Thesis Work

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(s)Pills

A Comparative Study into the Pharmaceutical Policies in Hungary, New Zealand and The Netherlands

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By my signature below, I pledge and certify that my M.A. thesis, entitled '(s)Pills' is entirely my own work. That is to say, I have cited all the sources I have used, whether from books, journals, letters, other media, including the Internet. If this pledge is found to be false, I realize that I will be subject to penalties.

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Rutger Pieter Noël Beerens

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Abstract

In this thesis I made a comprehensive comparison between the pharmaceutical policies in use in Hungary, The Netherlands and New Zealand. Key question was what the Hungarians could learn from successful alternatives used by the Dutch and the Kiwis. For answering the questions the research was divided into two parts: the qualitative part and the quantitative part. The latter showed that the Hungarian prices for generic pharmaceuticals are significantly higher, compared to those in the other countries. However, recent trends showed that the recently expanded blind bidding system has also led to a remarkable decrease in the prices of Hungarian pharmaceuticals. With these results in mind, the qualitative part did not only give answer to the question how the Hungarians could improve their pharmaceutical policies, within the borders of their existing institutional and political context, but also how the experience of other countries could help Hungary to empower the sustainability of their recently implemented successful pharmaceutical strategy. After analyzing all three countries the thesis presented possible incremental changes, suitable for the Hungarian context, which could help improve the results of the current policy and/or ensure the stability of these policies.

Foreword

By writing this foreword I start to realize that I find myself in the autumn of my study career, although I am not sure whether this expression is also used in English. The previous six years have undisputedly been the most vibrant ones in my life. What started as a big adventure as in living on my own in Nijmegen, became a worldwide traveling experience with semesters of study in South Africa, Slovenia and Hungary. I would therefor start this foreword by showing my gratitude to my private bank: mom and dad. Without their investments all of it would never had taken place.

Furthermore I would like to aim some attention to my sister, someone who has always supported me and has become an example to me by excelling in her work and becoming one the youngest managers within the Tommy Hilfiger enterprise. I can do nothing more but hope that my career will develop itself just as successful and with same pace as hers did.

I would like to continue by saying thanks to Dr. Lyndon Du Plessis from the University of the Free State in Bloemfontein, who was the first to introduce me to foreign local politics. The introduction made me curious for more of such examples ultimately leading to my application for the IMPACT Master Program. I consider myself privileged and lucky that I was able to experience South Africa so intense and that I met numerous fellow international students who I consider to be friends for life.

As I already shortly mentioned it, I would like to refer to the IMPACT Master Program by noting that it gave me a great deal of joy and education. Both socially as well as educationally, the program has given me a unique piece of luggage, which I hope and expect to be used in my future endeavors. I think it is very unfortunate that no future students will have the ability to experience what me, and my fellow students, have experienced. Although, I believe to know what is the cause of what became an inevitable premature end is, I would like to say not more than that I am utmost disappointed in those who lacked the motivation and efforts to remain to stay on board of this ship in an attempt to hoist all of the sails.

I would like to show my gratitude to the large majority of the staff, who all did their best to make the IMPACT program as challenging as it was: a great team of teachers who gave us, me and the other IMPACT students, a real feeling of receiving a truly unique education. Also thanks to the Slovenian government, who generously sponsored us with the infamous food coupons and to Hungary who gave us an unforgettable, and affordable, time in one of the most vibrant student cities in Europe.

Lastly, I would like to address all of those who have helped me to transform my thesis into what it is today. Without the help of my interviewees and my supervisors, undeniable I would not have been able to achieve what I, personally, believe is a fine piece of art. A thesis of which I am proud of myself, pride that sometimes might have led me to be stubborn but also thorough. At very last, thanks to the Tour de France, which has been a great and welcome distraction in what has been a bustling period during the finalization of my work.

During these precarious times in several respects, I hope for a future in which I hope to experience more of all and everyone above. I wish you a pleasant time reading my work.

Rutger Beerens

* * *

"When an employer sits down with his health care providers – the broker, the health plan, the physician, the hospital, the drug and device firms – everyone in the room wants it to cost more – and they're all positioned to make that happen."

