such negotiated supplies led to active attempts to exercise a choice over prescriber, and so to search for another doctor who was willing to acquiesce to patients' requests:

"I have a very stressful job, I was telling my previous doctor that I have trembles all day long if I don't take Helex [anxiolytic], and that I don't sleep well, and I tried all alternatives he offered, melatonin, valerian, but with no effect. He also said physical activity, but I'm too tired when I come home... He said Helex is addictive, but I was only taking one in the morning and one in the evening, sometimes skipped...He prescribed once or twice, then said I should consult a neurologist. I decided to change the doctor..." (Pat14)

Negotiating for medicines was described as well at the dispensing level. A few of the patients described situations when they could not obtain the medicine despite having a

valid prescription, often as a result of the unavailability of the required medicine at the pharmacy, due to the exhausted quotas for the month:

“At the pharmacy they would sometimes have only two of the four prescriptions I need, so I have to go to another pharmacy....it is frustrating to do it every month...I made arrangement with our local pharmacy that I leave the prescriptions with them and they call me in when medicines come...” (Pat6)

The negotiating at the pharmacy level also happened when there were no genuine medical reasons. This patient had already made the decision to obtain the medicines and found a way to effect her decision despite the circumstances:

“Here in the village we have no doctor, there was one but he closed the office...now we only have a dentist... When I need antibiotic I have to go to the town, and then get it from the pharmacy here, but usually I can’t go when I’m sick, I’ll get even sicker...so I ask the pharmacist for the medicine and I bring the prescription later...” (Pat14)

Further to this, in the patient group, such necessity to negotiate medicine supply has evolved into justification of ‘means’ towards the end goal of providing necessary or desired therapy for their treatment and resulting sometimes in subterfuge of regular mechanisms and unethical practices. The above quotes exemplify patients’ practices already described by providers and confirmed by elites who also shared these views:

“There are cases when the patient has already bought and consumed the antibiotic ... For example, the patient has bought himself Vibramycin [branded form of tetracycline antibiotic] because the dose is one pill per day, it costs 40-50 denars [less than one GB pound], five pills, he will take them and will then come to me and I have no other choice than to prescribe the same...” (PCP14)

As considered above, patients admitted to actively pressuring providers and encouraging non-compliance with regular prescribing and dispensing procedures. For them, this new reality was a justification of their practices - previous and current - of obtaining medicines on their own, especially if they anticipated the physician would consider their *choice* of medicines not to be necessary. They have very openly spoken of inclining towards a decision of taking medicines without prior health care professional consultation. Examples were given mainly for antimicrobials and anxiolytics, mostly among younger respondents but the elder alike; some referred to previous experience with the same medical condition:

“When I have a sore throat I know that I can’t solve it without antibiotics. I usually take Vibramycin [a branded form of tetracycline antibiotic], it helps me every time, and it’s very affordable. I always have a dose at home, ‘cause it’s best to take immediately when you feel the scratching in the throat” (Pat7)

“I don’t mind paying for the medicines, and I do...it is quicker and easier to go to a pharmacy and get what you need...some of the prescription medicines should be without prescription [over-the-counter] if you ask me...for example, my husband has a sleeping problem and he takes diazepam from time to time. For that, I don’t think it’s so necessary to go to a doctor... I think should not be on prescription, it seems like a matter of marketing...” (Pat3)

Further, these and other respondents are seemingly speaking of availability of medicines as a matter of material possibility to obtain them; the above examples reveal disregard for the necessity of medical consultation, and provide another explanation for their straightforward justification of self-medication practices. But, at the same time these excerpts also disclose that medicines can be obtained without prescription, i.e. that there are pharmacies enabling this practice. Here too, patients have inclined to

developing a new skill for identifying such pharmacies where obtaining *desired* medicines was not problematic:

"...needed antibiotic for my girlfriend, she was burning with fever and Paracetamol [branded form of acetaminophen] didn't help... The lady said she cannot give me any drug without prescription, no matter what...I had to go to the next and the next, and I bought it...I was scolded (laughing), but I got it..." (Pat13)

"Some pharmacists are very tough, they wouldn't give anything without a prescription, they tell you that such are the rules, and there are strict inspections...they are nice and apologize but will not give in...There are few that I know which sell you the same medicines without a prescription, and for them there are no inspections... even, they will give you an advice which is better than the other..." (Pat10)

These two quotes illustrate the justification, triggering the compensatory mechanisms of finding their own ways of dealing with the arising issues while at the same time not feeling the responsibility when those are outside of the normative, legal or ethical frames.

For one patient the request for a medicine without prescription was justified if supported by the provider, and, as in this quote, this could be for a variety of medicines including those with abuse potential:

"My wife's mother was in terminal stage of cancer and she [the wife] was very anxious, very nervous, I became anxious too, I didn't know what to do ...I went to a pharmacy and asked for diazepam or something similar...they didn't have diazepam and [the pharmacist] offered me helix [sic], Helix [a branded form of alprazolam, an anxiolytic] ... explained the dosage..." (Pat11)

Elites' accounts confirmed the above practice of circumventing primary care for obtaining a prescription, and going directly to a pharmacy with self-medication intentions, exemplified through the following quote:

“Still today patients don’t go to the doctor, they go straight to the pharmacy; if there are any family ties they would get the medicine without any problem...those who want to get the medicines through the Fund regularly take prescriptions, but there is one part [of the population] that doesn’t bother, obviously because they can afford it.” (E12)

The above quote also conveys the finding that despite policy changes restricting unregulated medicine supply, obtaining a prescription medicine was still viewed as a matter of financial affordability even by elite stakeholders.

5.4.3 Summary of pressures in practice

The theme of pressures in practice revealed providers' felt pressures from both system and patients, and patients' felt pressures for obtaining medicines they deemed necessary.

In providers' accounts there was an obvious tension between the necessity to respond to system's requirements and deliver on patients' demands. The system's pressure was mainly articulated as an increased pressure to adhere to the new rules under the conditions of perceived lack of involvement in policymaking and lack of support for implementation. The pressure from patients was articulated as both felt and perceived, forcing providers to unwanted practices of prescribing without medical indication and illegal dispensing without prescription. Although reluctant to abide, providers admitted to accepting such demands under pressure, which contributed to their feeling of isolation and detachment from the system.

What emerged in patients' accounts was a new found need to seek out and negotiate medicine supply both at prescriber level, but also through less regulated pharmacy supplies. A tension was shown to emerge in patients' identity, where they appeared to be somewhat empowered health consumers, yet still treated paternalistically. Providers had opposing views, as they found patients to be unjustifiably empowered and more supported by the system than themselves as its part. Elites agreed with providers that patients' behaviour significantly influences decisions in prescribing and dispensing, but were negligent of the fact that failed policy implementation was one of the key factors enabling such influence.

5.5. Summary of chapter

This chapter has provided detailed descriptions of the emerging themes resulting from the in-depth analysis of the interviews revealing several key findings related to the effects of policy changes on the prescribing and dispensing practices in primary care in Macedonia.

All groups expressed a positivity and attachment to the previous system, manifest as a positive nostalgia. This nostalgia was articulated by providers from the perspective of professional autonomy and belonging to the system, and by patients as less problematic and unlimited medicine supply in the past. Elite stakeholders also talked about the benefits of the previous policies, and agreed that professional autonomy was reduced with the new policies, but also understood the lack of sustainability of that system, justifying the necessity for change for improvement of efficiency of resource use.

With regards to the policy implementation, all groups similarly believed that this was lacking, however each group argued this was so for different reasons. For providers, it was a consequence of the lack of their involvement in policy-making, ambiguity of enforcement and lack of support from the system. While providers largely questioned the policy changes and patients were ambiguous, the views of the elites generally described the policy changes as being necessary, although they also made comparisons to the previous system, which was perceived more positively as being fairer and more oriented towards patients, though not sustainable in terms of cost efficiency.

The patients on the other hand, were much less aware of the details and drivers of the policy changes, beyond their experience in visiting a primary care physician or a pharmacist. When compared to the past system, they too, felt the previous system was much more oriented to address their needs, and were not quite ready to justify the cuts on prescribing and dispensing under the health insurance; with the exception of some, who had knowledge on policies through a person working in primary care. The policy makers held a more forthright view that resultant problems associated with the policy changes were attributable to the other groups. They identified perceived problems amongst providers and patients related to a lack of professional development for the former and a lack of health literacy amongst the latter.

Primary care physicians and pharmacists felt detached from the system, expressing themselves as being left alone to cope with policy implementation. In line with the feeling of detachment, another important issue was the lack of guidance and support for the policy implementation; to the physicians and pharmacists this meant that they had to find other ways of dealing with the arising problems, beyond the framework for which they have been engaged.

In addition to this, providers felt disempowered and their autonomy threatened. In their view, this resulted in a deteriorated appreciation for their profession across society, which also had negative ethical implications. This was manifest in terms of continuing the practices of overprescribing and supplying medicines without prescriptions. The elites stakeholders broadly shared a similar standpoint to that of providers with respect to the above, but were more cautious in justifying these practices. On the contrary, they distanced themselves from responsibility and considered improving implementation to be in the domain of providers and patients.

Another important theme arising from the interviews involved pressures in practice. As already noted, the analysis of interviews revealed differing perspectives, with providers feeling pressure from both regulatory and governmental bodies to adopt the policy changes but also from patients in relation to their expectations and demands for medicines. Their repetitive and ample examples of being pressured depicted changes in their relationship with patients; they feel subordinated - to the system, through privatisation and to the patients through the perceived patients' supremacy as a result of their empowerment with the patients' rights policies. While policy makers tended to generally agree with providers on the issue of patient pressure, patients' felt strongly that the situation was quite the opposite. They described being in an unfavourable position in their interaction with the system, making the case for their access to medicines, negotiating medicine supply and justifying self-medication.

Patients also did not consider their relationship with the physicians to have changed dramatically, but expressed a feeling of disempowerment when it came to negotiating what they argued were necessary medicines. Their attitudes, in fact, appeared to depend much on their ability to pay for the medicines out-of-pocket, and patients

openly stated that they would circumvent going to the physician and getting the prescription, if they could find a pharmacist that would dispense the medicine without it. Some extreme and negative opinions were identified in this respect, captured in one respondent's view that all recent prescribing and dispensing rules and policies were a *'matter of marketing'*.

The next chapter focuses on the interpretation of the findings presented in this chapter, along with further reflection on the emerging themes in the context of relevant literature and also Habermas' theory of communicative action.

CHAPTER 6: Discussion

6.1. Introduction

6.1.1 Overview of chapter

Social science approaches not only provide a means of describing particular socially occurring phenomena but also offer a way of seeing them that might not be immediately apparent (Cooper 2006). As evident from the previous chapter, the themes identified from the individual respondent's accounts reflect the lived experiences of individuals in different roles and often at a micro-social level, but always in relation to the macro-level framing of different policy initiatives. To this end, the identified themes were analysed from the perspective of their common underlying concepts while looking into patterns of behaviour through individuals' attitudes and practices, expressed through their accounts.

The key task in this chapter is to provide additional context and reflection on these emerging themes, and crucially to relate them not only to the extant literature but also to relevant theoretical concepts. Thus, beyond the attention to the excerpts from the respondents' individual accounts, provided in the previous chapter, the interpretation and contextualisation of these findings in the present time and more importantly in the theoretical framework chosen for this research is of equal importance and as such is elaborated in this chapter.

The chapter will reflect the findings in the context of the Habermasian social theory of the system and the lifeworld, and its notions of '*selective rationalization*' consequent on

the growth and dominance of the capitalist economy and state bureaucracy (Brand, 1990), and *'lifeworld colonization'* consequent on increasing systematisation of particular areas of the lifeworld, leading to deviation from or stagnation of the original purpose of the lifeworld and its communicative action (Barry et al 2001). Both selective rationalisation and lifeworld colonisation have direct relevance to understanding the prescribing and dispensing practices as part of the provider–patient interaction (Scambler 2001, p.21), and of decision-making in health care in general. Used as a framework for critical analysis of prescribing and dispensing which are of particular interest, Habermas' theory provides the grounds for understanding the behaviours and therefore practices on the part of both providers and patients, who are arguably inclined to resistance of their respective life-world colonisation.

6.1.2 Observations

Before discussing the findings reported in the previous chapter, it is useful to share some observations from the data collection and analysis processes. One of the most discernible is that the clearest voices in this study were those of the primary care providers. Such an observation is very natural since, compared to other stakeholders, and the interviewed groups in particular, they have to manage multiple interactions, processes and agents in their roles, described by Jones (2001) as being 'ambivalent' between decision making and mediation. In this sense, their engagement in the interactions with both the system and the lifeworld need to be understood as political rather than technical (Jones 2001) and this perspective will be used to frame the discussion that follows.

The second important observation from the interviews was that primary care providers did not appear to be comfortable offering criticism of the system and policy changes; there was an observable reservation together with disclaimers suggesting that their experience might be only that of a minority. As the interviews were progressing, the unfolding stories of their own and of their colleagues' experiences made them realise that in fact they were not satisfied, but on the contrary – they felt isolated and distanced from the system on one side and pressurized from patients on the other. However, they quietly acknowledged an acceptance of policy changes, yet were not ready to accept responsibility for failure of implementation, but rather considered themselves to be subject to pressures in practice resulting from the policy changes.

The third key observation from the data collection was related to ethical issues arising in policy implementation. It was evident that all of the interviewed groups clearly understood the unethical nature of some of their practices; however, these practices were in most cases spoken of in the third person, or as if they were happening to others. Most apparent were the examples in the providers' accounts, describing with condemnation the cases of prescribing without medical indication or dispensing without valid prescription. This partial disapproval could be understood as a search for justification for possibly their own practices that were not openly articulated, but at the same time as a reflection of the apprehension regarding possible sanctions against such practices. As noted in earlier chapters, this was an issue identified by Van der Geest (1982) in relation to the supply of medicines to the public from inappropriate or non-regular activities. In either case, it illustrates an understanding amongst providers that some acts were recognised as being unethical but arguably an inevitable means by which to deal with the ambivalent role earlier described.

6.2. The significance of findings in this research

The following section focuses on the significance of study findings and their meaning in relation to the wider literature. It begins by elaborating on the comparisons made by the respondents with regards to the previous system and the current policy context. This study is argued to have offered a greater understanding of how new policies have influenced and changed prescribing and dispensing in Macedonia from the perspective of different stakeholder groups, namely: primary care physicians and pharmacists, patients and elite stakeholders. Analysis revealed three main themes that are briefly summarized in the next paragraphs and discussed in more detail in the context of existing literature later in this chapter.

In brief, analysis revealed considerable attachment to the previous system. This was manifest as nostalgia and it will be shown that this is a recognised phenomenon in transition countries, in general and in the health sector (Bartlett et al 2012; Kamat 2008; McDonald, Waring and Harrison 2006). Nostalgia may offer a way for individuals to adapt to change and define their identity and given the impact of policy change for providers and patients in particular.

The findings also suggest a significant difference in the respective understanding of policy changes from the perspective of providers and elite stakeholders and most notably policy makers themselves. Part of the explanation for this mismatch could be based on the roles of each respondent group; however, it could also be interpreted as a result of the lack of communication and providers' involvement in policy making, which was also clearly noted by this respondent group. The findings from this research suggest

that the attitudes and practices of primary care providers and patients may be significant factors influencing the implementation of prescribing and dispensing policies. However, findings have also suggested that the uneven policy enforcement, especially in terms of dispensing without prescription plays a key role in policy outcomes.

In this sense, the findings offer a more comprehensive understanding of the policy implementation gaps and how the responsibility for overcoming these is perceived by the different stakeholders. Namely, the providers perceived these gaps in terms of a lack of support and guidance from the system, which contrasted with the accounts of elites, who delineated their role to be only that of policy making. The findings also suggested providers' and elites' perceived lack of understanding from patients, regarding the necessity to implement the stringent rules in prescribing and dispensing by the former and lack of health literacy by the latter. As will be shown later in this chapter, such tensions have been described in the literature, using Habermas' social theory to explain them (Mishler 1984; Britten 2001).

A further key finding – providers' dual pressure from the system and patients - will be shown to be similar to that previously identified in other research but in some cases contrasting. A final theme to be considered further and related to the literature concerned the effects of policy changes on both the system and the lifeworld. This will be done by focusing on providers and patients and their respective roles and positions in relation to the system and the lifeworld.

6.2.1 Reflections on past and recent policies: nostalgia for the past

As elaborated in the previous chapter, many of the participants' accounts appeared to involve a reminiscence and indeed nostalgia for the previous socialist system. Although

participants (other than policy makers) did not exhibit comprehensive understanding of the discussed policies, either previously or at the time of interviews, most of them articulated a preference for the previous system, viewed as more oriented towards patients, even at the expense of the economy. There was an apparent inclination of the state in becoming a coordinating economic entity consisting of interdependent inclusive associations rather than a mechanism of class and political control (Engels 1880). Bartlett et al (2012) described that health systems in centrally planned economies, at least formally, provided universal service and equal access. Such a perception in terms of social theory can be interpreted as the lifeworld dominating the system with its existence and experience (Habermas 1984). It can be also argued that the 'voice of lifeworld', pertaining to contextual understanding of health subsumed the 'voice of medicine', constructed of technical knowledge and instrumental efficiency (Mishler 1984).

Although it has been argued that the past communist system was typified by excessive state involvement (Rechel 2008; Bartlett et al 2012), such involvement was oriented towards maintaining communicative action with the lifeworld and supporting exchange towards mutual understanding between members of society (Braaten 1991, p.12). As the findings of this study indicate, it can be argued that participants identify with the lifeworld rather than with the system, despite some of them – namely policy makers and providers – representing the latter. The examples given by the respondents reveal that the past system was *colonized* by the lifeworld, to the extent of neglecting its basic aims of rationalisation, efficiency and even control. And while the past system as part of the socialist paradigm can be considered a suitable foundation for the Habermasian concept of 'regulatory ideals', understood as the social forms to which society can aspire

(Habermas 1989, p.115), at the same time rationalization of the lifeworld turns back destructively upon the lifeworld itself (Habermas 1989, p.186). This in a way was validated by the policy maker group who articulated that changes were not merely necessary but inevitable, as a result of the perceived and experienced lack of sustainability of the system.

Notwithstanding policy makers' realisation of the inevitability of change, they, along with providers and patients, expressed nostalgia for the past system. One explanation for such attachment to the past may be that, in the comparisons of the *past* and the *current* system, the disadvantage of the *current* is the lack of knowledge and experience with the past system in the current time. As noted by Garro and Mattingly (2000):

'as persons talk about their experiences, past events are reconstructed in a manner congruent with current understanding; the present is explained with reference to the reconstructed past; and both are used to generate expectations about the future.' (Garro and Mattingly 2000, p.72)

In other words, the two are compared in different time and circumstances, raising the emotions of nostalgia, subsequently leading to idealisation of what is no longer there. Conversely, the involvement in the *current* system is real, and therefore very strongly experienced as limited possibilities for communicative action in which the lifeworld attenuates through what Scambler (2001, p.13) terms hyper-rationalized social participation. Participants become part of interactions strongly confined to legal exchange and immediate returns, at the expense of thinking and mutual understanding (Crook et al 1992, p.28). And thus, the distinction between the two compared realities (past and current) becomes sharper, causing the participants – both part of the system

and of the lifeworld – to strive towards, and even act in line with, the premises of the past system.

In contrast to the perception of the past, the emerging reality under the new policies was an experience of lifeworld colonisation, which becomes:

'[...] increasingly state administered ("juridified") with attenuated possibilities for communicative action as a result of the commercialization and rationalization in terms of immediate returns.'
(Scambler 2001, p.13)

In the views of the respondents, this was particularly expressed as a perceived over-imposition of the system forcing the participants to engage in their interaction *'as parties to contracts rather than as thinking and acting subjects'* (Crook et al., 1992, p.28).

The notion of nostalgia in transition countries was also described by other authors. Todorova and Gille (2010) have published a volume of essays on post-communist nostalgia and its unexpected proliferation across the entire societal milieu, including health, welfare, and even music and arts (McCracken 2015). Rechel (2008) described this as a form of path dependency and a continued influence of the legacy of the past on contemporary policy decisions. And indeed, as shown throughout this thesis, the past played a significant role in the policy processes, from their development to implementation and follow up. This was evident mainly in the opinions of providers and patients who describe the conditions of the past system almost uncritically, despite the evidence from the wider literature of the socialist-time health systems describing suffering from lack of patient rights, low quality of care, and little technological

improvement (Kornai and Eggleston 2001). The effect of this nostalgic longing was described by Boyer (2010), as the:

'...very real propensity of Eastern Europe to govern and direct its own future is powerfully suppressed within a discourse environment where Eastern European citizens' estrangement from the external steering of their social transformation is labelled (also autolabeled) nostalgic, where "modernizing" Eastern European elites persistently apologize for their fellow Eastern European citizens...' (Boyer 2010, p.26)

In health care writing and research, the concept of nostalgia has been utilised and identified from both lay (Kamat 2008) and health practitioner perspectives (McDonald, Waring and Harrison 2006) and has been argued to emerge particularly in times of profound change and transition (Bissell 2005) and is therefore arguably a not unexpected theme. Although not explicitly articulated as such in interviews, the use of nostalgia may represent a narrative device that helps secure a sense of identity for participants. As such, it is important not to consider nostalgia simply as being bound up in the past, but as a current and powerful psychological means of coping with and adapting to change for individuals (McDonald, Waring and Harrison 2006). Gille (2010) suggested that this nostalgia in post-socialist societies is:

'not "mere" nostalgia, but neither is it false consciousness — rather, it is social critique, however confused, hidden, subtle, or cautious.' (Gille 2010, p.283)

The findings also suggest that such reminiscence can play a significant role in the acceptance and success of policies. The discourse of nostalgia, the *'longing for the past'* (Kumat 2008) was strongly present despite incremental policy change attempts over an extended period of time, as was the case in Macedonia. And, as Garro (2001) suggests,

such discourse of '*personal past has to be understood as cultural past*' and be taken into consideration in the processes of policy and decision-making for the present and the future. As also evident from the findings, personal experiences of providers and patients drawing on their personal past and present can be interpreted as collective experiences that have influenced prescribing and dispensing at an individual level, as well as the policy implementation on a macro level. Drawing on the former, the following section discusses influences of these experiences on perceptions on recent policies, beginning with reflections on professional autonomy.

6.2.2 Reflections on professional autonomy

Another important theme discerning from this research is the providers' perception of reduced professional autonomy. Physicians articulated this as pressure from patients to prescribe even when considered clinically inappropriate, and from the system through the imposition of budget ceilings. For pharmacists, professional autonomy was jeopardized through uneven implementation of dispensing policies, which allowed patients to obtain medicines without prescription. For both groups, this resulted also in a perceived reduction in respect for their respective professions from wider society. In their views, the policies were a trigger for reconsidering prescribing practices, but more so from financial and administrative perspectives rather than from the point of view of professional appropriateness of decision-making in prescribing. Some authors suggested that financial (dis)incentives can influence decision-making more in terms of changing the *quality* but not the quantity of prescribed medicines (Mossialos et al 2004), such as prescribing branded rather than generic medicines, or prescribing medicines that are not on the positive-drug lists. The literature in this area is conflicting, however, and it has been suggested that physicians can influence patient demand, both in terms of

quantity and quality (Rochaix 1993). However, the findings of this study suggest that the physicians were not confident in their ability to influence the demand, as a result of their reduced professional autonomy.

The concept of professional autonomy has been of interest to medical sociologists for several decades (Freidson 1970) and although it has focused more on medical dominance, other professions such as pharmacy have also been explored (Cooper et al 2012). Elston (1991) distinguishes clinical (or technical) autonomy as the right of the physicians to set their own standards and devise clinical performance. It is in some cases, brought into relation with clinical freedom (Davis 1997), to which, as described later in the chapter, the respondents also relate. Further to this, literature suggests that prescribing exemplifies clinical autonomy (Davis 1997), predominantly as it represents one of the core activities of physicians that differentiate them from other health professionals (Britten 2001). For physicians in British general practice it has been asserted that *'prescribing is a battleground on which the cause of clinical autonomy is defended'* (Britten 2001).

Scambler and Britten (2001) continue the discussion of Haug (1975) to describe this reduced professional autonomy as a 'proletarianisation' and 'de-professionalization' processes in which physicians are drawn into a factory-like system of production that imposes a loss of both autonomy and skills that also affect the physician-patient relationship. This, in conjunction with further rationalisation of the medical profession and increased lay knowledge on health have undermined the cultural authority of the medical profession (Scambler and Britten 2001); the more informed and critical patients are becoming, the more assertive they are in decision-making related to their health or disease. The providers in this study felt such assertiveness as increased pressure from

patients, who were supported by the system – with these and other policies, such as the option to change their provider without any formal explanation – to act as agents of social control of health professionals’ work and decision-making (Zola, 1972). Providers perceived this as a shift of power, in which their position of knowledge supremacy and monopoly was marginalized, both at the level of decision-making for individual patients, as well as on a more systemic level of policy and decision-making. This marginalisation and the lack of support from the system in policy implementation, articulated rather strongly among the providers, is discussed in the next sections.

6.2.3 Involvement in policy making

In addition to the themes of nostalgia and professional autonomy, the third key theme discerned from the interviews concerned provider and patient relationships to policy. This arose both in terms of policymaking and also implementation and was perceived negatively by participants. In this section, it will be argued that such findings contrast with existing literature and theory but that there may be opportunities to involve such groups more actively in the future.

One of the experiences of the physicians and pharmacists arising from the policy changes was their involvement – or rather non-involvement – in the policy and decision-making processes. Findings suggest that the practice of involving providers in policy making is not yet in place, with the exception of a few formal representatives of professional associations. However, in the views of the respondents, such representation is not sufficient, as this institutionalized form of ‘problem-solving discourses on questions of general interest’ axiomatically has only limited scope of action (Habermas 1996, p.372). They perceived their ideal involvement, in line with

Habermas' suggestions, as one enabled by a public sphere characterized by open political discussion, informed by inputs of expert knowledge (Habermas 1996, p.169). Their narratives of marginalisation and segregation from the processes of policy making and power to make decisions were pointed at the system, which in their view failed to ensure their participation in the process. In the wider literature, examples of non-involvement have been described mainly for the nursing profession (Richter et al 2012; Arabi et al 2014), and explore the possibilities for transforming nurses' roles and participation in health policy making, based on their professional experience and effective communication (Institute of Medicine 2011).

The literature suggests that involvement in the policy making process of those who play a part in implementation increases the possibility for interaction, familiarisation and ultimately adherence in the process of policy implementation (Kingdon 2003, p. 160; Dunn 2004, p.64; Abood 2007). Thus, along these lines, and in contrast to the findings of this study of non-involvement of physicians and pharmacists at primary care level in Macedonia, the wider literature suggests that providers, through their professional bodies or at organizational level, have been very much and actively involved in policy and decision making (Garpenby 1989; Griesler 2012; Yariv 2015). Indeed, as noted by Buse, Mays and Walt (2012) and drawing on the influential work of Alford (1975) in relation to structural interests, not inconsiderable influence is exerted by:

'professional monopolists – the doctors and to a lesser extent the other health professionals whose dominant interests are served by the existing economic, social and political structure of government and health systems.'
(Buse, Mays and Walt 2012. p.113)

As noted, it was not only providers but patients, too, who perceived themselves not to have been involved in policy formation or having the possibility of doing so. Recognition of the role of individuals or the public as key agents in health policymaking have been well documented (Buse, Mays and Walt 2012) and is associated with wider debates about the democratisation of policy making. There is a considerable literature describing recent trends of democratisation of policymaking processes through examples such as patient advocacy groups and patient and public involvement (Smith et al 2003, p.303). A further aspect of Habermas' theory of communicative rationality – discourse ethics - has been invoked in this area, drawing on his arguments that open dialogue enabling the public opinion to be heard can lead to more democratic decision-making (Godin et al, 2007; Habermas, 1987). The main rationale for and value of such involvement is captured by Farrell (2004, p.41) as one of exploring the differences, in particular, between professional and lay perspectives on health needs and demands. The findings of this study in relation to patients, and particularly their negative experiences and views about the system, raise questions as to the degree to which they could have been included in the policy process. Habermas' vision of a more open society offers one way of achieving this. However, enduring barriers and power imbalances (Buse, Mays and Walt (2012) may threaten such aims. Britten (2008, p. 84-85) questioned how the public obtains information, providing arguments that much of the policy process is conveyed behind closed doors. She argues that system imperatives need to be challenged by the lifeworld perspectives, including by means of greater patient involvement through organized forms of self-help groups and voluntary organisations (Britten 2008, p.181), or even through a system for individual reporting of experienced adverse effects (Britten 2008, p.84). This is particularly relevant to Macedonia, where, as findings have

suggested, involvement of patients – and health professionals – in policymaking is still a declarative category. Illustrative of this is that in the Governing Board of the Health Insurance Fund the one mandatory seat for patients' representative is always given to one organization, despite there being over 5000 registered civil society organisations in the country (MCIC 2017). Thus, increasing patients' involvement in the policymaking process is advocated, especially in light of the findings suggesting their influence over prescribing and dispensing and their self-medication practices. As elaborated in the final chapter, this could be either through approaches suggested by Britten (2008), or through other forms appropriate to the researched context.

6.2.4 Lack of support in policy implementation and detachment

Findings have also revealed a providers' perceived lack of support in policy implementation, articulated as a feeling of detachment from the system. According to them, policy changes resulted in a separation of primary care from the rest of the system; although their role continued to be serving patients within the public domain, their removal from the public to the private sector imposed a sense of estrangement, a notion of *'them and us'*. In the wider literature, this notion, described as professional isolation, was researched for physicians, nurses (Magola, Willis and Schafheutle 2017) and community pharmacists (Cooper, Bissell and Wingfield 2009). Professional isolation was argued to stem from different factors, such as heavy workload, limited resources, and high expectations from patients (Szfran 2017), leading to increased stress and fear from professional errors (Linzer et al 2005; Lee, Stewart and Brown 2008). Cooper et al (2009) have also noted that it might be inimical to Habermas' communicative action, as it negatively influences the provider-patient relationship (Cooper, Bissell and Wingfield 2009).

From the findings, it can be argued that the occurrence of a '*them and us*' notion was a result of privatisation and other policy changes, but could also be associated with the reminiscences of the past, elaborated earlier. Namely, for providers the previous system supported communicative action through the '*no limitation*' on prescribing and dispensing policies and alleged universality of access to medicines. It provided for social interaction in which reaching mutual understanding was facilitated, at the expense of material success and efficiency, which are the prime aims of the system's instrumental rationality (Scambler 2001). Thus, introducing limitations on medicines through prescribing or dispensing – a manifestation of system's natural inclination towards instrumental rationality – was perceived by providers as reduced support in implementation and detachment.

It can be argued that through the feelings of detachment, providers became aware of their dual role – being an agent for the system in achieving strategic action, oriented at success and efficiency, while at the same time playing a part in communicative action towards reaching understanding with patients for their wellbeing (Scambler and Britten 2001). The detachment and professional isolation were interpreted as superimposition of the system over the lifeworld. This unaccepted lifeworld colonisation also raised the issue of providers' identification with their role of system's agency, as arguably this role was performed by the system in the past.

6.2.5 Perceived reasons for inadequate policy implementation and accepting responsibility

A key finding from all respondent groups was the perceived lack of successful policy implementation. This was also shown with prescribing trends over time in Chapter Two, suggesting that policy interventions have not led to the intended or desired outcomes. There is a significant body of literature on policy implementation which recognises that policies do fail often for a variety of often context-specific reasons (Fotaki 2010; McConnell 2015; Barreto 2011), including economic (Friedman 1982; Snower 1993; Le Grand 2006), political (Coleman 1990) and social (McConnell 2015) or not achieve what was intended, and:

“[...] it is common to observe a ‘gap’ between what was planned and what occurred as a result of a policy.” (Buse, Mays and Walt 2012, p.121)

In this research, understandably, each group perceived the lack of policy implementation from their respective position and roles. For providers, their lack of involvement in policy formulation was a very serious concern, and in line with the literature, which also suggests that stakeholder involvement is as an essential part of the policy process and is intended to produce particular outcomes from its implementation (McConnell 2015). Policy implementation, as the step following policy formulation is considered a *‘process of carrying out a basic policy decision’* (Sabatier and Mazmanian 1983, p. 143), which is actualised, applied and utilized in the world of practice (Ali 2006; Bhola 2004). And, thus, providers tended to value the importance of their role in policy development, given their subsequent key role in implementation. Fotaki (2010) considered that the fact that policies are often designed as *‘social fantasies’* of the elites,

and lack of involvement of multiple stakeholders, is a major reason for under-achievements in policy implementation.

The under-achievement of policy implementation was perceived by patients through their reduced access to medicines, which is discussed in more detail in later sections. For policy makers, lack of implementation was considered to be linked to lack of providers' adherence to clinical guidelines and patients' health illiteracy. Elite stakeholders suggested ideas for addressing policy implementation through measures directed at patients, in improving their health literacy, and providers, in additional training in current clinical guidelines and improving their communication skills for negotiating prescribing decisions with patients. These are elaborated further later in the chapter.

The recognition of policy failure highlights the need to identify and understand the root causes or independent influences that have led to such failure (Walsh 2006; McConnell 2015; Howlett 2012). Changes of policies follow the initial failure when alternative policies are viable and feasible to implement, as well as when the reasons for the failure itself have been understood (Walsh 2006). In this sense, this section will now attempt to provide explanations for policy failure, through the perceived responsibility for proper policy implementation and the potential ethical issues that might have interfered in the process.

As already described in the previous chapter, all groups interviewed in this research provided their views about where the responsibility lay for lack of policy implementation. Due to their different roles and positions, all groups had different understanding and acceptance of responsibility. In summary, for providers, the largest share of responsibility lay with the government and responsible authorities; this was

justified by noting their lack of involvement in policy making. To some extent, however, the providers also considered some responsibility to rest with patients, and with professionals other than themselves. Patients were more interested in denouncing their own responsibility than with assigning it to the other groups. The policy makers, too, in general distanced themselves from either direct or indirect responsibility for policy implementation, arguing for their role as being one of policy setting not policy implementation – a stance that has been described in the literature as distancing of the theorists by rejection of realism (Llewellyn 1996).

While many factors are taken into consideration in policymaking, there is little certainty into whether the chosen policy options would actually produce any of the desired effects (Dunn 2004, p.24). When a policy is successful, there is little to be said about responsibility, as many would claim their involvement, contribution or ownership for the success, and probably rightfully so, as policy implementation indeed depends on many stakeholders and their interests for such success (Howlett 2012; McConnel 2015). However, it is far more complex and sensitive, sometimes even painful, to discuss the issue of responsibility in the case of policy failure, or the lack of successful implementation, as responsibility for failure may be linked to material and even moral consequences (Clark and Wildavsky 1990). It would be easier to discuss this issue if responsibility solely relates to defined policy implementation protocols. It becomes more complex when responsibility is associated with discretionary right, such as 'autonomy' for example, in which providers assume a higher level of responsibility due to their professional knowledge (Scambler and Britten 2001). Further complexity is added in the context of health, where policy implementation relates to partially

subjective judgements about a patient's current health and whether prescribing or dispensing is clinically indicated.

In prescribing and dispensing, several key milestones are important for defining the responsibility of the decision. As explained earlier, multiple stakeholders are involved, and the transfer of responsibility goes from one to another, or involves several at the same time. Delineation of responsibility can be subdivided as follows: the act of prescribing as a responsibility lies with the prescriber, although it is influenced by a range of factors that were reviewed earlier; the act of dispensing, on the other hand is with the pharmacist, and is again influenced by a number of factors that have been discussed. The patient's involvement occurs throughout the process, bringing a shared responsibility with the other actors. In this context, it is difficult to grasp the normative and ethical aspects of the responsibility for policy implementation. As Britten argued (2001) in her paper on prescribing and clinical autonomy, the responsibility can be spilt from one to another step on the ladder (Britten 2001), where the patient usually bears the final consequences.

6.2.6 Non-prudent dispensing and illegal medicine supply

Data in this study has suggested that illegal practices in terms of medicine supply have occurred following policy change. All respondent groups pointed to the lack of effective implementation and associated enforcement of the policy on mandatory prescription dispensing. Policy makers attributed this to a lack of responsibility amongst pharmacists and patients. Whyte, Van der Geest and Hardon (2002) summarized these practices at community level, pointing to a phenomenon of 'pharmacists as doctors' wherein pharmacists provided a range of medicines without the need for patients to consult a

physician. Van der Geest (1982) argued that there are economic and commercial drivers, which can influence pharmacists to make such supplies (Van der Geest 1982 p.211). This was to some extent confirmed with the findings of this research, with pharmacists articulating the new policy circumstances and introducing budgetary limitations to play a role in making illegal dispensing decisions. But they also recognized the inappropriateness of this practice and its effects on undermining of their profession. They justified the practice as being a productive tension between the regulatory roles that they play, and patient-focused care.

The findings also suggested that patients play a significant role in illegal medicine supply. Self-medication practices were found regularly across the accounts justified by the perceived reduced possibility for obtaining medicines and imposed need for negotiating medicine supply. Such practices of obtaining medicines from pharmacies without prescription have been described in the literature as a global phenomenon, including Europe (Orero et al 1997; Gonzalez Nunez et al 1998; Contopoulos-loannidis et al 2001; Mitsi et al 2005; Stratchounski et al 2003; Borg and Scicluna 2002), and Eastern Europe specifically (Grigoryan et al 2006; Versporten et al 2014). Most of these studies point to the lack of enforcement of policies as the main enabler of practices involving the supply of medicines without medical consultation. Some of them, however, suggested that pharmacists' perception of their underestimated role in constructing health could be the driver for taking additional professional roles (Caamano et al 2005).

This study offers a similar explanation and, as already described, there was an identified lack of policy enforcement. In addition findings in this study suggested that pharmacists recognized under-appreciation of their professional role, implying that such might also be the underlying reason for pursuing illegal medicine supply practices. Another aspect

that should be taken into consideration is pharmacists' felt pressures from patients. Borg and Scicluna (2002) found that in Malta, pressures over pharmacists to dispense without prescription were higher than pressures on physicians to prescribe without medical indication (Bord and Scicluna 2002). All of these policy implementation aspects were also found in this research to have been neglected by the system, felt by providers also as pressures from the system and these are discussed in the next section.

6.2.7 Providers' perceived pressures in practice from the system

Providers' perceived system pressures were mainly articulated as an increased pressure to adhere to the new rules under the conditions of perceived lack of involvement in policymaking and lack of support for implementation. There was an obvious tension between the necessity to respond to the system's requirements and deliver on patients' demands. Further adding to this tension was providers' perceived lack of support from the system in acting upon reducing the levels of medicine supply patients were accustomed to. In this fine balancing act, providers felt professional disempowerment, associating it with reduced clinical autonomy in prescribing, re-enforcing Britten's (2001) notion of prescribing, also mentioned earlier as a *'battleground on which the cause of clinical autonomy is defended'*.

Explanation of professional disempowerment could be offered using Mishler's operational concepts of 'voice of medicine', representing technical, decontextualized scientific assumptions of medicine, and 'voice of lifeworld', pertaining to contextual understanding of health issues (Leanza et al 2013), professional disempowerment was associated mainly with the system's requirement for providers to represent the 'voice of medicine' in exercising rationalization and lifeworld colonization (Habermas 1984),

whereas in providers' view the system itself was inclined to support the 'voice of a lifeworld' – articulated through intensive promotion of patients' rights and imposing huge penalties on providers. Although reluctant to abide, providers accepted such perceived distortion of roles, which contributed to their feeling of isolation and detachment from the system, discussed in earlier section in this chapter.

6.2.8 Providers' perceived pressures in practice from patients

The findings suggest that primary care providers experience dual pressures from both the system and patients. The pressure and expectations from patients were not necessarily related only to policy changes, although the findings suggest that the changed policy context exacerbated these, making the providers' position more difficult in addressing them. There is ample literature on pressures and expectations from patients during prescribing; these pressures are cited as a barrier to evidence-based medicine and a perceived cause of irrational prescribing (Butler et al 1998; Young and Ward 2001; Lewis and Tully 2009). Lewis and Tully (2011) consider several causes of increased pressures and expectations from patients; in particular, patients' right to involvement in decisions about their care and a general rise in consumerism, which '*may have inadvertently facilitated a rise in public expectations of health care and, hence, patient demand*' (Lewis and Tully 2011). The findings of my research are linked to extant literature, in particular studies confirming patients' expectations and their influence on prescribing (Cox et al 2007; Britten and Ukoumunne 1997; MacFarlane et al 1997; Cockburn and Pit 1997), and physicians ceding to patients' expectations (Little et al 2004; Kumar, Little and Britten 2003); both of which have been associated with unnecessary prescribing and overtreatment (Stevenson et al 2000). The literature suggests that patients come to the physician with certain expectations, and the patients'

influence on prescribing is far more evident when patients want the prescription, rather than when they don't (Britten 2008, p. 134). Patients' expectations in themselves play a role (Kravitz et al 1996), but so too does the awareness or perception of the physician about those expectations (Rao et al 2000; Butler et al 1998).

Scambler and Britten (2001) used the 'de-professionalization' thesis, which is focused on changes in physician-patient relationships, arguing that the increase in lay knowledge and reduced trust in the professions led to rejection of the paternalistic approach and acceptance of consumerist behaviour in health care (Roter and Hall 1992). Habermas speaks of 'grammar of forms of life' (1981, p.33, 36) in the sense of changing relationships of knowledge and power between ordinary citizens or patients and their professionals, as a result of the increasing inclination of professionals towards politics and power, and reduced trust of patients in their expert judgements.

In this sense the influence of increased lay knowledge and reduced trust in professional knowledge should not be underestimated (Scambler and Britten 2001; Curry 1996), given that they play a part – through the patient – in individual decision making and negotiation for medicine supply, manifest as improper policy implementation at a system level.

In addition, findings suggested providers' decision-making to be challenged by empowered patients and their intention to actively participate in prescribing or dispensing decisions. This was also found in primary care settings in Canada (O'Connor et al 2003) and Australia (Davey et al 2002). In Macedonia, such empowerment was negatively associated with professional autonomy, discussed earlier in this chapter.

It could be argued that patient empowerment also comes from increased information access through the Internet and further rationalisation of medical knowledge and practice (Scambler and Britten 2001). Thus, the communicative action between providers and patients is becoming more complex and requires additional skills (Cox et al 2007; Britten 2008). Elite stakeholders' accounts suggested the need for providers' improved skills in patient communication for conveying messages of professional knowledge in lay language terms. Improvement of providers' proficiency in communicating with patients regarding prescribing decisions might be understood as an attempt to regain the battle over professional autonomy (Bond et al 2012; Elwyn et al 2003; Weller 2012; Stenner et al 2011).

6.2.9 Patients' perceived pressures: Negotiating medicine supply

The findings suggested that patients also felt pressurised by the new reality. Like other participants, patients too felt nostalgia for the past, but appeared to have developed strategies for managing the current situation, which for them was characterised by limited access to medicines, and therefore the necessity to negotiate medicine supply. As apparent from their accounts, they have used loose policy implementation as a basis for establishing and maintaining such practices, including obtaining multiple prescriptions and prescriptions on another patient's name and self-medication. Thus, despite the lack of patients' knowledge of the overall policies and their expressed dissatisfaction with the consequences of the reforms, it can be argued that they acquired skills to negotiate for their medical supply, through pressure on physicians or pharmacists. Through this process, they developed a set of justifying arguments for their non-adherence and subterfuge of regular prescribing and dispensing procedures. As noted earlier, for patients, evocations of nostalgia may also reflect identity claims and

also attempts to manage the scale of such changes for individuals' lives; changes that may have led to new found responsibilities to obtain medicines that require considerable understanding and insight into supply sources. In current literature, there are studies resonating with this finding (Ford et al 2003; Gattellari et al 2001). The perceived necessity for over-involvement in prescribing decision making or self-medication might be due to a documented physician underestimation of patients' desire to participate (Cox et al 2007) or patients' dissatisfaction from not achieving their desired role in decision making when consulting with physicians (Ford et al 2003). To overcome such challenges, Mishler (1984) suggested that: 'achieving humane care is dependent upon empowering patients' (Mishler, 1984, p.193), which could be done through increasing their involvement and active participation in decision-making about their own health (Mishler 1984; Scambler and Britten 2001).

The following section discusses the influences of prescribing and dispensing policy changes through the Habermas' perspective, bearing in mind the relationships between and identity of the different participant groups.

6.3. Medicine supply policy changes - a Habermasian perspective

This thesis has provided a range of empirical insights into prescribing and dispensing policy change in Macedonia and has at several points made reference to the relevance of Habermas' various theories. In this section, a more sustained attempt is made to expand on such theory in the context of the findings with the aim of indicating how many aspects of the identified themes can be viewed through Habermasian concepts. More specifically, and given the inherent normativity in Habermas' work, it will be

argued that important aspects of his ideal construction of society and associated mechanisms offer insights into how medicine supply in Macedonia could not only be conceptualised but improved.

6.3.1 Considering participant groups through a Habermasian perspective

Linked to the preceding sections has been consideration of the respective power (or lack of power) of different groups – whether this is providers who are excluded from policy change, or patients who are now empowered health consumers who must seek out sources of medicines in contrast to previous systems. Although not anticipated in the design of this study, involving these different participant groups in interviews may perpetuate or reinforce the separate nature of their status and involvement in prescribing and supply of medicines. With the exception of patients’ perceived pressure upon prescribing for doctors, it is possible to view these as quite separate groups but in the literature closer connections have been identified. For Britten (2008), for example, physicians may be capable of supporting patients using a Habermasian perspective and simultaneously be also able to side with the ‘state’ and gain mutual power from such links. As a result, the different groups may operate with additional links and resulting power dynamics:

“Even in private systems of health care, there are common interests between the state and health professionals if only in terms of state legitimization of professionals’ claims and the social management of ill health by legitimating work absence for example. [...] They may also see their role in part as patient advocates and therefore representative of the lifeworld in the public sphere. However, these claims to act on behalf of patients may also serve professional interests.” Britten (2008 p.180)

A further concern related to this and not captured in Britten's quote above¹⁰ is that health care professionals are also individuals and it is arguably incorrect to view them as being only representative of the system. This is an important concern and through the data presented in this study, it has hopefully become apparent that health professionals at the micro-level experience difficult and personal situations and threats to their work and identities. The significance of this need to distinguish between individual health *professional* experience and the health *profession* is captured by Greenhalgh and Heath (2010), in their use of a Habermasian perspective when trying to understand therapeutic relationships:

"The 'micro' of interpersonal relationships link with the 'macro' of society and state. In other words, any particular GP-patient encounter is a product of the roles of 'GP' and 'patient' in wider society, and is influenced by wider political and economic forces." Greenhalgh and Heath (2010, p.1)

In this sense, Waitzkin (1991, p. 83-92) makes an important contribution, arguing that therapeutic relationships between doctors and patients can only be comprehensively understood if they are considered within the broader social contexts and structures, so as to understand whether they are based on communicative action oriented at understanding or on strategic action oriented at success (Habermas 1984, p.289).

A final point in relation to this positionality of the participant groups concerns the inclusion of a range of elite stakeholders (policy makers) and as noted earlier, it is important not to over-state some of their claims about providers or patients but instead to reflect more on why they hold such views. The choice of elites reflected a desire to include perspectives from several different areas – industry, government, and academia

¹⁰ See Scambler and Britten 2001 for a more detailed discussion in terms of the doctor-patient relationship

– and as such these must not be viewed as being either more objective or necessarily more informed.

6.3.2 System and lifeworld perspectives

As already discussed in previous sections, it can be argued that Habermas' theoretical construction of the relationship between system and lifeworld '*justifies the exploration of rationalities in everyday life*' (Williams and Popay 2001, p.41). As such, it can then be used as a theoretical concept to understanding prescribing and dispensing within the already explained medicine supply policy changes. In this respect, several key issues are considered as part of the exploration of such rationalities with regards to the findings of this thesis: the influence of policies on the interactions between the providers and the system, provider-patient relationship, and changes of attitudes and thereof practices as a result of the imposed policy changes and constructed realities.

As already established in the findings, there is evident influence of the policy changes on the interactions between the providers and system on one hand and the lifeworld on the other. Within these complex interactions, the providers are acting as a mediator in the dialogue between the lifeworld, represented by the communicative reason of language and culture, and the system, represented by instrumental reason of power and resources (Habermas 1987).

The system's perspective on the policy changes has been one of necessity; increased efficiency of resource use is central to the rationality process, and has been pursued through further formalisation of relationships, in particular the juridification of prescribing and dispensing. The findings suggest that there is an intention towards further structuring and imposition of the system over the lifeworld. As described by

Britten (2008, p.19), the 'colonisation of the lifeworld' (Habermas 1987) occurs when system imperatives begin to dominate and disrupt the lifeworld, gradually imposing its systematisation. Cuff et al (2006) view this as a process of reshaping of the lifeworld in systems' terms. The system is more inclined to the strategic rather than communicative action, pursuing what can be called an ulterior motive for achievement of its set goals using the necessary means.

The lifeworld perspective of the policy changes has been one of reduced space for communicative action and exchanges for mutual understanding. The new policy environment was considered as one distancing the providers from the patients, by setting barriers to their mutual understanding. The curtailing policies have disabled the 'ideal speech' described by Habermas (1987), which implies the non-existence of any coercion on communicative action except the power of the better argument. Although already established in the literature that such a situation is not entirely achievable in practice (Barnes et al 2006; Hodge 2005), the reminiscence about the interactions of providers and patients in the past suggested their belief in the existence of the 'ideal speech' situation, in which both providers and patients had their perspective on how the mutual understanding was achieved.

Providers' belief that their relationship with patients had not changed arguably suggested some degree of attachment to the lifeworld. This is perhaps understandably so, as the findings also suggested their distanced relationship with the system, with which they are legally and normatively more bound compared to patients. While this situation of occupying a middle ground between the patients and the system is evident from the setup of the health systems in general, the feeling of 'middleness' of the physicians also appears strongly as conclusion from the literature (Scambler and Britten

2001; Higgs and Jones 2001; Scambler 2001). The detachment from the system identified in this study might also be considered as contributor to enhanced proximity to the lifeworld.

The above highlights the debate around the plausibility of the patients feeling themselves to be informed enough to participate in decision-making (Cox et al 2007; Britten 2008). The literature in this area suggests that in recent years the trend of simply following the instructions of the physician who is regarded as the one that knows what is in the best interest of the patient (Emanuel and Emanuel 1992; Street 2001), is replaced by a partnership producing communicative action between the physician and an empowered well-informed patient in reaching understanding on defining what that best interest is and how it can be optimally achieved (Wald et al 2007; Street et al 2003). But, as discussed earlier, although trends of decision-making 'democracy' are slowly becoming a reality for part of the population, still the paternalistic relationship remains widely practiced across the Macedonian healthcare system.

In summary this section has suggested that the findings of this study reflect similar situations in other countries and health systems and moreover that a Habermasian perspective can similarly be considered of value in framing the various themes. Several issues related to the literature give suggestions as to how things may be improved in Macedonia in the future and are considered later in this chapter. Before doing so, it is necessary to reflect on the overall process and consider reflexively and transparently strengths and limitations to this study.

6.4. Methodological challenges and limitations of the study

6.4.1 Methodological challenges

Throughout this research I have encountered a number of methodological challenges that have taught me that a pragmatic approach in doing research is very important, while maintaining scientific rigour and objectivity. In this section I briefly consider some of these, as they might provide additional clarity regarding the methodological choices made during the research, which inevitably brought some limitations to the study, also discussed in this section.

The first challenge that I encountered was regarding the access to certain forms of proposed data. As explained in the methodology chapter, the initial proposal was to conduct a mixed-methods study, in which the findings from the quantitative data about trends in levels of medicines prescribed and dispensed would complement the qualitative part so as to be able to specifically understand and research in depth the most important factors influencing prescribing and dispensing in the country of interest. However, due to a number of factors, such as unavailability of reliable or comparable data for the study period, as well as lack of resources to retrieve the data from the 20 years of paper archives, this initial approach was reconsidered and a decision was made to focus on a qualitative study, in which the factors of influence would be first researched theoretically and empirically from the existing literature, and the findings would inform the interview guides for the research. However, to illustrate the situation in the researched context, I have provided a summary of the available, but incomplete, data on prescribing. These data, described in Chapter two, not only confirmed the hypothesis set for the quantitative analysis - that despite policy changes the prescribing

levels remained unchanged or showed a growing trend - but also raised questions, which I hope to be able to inform through other research activities in the future.

The second methodological challenge was the language barrier. While it is much easier to do quantitative research in different contexts due to the universality of the language of numbers, in qualitative research it is from the subtleness of the communication of the language that sometimes the most important findings emerge. In this sense, while with the full support from my supervisors, it has been unavoidable that I would have sole responsibility for the analysis and interpretation of the qualitative data. Understanding that the finesses are important, and that the 'devil is in the detail', I have considered, as explained in the methodology chapter, all possible strategies to avoid as much as possible the influence I might have on the data interpretation and translation, through my personal beliefs and attitudes, my knowledge and experience.

Another methodological challenge that I faced related to my knowledge of and experience in the country of interest. Professional and personal contexts affect the way research is undertaken. In the literature, a researcher with familiarity with the context and people being researched is defined as an insider-researcher, and due to their specific knowledge and position, this issue requires due attention. The insider is 'someone whose biography (gender, race, class, sexual orientation and so on) gives her [sic] a lived familiarity with the group being researched' (Griffith, 1998, p. 361), and as such has a unique position to study a particular issue in depth, from a perspective of different knowledge, and easier access to people and information that can further enhance that knowledge (Costley 2010, p.7). And, as a researcher works with the participants and data to create an interpretation of their reality, an insider position could be viewed as potentially enhancing, as an insider's knowledge could be valuably

used to obtain richer data. With this in mind, I considered the benefits of the insider-researcher position and the insights it offered were ultimately an advantage for this research. However, on the other hand, the insider's knowledge could also influence the research in a negative way, if the researcher's pre-understandings guide or dominate the research process (Finlay 2003). Since insider knowledge could be both a benefit and a threat, as principal researcher I felt that I needed to consider my position throughout the entire research process. Whilst being 'insider-researcher' has possible benefits in terms of access to participants and rapport, it can lead to difficulties. Making assumptions and treating some topics as tacit was possible and may have led to their under-representation and also influenced how some participants interacted and offered accounts. In this respect, keeping the reflexive journal and immediate transcribing of interviews helped me a lot, since I had a chance to observe these interactions and reconsider the approach if I felt that the insider influence was interrupting the interactive process with the respondents. Throughout this process, and as described earlier, Gadamer (1996, p.360) was a useful resource through his emphasis on the essence of the continuing activity of questioning and reflecting on both questions and responses.

6.4.2 Limitations of this study

Scientific rigour also requires to recognise and give due consideration to limitations associated with the research process. This section deliberates on the limitations of this study.

One limitation relates to the time period over which this study was undertaken and particularly the data collection. The policy changes at the centre of this study occurred

during 2005 and 2011 and interviews were conducted between 2014-2015 and this reflects two possible limitations: one is that the interviews may have been shaped by some degree of recall bias and the other is that the views and experiences captured may not reflect those current at the time of writing this thesis.

Another limitation to this study was the sampling. While the use of purposive sampling was considered an appropriate widely used sampling strategy in qualitative research, it has to be pointed out that it has its disadvantages, in particular related to ever present concern of possibly not reaching some participants who may not want their potentially negative practice to be made known.

A further limitation of this study was related to validation of the findings. As elaborated in earlier chapters, quantitative data was difficult to obtain and thus a mixed methods study could not be conducted. In addition, the observation method was also considered at the initial stage, but due to legal limitations of privacy protection of patients, such method was rejected. As a result, triangulation of findings was not possible to perform, and this study relies on self-report and researcher's analysis and interpretations of collected data. All of the above limitations open space for further and improved research in this field, to which the next section is dedicated.

6.5. Future research questions

In this thesis I have explored the effects of recent policy changes on attitudes and practices related to prescribing and dispensing in transition countries, through analysing the specific context of Macedonia. This research was based on qualitative interviews and interpretation of the findings using existing social theories, and in particular the

Habermas' social theory of system and lifeworld. In the process I have arrived at the findings presented above, which gave rise to further research questions. The purpose of this section is to summarise possible research questions around prescribing and dispensing policies and practices in transition countries.

Future research based on the findings from this study are argued to be possible in the following methodological and topic related domains:

1. Expanding use of qualitative research in healthcare for understanding societal, cultural and other factors influencing decision-making, and prescribing and dispensing practices and behaviours in the transition countries, and in particular:
 - a. Understanding the cultural influences of the past system and its effects on present policy development and implementation;
 - b. Exploring the current power dynamics in policy making, in particular involving suppliers, providers and service users;
 - c. Exploring the current and potential patient participation modalities for democratisation of health policy and decision making;
 - d. Exploring the influences of the supply side, in particular of the pharmaceutical industry, on decision-making in prescribing and dispensing;
 - e. Exploring the practices and attitudes in prescribing and dispensing at other levels of care, especially hospitals and other in-patient facilities and researching how policy changes in other levels of care have affected prescribing practices.
2. Extending quantitative research in order to better estimate actual levels of medicine consumption, and in particular:
 - a. Exploring medicine consumption at primary care level, with a focus on out-of-pocket medical supply, to assess the influence these policies have on the economic and social welfare of patients; and

- b. Exploring non-prescription dispensing, to identify pockets of non-prescription dispensing that will inform the policy making process for addressing potential policy gaps.

Expanding on point 1 above, the body of knowledge related to the health consequences of political and economic transition in post-socialist societies is growing in recent years (Perlman and Balabanova 2011; McKee and Nolte 2004; Aleshkina et al 2011; Jakab and Kutzin 2009; Versporten et al 2014). As the literature review indicated, qualitative methodology is not widely used to explore societal phenomena in post-socialist economies. This may be related to the priority of analysing the impact of changes on the economic indicators traditionally used to measure the success of a democracy or welfare state (Choe 2011). Following the present study, I suggest that future research might make greater use of qualitative methods, as they might provide additional insights and more in depth understanding of why and how certain changes are perceived, accepted and implemented in practice. There are, however, challenges to qualitative research; domestic researchers especially still do not fully recognise its ability to address a wider range of questions through collection of richer and more authentic data (O’Cathain et al 2007; Foss and Ellefsen 2002); while for other researchers the language barrier may be considered a problem. However, as with this thesis, these perceptions are changing (Kaae et al 2016), and in the future it is expected that more focus will be placed on qualitative research in these countries, which could potentially reveal new knowledge on the perceptions, values and the meaning of health in transitional contexts. And, as Scambler (2001) encourages:

“One general ramification of the preceding discussion for ‘future research’ is perhaps worth reiterating. The positivist methods still adopted by many medical sociologists tackling health inequalities, especially but not

exclusively in the quantitative vein, have unsurprisingly had a limited yield. What is required in their place, it has been contended, is a critical and post-positivist mix of theoretical, conceptual and methodological innovations.” (Scambler 2001, p.110)

6.6. Summary of chapter

As stated earlier, there are many stakeholders involved in the process of prescribing and dispensing - government, prescribing physicians, dispensing pharmacists, patients and the pharmaceutical and insurance industries. Yet, the link between them is the prescribing physicians and dispensing pharmacists, who are also the key decision makers on the demand-side of the pharmaceutical market. Thus, it is very important that physicians approach prescribing as the:

“appropriate choice of medicine not only from the perspective of the physician but also that of the patient, while at the same time aiming to maximize effectiveness minimize risk and minimize cost.” (Barber 1995)

The focus of this research has been on the effects of policy changes on prescribing and dispensing practices in primary health care in the specific context of a transition country that is very applicable to similar contexts.

Prescribing policy changes in Macedonia were perceived negatively overall compared to the previous system, and many identified themes reflected those found in other health systems, such as patient pressure, threats to autonomy and a lack of involvement and consultation in the policy making process, as well as lack of support in policy implementation from the system to primary care physicians and pharmacists. A key aspect of this study appeared to be the threat posed by increasing regulation which both

marginalised professionals and patients in relation to consultation and involvement and threatened their autonomy and capacity to make independent decisions about prescribing and obtaining medicines. Habermas' concepts of system and lifeworld and particularly the encroachment of the former on the latter are argued to be relevant in framing the themes in this study. The introduction of increasing waves of policy represent juridification, and professionals' perception of being isolated and un-involved and unsupported reflect disruption of important forms of communicative acts and justice. Using a Habermasian perspective, it is apparent that the policy change within Macedonia is but one example of many such threats to individuals' lifeworlds. This study and these associated theoretical insights suggest the need to improve communication between different stakeholders and to ensure that policy change is undertaken in a way that is sensitive to, and not a threat to individuals' autonomy - in professional practices such as prescribing and dispensing, and public aims of obtaining appropriate medicines.

CHAPTER 7: Conclusions and recommendations

7.1. Conclusions

The market-driven policy changes that were introduced in Macedonia in relation to regulating prescribing and dispensing are associated with various negative consequences from the perspective of a range of stakeholders. For primary care providers these changes meant detachment from the system, reduced professional autonomy and diminished appreciation of their profession in the wider society. The new policy environment created dual pressures on them – from patients wishing to obtain medicines, and from the system through the regulatory and legal mechanisms. Providers also articulated lack of guidance and support for policy implementation; their feeling of detachment from the system is amplified by lack of involvement in policy making, and by government support for patients' empowerment through unlimited right to choice of provider. While the elite stakeholders tend to generally agree with the healthcare professionals on the issue of patient pressure, the patients' group described their position as unfavourable and marginalized, making the case for unregulated access to medicines, negotiating medicine supply and justifying self-medication.

However, providers and policy makers tend to agree on the persistence of irrational prescribing and inappropriate dispensing but on a more theoretical level; most providers consider it inappropriate to prescribe without clinical indication or to dispense without prescription, however, they admit adherence to such practice upon patients' pressure. This implies that not only providers but also other interviewed groups, as described in

the findings, placed the major responsibility for the lack of policy implementation with a group other than their own.

Patients were not concerned with irrational prescribing, but for them the main concern was the access to medicines, and negotiating medicine supply. Their attitudes, in fact, depended a lot on their ability to pay for the medicines out-of-pocket, with many openly stating that they would circumvent going to the doctor and getting the prescription, if they could find a pharmacist that would dispense the medicine without it.

With regards to policy implementation, all groups similarly believed that this was lacking, however due to different reasons. Providers considered it a consequence of non-involvement, ambiguity of enforcement and lack of support from the system; the elites held a more forthright view that resultant problems associated with the policy changes were attributable to the other groups. For the patients the lack of implementation was not considered as such, but was rather used as a justification for circumventing the regular procedures of prescribing and dispensing.

While providers largely questioned the policy changes and patients were ambiguous, the views of the policy makers generally described policy changes as being necessary. All groups made comparisons to the previous system, which was perceived more positively as being fairer and patient-centred, but not sustainable. To this end, it can be concluded that future policy requires consultation and communication to ensure different individuals are not isolated, threatened or denied medicines.

7.2. Current policy insights

This research is argued to be timely, given the evolving policy context and the focus on primary care reform in Macedonia. During the research, the number of interviews conducted with key policy makers might have had a small – if any – influence on some of the additional policy changes that were proposed and adopted thereafter. Nonetheless, either as policy reactivity or due to other factors, in the past year the Health Insurance Fund proposed and the Government adopted several measures aimed at reducing the pressures on providers, including (HIF 2015):

- Reduced fines for providers, especially for clerical errors in issuing prescriptions and dispensing medicines;
- Introduced mechanisms for covering the patients of a provider on longer-term sick leave without affecting budget ceilings of the designated replacement physician;
- Expressed will for revising levels of preventive goals in the coming period.

These changes are likely to increase the confidence of providers in their relationship with the system, which might further promote their increased participation in policymaking and adherence to policy implementation. Furthermore, the professional associations of primary care providers have initiated wider outreach and increasing visibility activities aimed at their members, especially in relation to their interactions and negotiations with the Health Insurance Fund.

It is therefore important to reiterate that policies need to be developed with involvement of those directly responsible for their implementation, and that strategies should be put in place to communicate with the providers and support them in their gatekeeping role at primary care level so they can be a successful part of an ever-evolving healthcare system.

7.3. Policy recommendations

This section describes how the findings of this study may inform the design of future policies in prescribing and dispensing, as well as the wider agenda setting and policy process in Macedonia, and in similar political and societal contexts. It will explore in turn five key areas, relating to: increasing the involvement of provider and patient stakeholders in policymaking and implementation, increasing awareness of policy change through enhanced information, providing training for providers, and raising public awareness and understanding in health-related matters more generally (see Table 14 for summary).

Table 14. Summary of key recommendations

Agent targeted	Broad Recommendation	Specific Actions
Patients and Providers	Increase involvement in policy making process	Through recognition by government of the value they can add to policy process. Importance of working towards communicative action and removing power imbalance. Ensure previous feedback about practice experience is considered in the process.
Providers	Increase information about policy change	Ensure proper communication of policy changes. Enable assistance for practical questions from providers on implementation of these.
Providers and Patients	Increase involvement in future policy implementation	Ensure advisory and consultative support upon introduction of policy changes. Encourage feedback about practice experiences, and make it available (in anonymised form) for other providers. Actively involve agents in the implementation process.
Providers	Training on guidelines and communication	Introduce requirement for mandatory continuous medical education training to be linked to specific guidelines with peer-to-peer experience exchange. Introduce communication with patients' module in senior years of health science curricula at undergraduate and specialisation levels.
Patients	Increase awareness of prescribing and dispensing policy and law	Continue and fortify awareness-raising efforts for health literacy using examples and key messages from practice experience.

7.3.1 Involvement of stakeholders in policymaking

There are three key policy implications that can be identified through the findings of this thesis. The first and most obvious one is the wider consideration of all stakeholders and their interests in the process of policymaking and decision-making. As suggested in Habermas' theory on communicative rationality, democratisation of decision-making means providing open dialogue that enables stakeholders to have their voice at the decision-making table. In this case, it means involving patients but also health professionals through organized forms of professional associations and via other means, as their involvement might provide the practice 'street-level' perspective on the issues that are otherwise invisible to the desk policy maker. Government recognition of the value these stakeholders can add to the policy process is essential, given the importance of working towards communicative action and removing power imbalances. At the same time, failure to take into consideration the interests of all involved is very likely to produce resistance to policy implementation, subterfuge of procedures and use of loopholes to address the problems in implementation. In addition, ensuring consideration of previous feedback about practice experience in the process can also add value to learning from the implementation gaps, also raised as a concern in this research. As illustrated in further paragraphs, such involvement might already be underway as part of the communications and discussions undertaken with policy makers during the course of this research.

7.3.2 Provision of information on policy changes

Secondly, this research has drawn upon the importance of articulation and exchange of information related to policies if proper and successful implementation is desired. Following on from the importance of stakeholder involvement, a pivotal factor is the proper and timely exchange of information and communication on the envisaged and introduced changes. The sense of detachment perceived by the providers and the self-perceived disadvantaged position of patients can be largely attributed to a lack of information and understanding. While no policy can be ensured full implementation solely on the grounds of equality of information, proper articulation of its goals, mechanisms and intended outcomes is a certain way to contribute to it. In this sense, some of the recommendations include ensuring establishment of regular and proper communication channels for sharing information on policy changes, but also for assisting with practical questions providers might have for implementation. These channels would certainly include professional associations' updates and events, but for expanding outreach, it is essential to consider other forms offered by new technologies, such as Internet and social media.

7.3.3 Involvement in policy implementation

Pertinent to the findings on policy implementation, and in particular the lack of support perceived by providers, future policies could benefit from encouraging feedback about practice experiences from both providers and patients. This feedback would not only inform policy making, but also practical aspects which might stand in the way of successful policy implementation, as they were neglected in the desktop policy development process. Such feedback could also assist other providers, and thus it is

important that an appropriate anonymised form of it is made publicly available. Also, as one of the key aspects of lack of support in policy implementation was the newly imposed administrative burden and arising penalties for clerical errors, it is advisable to consider introduction of advisory and consultative support to providers, as a prior step to penalisation. These consultations by peers or public officials could be also used as a vehicle to sharing information on policy changes and for educational purposes on clinical guidelines.

7.3.4 Guidelines and communication training for providers

While admitting the problems with policy implementation, for which they did not consider themselves responsible, the policy makers provided ideas for its improvement through actions targeting providers and patients. Some of the key issues in their view were improvement of health literacy of patients (elaborated in more detail in the next sub-section), along with further rationalisation and formalisation measures for providers, through reinforcement of existing, and adoption of new, clinical guidelines for prescribing in primary care. In addition, they consider the improvement of communication and negotiation skills of providers in their interaction with patients to significantly contribute to better policy implementation regarding prescribing and dispensing. Mishler (1984) argued that if providers listened more and translated technical language into the voice of the lifeworld, they would become more effective practitioners. It is thus imperative to consider ways of improving communication skills of providers throughout the educational process, starting from undergraduate level, and also during specialisation. This could be effectively done through introduction of a specific module on communication with patients in the final years of education, when students have required medical expertise and could more practically understand and

incorporate this knowledge into their future practice. In addition, practical aspects of clinical guidance application should be introduced as mandatory components of current continued medical education system. In this sense, peer-to-peer experience exchange is underutilized but could be a valuable asset to improving guidance adherence.

7.3.5 Patients' literacy and awareness raising campaigns

Despite articulation of prudent prescribing and dispensing, accounts from providers and policy makers suggested a continuing practice of irrational prescribing. Whilst this study did not set out to verify or measure such practices, the emergence of these contrasting accounts does suggest some concern. This research also underlined the importance of the patient in prescribing and dispensing.

Policy proposals for addressing irrational prescribing from the demand-side mention parallel interventions of individual and collective health literacy improvement of the population. These include patients' education by providers – either physician or pharmacist - during their consultation, and public campaigns. This section provides elaboration on the latter, as the former was addressed as part of the previous section on communication skills for providers.

Extensive efforts were made at national level and globally to address irrational prescribing (Goossens et al 2006; Earnshaw et al 2014). On the demand side, these efforts were directed at improving health literacy and information access through awareness raising campaigns (Goossens et al 2006). In Macedonia, public awareness raising campaigns for rational antibiotic use have been systematically organized in the country since 2008, with endorsement of the European Antibiotic Awareness Day

(EAAD) by the European Centre for Disease Prevention and Control (ECDC) (Earnshaw et al 2014) and more recently with the World Antibiotic Awareness Week (WAAW).

Building on the above experience, further efforts should be made in continuing and fortifying awareness raising efforts for prudent antibiotic use among patients. In addition, the messages conveyed to the public should be related to practice experience and qualitative research on underlying reasons for irrational prescribing. The results of this research could build upon and inform future public campaigns.

7.4. Final reflections

Post-communist policy changes have been shown to exert considerable and often unintended consequences upon key stakeholders in Macedonia, resulting in negative experiences and inappropriate practices. These may be arguably linked to problems relating to stakeholders not being involved in policymaking and implementation, inadequate communication of policy changes and insufficient providers' skills for communication with patients. In addition, such negativity might be linked to experiences from the past, which future policy formation should consider. Recognition of these problems as identified in this research suggest important areas in which to consider change and involve physicians, pharmacists and patients much more, and offer respect and protection of their threatened lifeworlds.

APPENDICES

Appendix A: ETHICS APPROVALS



Kirsty Woodhead
Ethics Committee Administrator

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Our ref: 0666/KW

22 May 2013

Neda Milevska Kostova
ScHARR

Dear Neda

Effects of prescription policy changes on the practices and attitudes towards prescribing in the primary healthcare in Macedonia.

Thank you for submitting the above research project for approval by the ScHARR Research Ethics Committee. On behalf of the University Chair of Ethics who reviewed your project, I am pleased to inform you that on 22 May 2013 the project was approved on ethics grounds, on the basis that you will adhere to the documents that you submitted for ethics review.

The research must be conducted within the requirements of the hosting/employing organisation or the organisation where the research is being undertaken. You are also required to ensure that you meet any research ethics and governance requirements in the country in which you are researching. It is your responsibility to find out what these are.

If during the course of the project you need to deviate significantly from the documents you submitted for review, please inform me since written approval will be required. Please also inform me should you decide to terminate the project prematurely.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'K. Woodhead'.

Kirsty Woodhead
Ethics Committee Administrator

From: "Liljana Maneva" <lmaneva@freemail.com.mk>
Subject: Re: Fwd: Inquiry about Research Ethics Review in Macedonia
Date: May 30, 2013 09:41:23 GMT+02:00
To: Neda Milevska <nmilevska@studiorum.org.mk>
Reply-To: <lmaneva@freemail.com.mk>

Dear Neda,

Thank you for your e-mail.

I have read the original letter from the Research Ethics Committee at your University in UK, and the explanations you have given in your e-mail. Based on the above, it is my opinion, as Chair of the Ethics Committee at Faculty of Medicine in Skopje that the research ethics review approval obtained from the University in United Kingdom is sufficient for undertaking the research, under the conditions given in the approval letter. I wish you good luck with the research and your PhD thesis, and I am looking forward to having a chance to learn more about the outcome of the research.

Kind regards,

Prof. Liljana Maneva, MD, PhD
Chair of Ethics Committee
of the Faculty of Medicine Skopje

Appendix B: INFO SHEET FOR PARTICIPANTS

Research Project Title:

Effects of prescription policy changes on the practices and attitudes towards prescribing in the primary healthcare in Macedonia

Researching institutions:

*School of Health and Related Research (SchARR), The University of Sheffield, UK
Centre for Regional Policy Research and Cooperation 'Studiorum', Macedonia*

Researcher: **NEDA MILEVSKA-KOSTOVA**

Dear Participant,

Thank you for accepting to read the materials provided.

You are invited to take part in this research study, closely related to your everyday life and work. Before you decide whether to take part in this research, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and do not hesitate to ask should you find anything to be unclear or if you want to have more information.

Giving of this information to you is by no means obliging you to participate - if you decide to take part you will be asked to sign the attached Consent form, which you should also read carefully before signing.

Background on the research

The aim of this study is to investigate what are the effects of the policy changes affecting the regulation of prescription medicines and incentives available to healthcare providers and pharmacists on providers' experience and perception of the policy changes.

The research will consist of qualitative data gathering and analysis – performed through semi-structured interviews with different stakeholder groups, including key informants (policy and decision makers, experts and academia, professional associations and private sector), health providers (general practitioners and pharmacists involved in prescribing and dispensing of medicines) and patients.

Why have you been chosen?

A number of persons were invited in four different groups to participate in this study, based on their experiences and/or expertise.

You have been invited as part of the group of key informants, constituted of policy and decision makers, experts and academia, professional associations and private sector.

What are you expected to do? The procedure

Your involvement is expected as key informant to the group of policy and decision makers, experts and academia, professional associations and private sector.

After consenting to participate (by signing the consent form), you will be asked by the researcher a number of open questions, that allow you to talk about issues for as long as you want and to express yourself fully and to the best of your knowledge. Please also consider that there are no right or wrong answers, and that actually your knowledge and experience in the field is of great value for the study.

The interview will take no longer than 40-60 minutes of your time. For this however, a suitable location is a prerequisite, and it can be chosen by you – it can be your office/working space, a space within the research institution mentioned above. If neither of these is suitable, a mutually acceptable venue can be selected.

The interview will be voice-recorded unless you request that it not be.

The recorded interview will then be anonymously transcribed into written form to allow for better and more accurate interpretation by the researcher. You can, if you wish, receive the full transcript of the interview taken with you.

After that, all interviews will be analysed and used in the research study that forms part of a doctoral thesis of the researcher named above.

Deciding whether to take part or not

Accepting to read this Information Sheet is in no way obliging you to take part - it is entirely up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a Participant Consent Form, attached herewith.

As this is academic research, there are no envisaged risks to taking part. The methods and the subject chosen for this research have been approved by the Ethics Committee of the University of Sheffield, UK and the Ethics Committee of the University of Skopje, Macedonia.

However, if you decide to take part you are still free to withdraw at any time and without giving a reason for such decision.

Confidentiality and privacy

All information that is collected about you and from you during the course of the research will be kept in secure database and with strict confidentiality. If you explicitly require, any information, which will be used for the research study, will be anonymous, meaning that all personal information will be removed accordingly.

The audio recordings of your interview during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the research will be allowed access to the original recordings.

Research outcome: What will the research results be used for?

The results of this study will be used primarily as part of a PhD thesis that will be written

up and submitted by the researcher named above. You are welcome to read and access the thesis once it has been defended and published.

Contact for Further Information

If you require clarification, further information or want to discuss any aspect of this research, please do not hesitate to contact the researcher, NEDA MILEVSKA-KOSTOVA:
(mobile: +389 71 225 446, e-mail: N.Milevska@sheffield.ac.uk)

Thank you.

Appendix C: CONSENT FORM

Participant Consent Form

Title of Research Project:

Effects of prescription policy changes on the practices and attitudes towards prescribing in the primary healthcare in Macedonia

Name of Researcher: **NEDA MILEVSKA KOSTOVA**

Participant Identification Number for this project: _____

Please initial box

1. I confirm that I have read and understand the Information sheet dated _____ explaining the above research project and I have had the opportunity to ask questions about the project.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. *Insert contact number here of lead researcher/member of research team (as appropriate).*
3. I understand that my responses, if I wish so will be kept strictly confidential. I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research, if I express such wish.
4. I agree for the data collected from me to be used in future research
5. I agree to take part in the above research project.

Name of Participant
(or legal representative)

Date

Signature

NEDA MILEVSKA KOSTOVA

Lead Researcher

Date

Signature

To be signed and dated in presence of the participant

Copies: 2

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/pre-written script/information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be placed in the project's main record (e.g. a site file), which must be kept in a secure location.

Appendix D: INTERVIEW SCHEDULE QUESTIONS FOR ELITES

Elites: Policy/decision makers, experts/academia, professional associations/ private sector

[Introductory questions]

1. Have you been (and how long) involved with the PHC reforms in Macedonia? How?
2. Have you been involved with the prescribing policies in Macedonia? How?
3. **Who is responsible for preparation and execution of prescribing policies? Who should be involved?**
4. Have/Do you participate/d in the preparation or execution of prescribing policies?
5. **In your opinion, what are the main goals of the prescribing policies?**
 - a. Are these goals addressed?
 - b. Are these goals met? If not, why?
6. **What are the most important achievements of the prescribing policies?**

[Policy of 2005/7: limitation on number of prescriptions]

7. In 2005/7, with the transformation (privatization) of the primary healthcare (PHC), the prescribing policy has changed to involve limitations on the number of prescriptions per patient, replacing the pre-2005 policy (of no-limited prescribing).
 - a. What is your opinion on its design and effectiveness?
 - b. Is this policy better/worse than the one before 2005 (no limitations, no privatization)? For whom and in what way?
 - c. Do you think this policy contributed to rational prescribing (of PHC goals)?
 - d. Was the policy incentivising/dis-incentivising for PHC doctors and how?
 - e. Had this policy any influence on the freedom/levels of prescribing for PHC doctors? In what way?
 - f. How do you think this policy affected the access to medicines?

[Policy of 2009: budget ceiling for prescribing]

8. In 2009, the prescribing policy in primary care was redefined using budget ceilings for PHC doctors. How is this policy compared to the policy of 2005/7? Compared to the pre-2005 policy?
 - a. Do you think it is well designed and fair? If not, why? To whom it is not fair?
 - b. Who is responsible for this?

- c. Do you think this policy contributes to rational prescribing (of PHC goals)?
 - d. Is the policy incentivising/dis-incentivising for PHC doctors and how?
 - e. Has this policy any influence on the freedom/levels of prescribing for PHC doctors? In what way?
 - f. How do you think this policy affected the access to medicines?
9. Of all policies (pre-2005, 2005/7 and 2009), which gave best results in:
- a. Rational prescribing?
 - b. Access to medicines?
 - c. Better off and worse off? Who and why?

[Overall: Policies on prescribing]

10. Are prescribing policies are (fully or partially) implemented?
- a. If not, what parts are not implemented and why?
 - b. How can this be overcome?
 - c. If not, who is responsible for lack of implementation?
 - d. How can this be overcome?

[General: Policies on dispensing]

11. Although rather stringent policies exist on the dispensing of prescription medicines, those are not well implemented. In your opinion (and experience), where the main problem lays? (enforcement, incentives, etc.)
- a. Who is responsible for such low enforcement?
 - b. How can this be overcome?
 - c. How is the low enforcement reflected on the rational prescribing?
 - d. What can be done to reduce the non-prescription dispensing?

[EXTRAS]

12. If you were a PHC provider, what would you say/do about the prescribing policies? Would you think the policies are: fair, incentivising, backward?
13. If you were a pharmacist, what would you say/do about the dispensing policies?
14. If you were the patient, what would you say/do about the prescribing policies?
15. Any other comments or opinions?

Thank you.

Appendix E: INTERVIEW SCHEDULE QUESTIONS FOR PHYSICIANS

[Introductory questions]

16. How long have you been working in the PHC?
- 17. Who is responsible for preparation and execution of prescribing policies? Who should be involved?**
18. Have/Do you participate/d in the preparation of prescribing policies?
- 19. In your opinion, what are the main goals of the prescribing policies?**
 - a. Are these goals addressed?
 - b. Are these goals met? If not, why?
- 20. What are the most important achievements of the prescribing policies?**

[Policy of 2005/7: limitation on number of prescriptions]

21. In 2005/7, with the transformation (privatization) of the primary healthcare (PHC), the prescribing policy has changed to involve limitations on the number of prescriptions per patient, replacing the pre-2005 policy (of no-limited prescribing).
 - a. What is your opinion on its design and effectiveness?
 - b. Is this policy better/worse than the one before 2005 (no limitations, no privatization)? For whom and in what way?
 - c. Do you think this policy contributed to rational prescribing (of PHC goals)?
 - d. Was the policy incentivising/dis-incentivising for PHC doctors and how?
 - e. Had this policy any influence on the freedom/levels of prescribing for PHC doctors? In what way?
 - f. How do you think this policy affected the access to medicines?

[Policy of 2009: budget ceiling for prescribing]

22. In 2009, the prescribing policy in primary care was redefined using budget ceilings for PHC doctors. How is this policy compared to the policy of 2005/7? Compared to the pre-2005 policy?
 - a. Do you think it is well designed and fair? If not, why? To whom it is not fair?
 - b. Who is responsible for this?
 - c. Do you think this policy contributes to rational prescribing (of PHC goals)?
 - d. Is the policy incentivising/dis-incentivising for PHC doctors and how?
 - e. Has this policy any influence on the freedom/levels of prescribing for PHC doctors? In what way?
 - f. How do you think this policy affected the access to medicines?

[Overall: Comparing policies]

23. If you compare all policies (pre-2005, 2005/7 and 2009):
- a. Do you have more/less patient visits now (after 2009) than before (pre-2009)? Pre-2005?
 - b. Do you have more/less prescriptions (in absolute terms) now than before?
 - c. Do you think the HIF spending on medicines is higher/lower now (post-2009) than with the prescription-limit policy (2005/7)? Why do you think so?

[Overall: Policies on prescribing]

24. Are prescribing policies are (fully or partially) implemented?
- a. If not, what parts are not implemented and why?
 - b. How can this be overcome?
 - c. If not, who is responsible for lack of implementation?
 - d. How can this be overcome?

[General: Policies on dispensing]

25. Although rather stringent policies exist on the dispensing of prescription medicines, those are not well implemented. In your opinion (and experience), where the main problem lays? (enforcement, incentives, etc.)
- a. Who is responsible for such low enforcement?
 - b. How can this be overcome?
 - c. How is the low enforcement reflected on the rational prescribing?
 - d. What can be done to reduce the non-prescription dispensing?
 - e. Do you think a patient should be allowed to obtain medicine without prescription? If not, why?
 - f. Do you think it is appropriate that a patient can get a medicine without prescription? If not, why? How do you feel about this situation?
 - g. Do you think it is your responsibility to prevent patients from obtaining medicines without prescription? If not, whose responsibility it is?

[EXTRAS]

26. If you were the patient, what would you say/do about the prescribing policies?
27. Any other comments or opinions?

Thank you.

Appendix F: INTERVIEW SCHEDULE QUESTIONS FOR PHARMACISTS

[Introductory questions]

1. How long have you been working in a pharmacy?
2. **Who is responsible for preparation and execution of prescribing policies? Who should be involved?**
3. Have/Do you participate/d in the preparation of prescribing policies?
4. **In your opinion, what are the main goals of the prescribing policies?**
 - a. Are these goals addressed?
 - b. Are these goals met? If not, why?
5. **What are the most important achievements of the prescribing policies?**
6. **In your opinion, what are the main goals of the dispensing policies?**
 - a. Are these goals addressed?
 - b. Are these goals met? If not, why?
7. **What are the most important achievements of the dispensing policies?**

[Policy of 2005/7: limitation on number of prescriptions]

8. In 2005/7, with the transformation (privatization) of the primary healthcare (PHC), the prescribing policy has changed to involve limitations on the number of prescriptions per patient, replacing the pre-2005 policy (of no-limited prescribing).
 - a. Do you think this policy contributed to rational prescribing (of PHC goals)?
 - b. Had this policy any influence on the freedom/levels of prescribing for PHC doctors? In what way?
 - c. How do you think this policy affected the access to medicines?

[Policy of 2009: budget ceiling for prescribing]

9. In 2009, the prescribing policy in primary care was redefined using budget ceilings for PHC doctors. How is this policy compared to the policy of 2005/7? Compared to the pre-2005 policy?
 - a. Do you think this policy contributes to rational prescribing (of PHC goals)?
 - b. Has this policy any influence on the freedom/levels of prescribing for PHC doctors? In what way?
 - c. How do you think this policy affected the access to medicines?

[Overall: Comparing policies]

10. If you compare all policies (pre-2005, 2005/7 and 2009):
 - a. Do you believe that the change to 2009 policy for prescribing affected the levels of private purchased medicines by patients?
 - b. Do you have more/less patients asking medicines without prescriptions

- now than before?
- c. Do you think the HIF spending on medicines is higher/lower now (post-2009) than? Why do you think so?
 - d. Do you think that patients now spend more/less on prescription medicines than before?

[Overall: Policies on prescribing]

- 11. Are prescribing policies are (fully or partially) implemented?
 - a. If not, what is not implemented and why? How can this be overcome?
 - b. If not, who is responsible? How can this be overcome?

[General: Policies on dispensing]

- 12. Although rather stringent policies exist on the dispensing of prescription medicines, those are not well implemented. In your opinion (and experience), where the main problem lays? (enforcement, incentives, etc.)
 - a. Who is responsible for such low enforcement?
 - b. How can this be overcome?
 - c. How is the low enforcement reflected on the rational prescribing?
 - d. What can be done to reduce the non-prescription dispensing?
 - e. Do you think a patient should be allowed to obtain medicine without prescription? If not, why?
 - f. Do you think it is appropriate that a patient can get a medicine without prescription? If not, why? How do you feel about this situation?
 - g. Do you think it is your responsibility to prevent patients from obtaining medicines without prescription? If not, whose responsibility it is?
- 13. Have you ever dispensed a prescription-only medicine without prescription? Do you think it was right?
- 14. How do you feel about medicine dispensing without prescription? Do you think that it is related to the current setup in the prescribing policy? Was it different in the past? How?
- 15. Do you think that dispensing-on-prescription policy should be strictly enforced? What effect would that have on the pharmacies? On the patients?
- 16. If dispensing-on-prescription policy is fully enforced, how do you think that will affect your business (e.g. relationship with pharmaceutical companies would change, less patients would use your services, etc.)?

[EXTRAS]

- 17. If you were the patient, what would you say/do about the prescribing policies?
- 18. Any other comments or opinions?

Thank you.

Appendix G: INTERVIEW SCHEDULE QUESTIONS FOR PATIENTS

[Introductory questions]

1. Are you taking any long-term therapy? For how long?
2. **Who is responsible for preparation and execution of prescribing policies? Who should be involved?**
3. Have/Do you participate/d in the preparation of prescribing policies?
4. **In your opinion, what are the main goals of rules for medicine prescribing?**
5. **In your opinion, what are the main goals of rules for medicine dispensing?**
6. Do you agree that a doctor and pharmacist should make a decision on your therapy?

[Policy of 2005/7: privatization of PHC – limitation of prescriptions]

In 2005/7, with the transformation (privatization) of the primary healthcare (PHC), the prescribing policy has changed, replacing the pre-2005 policy (of no-limited prescribing).

7. If you remember, how did you feel about the change in PHC? Did you have any problems with your therapy? If yes, was it related to:
 - a. Obtaining prescription from PHC? How?
 - b. Obtaining medicine at pharmacy? How? Or both?

[Policy of 2009: budget ceiling for prescribing]

In 2009, the prescribing policy in PHC was redefined using budget ceilings for PHC doctors.

8. Did you have experience of changes in attitude or practice of your doctor related to your prescription medicines?
 - a. If yes, in what way?
9. Did you have experience of changes in attitude or practice of the pharmacist related to your prescription medicines?
 - a. If yes, in what way?

[Overall: Comparing policies]

If you compare your experience with medicines over the past decade, from 2004 until today (if applicable):

10. Access to your medicines at your PHC doctor:
 - a. Have you experienced any changes in access to your doctor?
 - b. To his/her readiness to prescribe the medicines to you?
 - c. If yes, in what way has this changed?
11. Access to medicines at the pharmacy:
 - a. Have you experienced any changes in access to medicines at the pharmacy?
 - b. Have you experienced any changes to obtaining HIF-covered medicines?

- c. If yes, in what way has this changed?
- d. Do you think that the levels of your spending on prescription medicines have changed compared to before? If yes, in what way?
- e. Have you ever asked prescription medicine without prescription? Why? Do you think it was right?
- f. Have you ever got a prescription medicine without prescription? Why? Do you think it was right?

[Overall: Policies on prescribing]

12. Do you think it is right that a patient should always get a prescription for a prescription medicine? If not, why? How can this be overcome?

[General: Policies on dispensing]

13. Do you think it is right that a patient should always present a prescription to a pharmacist to obtain a prescription medicine? If not, why?
- a. Do you think a patient should be allowed to obtain medicine without prescription? If yes, why? If not, why?
 - b. Do you think it is appropriate that a patient can get a medicine without prescription? If yes, why? If not, why?
14. If dispensing-on-prescription policy is fully enforced, how do you think that will affect your health and access to medicines? (not be able to get all medicines, no freedom of choice, etc.)

[EXTRAS]

15. Any other comments or opinions?

Thank you.

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