Lynn Jennings – CEO of WeCare TLC

Definitions

Me-too drugs:	Me-too drugs can be broadly defined as chemically related to the prototype, or other chemical compounds which have an identical mechanism of action[1].
Innovative Medicines	The Innovative medicines are newly developed medicines which are brought to the market under a patent protection. Therefor there are no alternative generics available.
Generics	Generics are pharmaceuticals which are legally introduced to the market after the patent of an innovative medicine expires. The generics are almost identical to the innovative medicine it is derived from and can therefore be used as alternative for similar treatments.
Orphan Drugs	Orphan drugs are pharmaceuticals that target specific and rare disorders or diseases. Due to the small niche market the prices of these orphan drugs are, in most cases, significantly higher compared to drugs used by large target populations.
Preference Policy	The policy used for purchasing medicines in the Netherlands.
PHARMAC Model	The policy used for purchasing medicines, medical treatments and -devices in New Zealand
Blind Bidding	Instrument used for purchasing medicines. The blind bidding procedure involves pharmaceutical manufacturers bidding (lowest price) for the right to (solely) supply the market with a particular medicine for a certain period of time.
PPF	Framework used to analyze the political and institutional context of the different countries in order to identify the barriers to change/reform
Paradigm	a framework, of ideas and standards which policy makers use that specifies not only the goals of policy and the kind of instruments that can be used to attaint hem, but also the very nature of the problems they are meant to be addressing.
Social Learning	Situation in which decision-making authorities change, or let go, of their policy beliefs due to influences from the environment
Welfare State	A state in which the government tries to create society by using the authority of taxing and (re)distribution
Regulatory State	A State in which the government decides to guide society trough regulation. The tasks of the gathering and spending of financial resources is left to the market or (governmental) specialized agencies. The extent of government regulation determines the autonomy these executive actors have

[1] Garattini, S. (1997)

Abbreviations

ACF	Advocacy Coalition Framework
PPF	Policy Perception Framework
Nza	The Dutch Health Authority (NL)
IGZ	The Dutch Health Inspection (NL)
CVZ	Council for Health Insurances (NL)
CFH	Committee for Pharmaceutical Support (NL)
PHARMAC	Pharmaceutical Management Agency (NZ)
Medsafe	New Zealand Medicines and Medical Devices Safety Authority (NZ)
CPSOG	Community Pharmacy Services Operational Group (NZ)
NHIFA/NHIF/HIF	National Health Insurance Fund (HU)
SKGZ	Foundation for complaints and Problems Health Insurance (NL)
WHO	World Health Organization
HCO	Health Care Obligation
KNMP	Industry Association for Pharmacists (NL)
DHB	District Health Boards (NZ)
MNZ	Medicines New Zealand (NZ)
NZORD	New Zealand Organization for Rare Disorders (NL)
GYEMSZI	National Institute for Quality- and Organizational Development in Healthcare and Medicine (HU)
ANTSZ/NPHMOS	National Public Health and Medical Officer Service (HU)
EMEA	European Medicines Authority
CBG/MEB	Medicines Evaluation Board (NL)

1. Introduction

FOR DECADES WESTERN SOCIETIES have developed themselves along a line of economic growth. With economies growing, so did expenditures. Extensive social welfare states have been established with elaborate facilities for retirees, unemployed, elderly and the sick. Never was to worry about the costs as for the future economic growth would ensure the conservation of the systems. However, predictions have shown to be overoptimistic as economic growth in the modern western societies seems to have reached a standstill. The annual growth levels are shrinking and periods of serious economic contraction, like the economic crisis of 2008, are appearing more frequently.

Governments have tried to sustain their welfare states for as long as possible, but the future promises that these systems cannot be sustained. The costs of pensions, health care and other social benefits are demanding larger shares of shrinking governmental budgets. Societies are aging, demanding longer pension benefits and more medical treatments, while simultaneously on the input side, the amount of employees paying the premiums for these services, is shrinking by the day.

Governments will have to come up with innovative ideas in order to keep standards high but expenditures low. If they do not manage to come up with such ideas only two options remain: increasing tax burden or decreasing quantity and quality of their services.

The innovative ideas seem to be the more attractive path to follow, but at the same time the most challenging one. The main challenge is how to come up with such ideas? The idea of an idea is that it will have to be invented. Coming up with these ideas within the existing institutional frameworks is not as easy as it may seem. Polarization of the political field has shown to make revolutionary ideas hard to transform into policies. Ideas might work in theory, but without implementation, and the empirical results, political opposition is hard to convince: w*ithout convincing, it is hard implementing, but by implementing, it is easier convincing.* But, how can this logic put to use?

In fact, national governments are not obliged to think of (new) ideas themselves. Instead they might also turn their eyes beyond their geographical borders. Innovative policies that have already been implemented by other countries and have shown to achieve positive results are often adapted, especially when environments are alike. We might be wise to accept that, if countries are to tackle their forthcoming challenges, a search for best practices might best be their start.

One of such challenges is controlling health care costs. European countries currently face the consequences of their graying populations. People are getting older and, inherently, require more medical attention. Over the last decades governments have responded dissimilarly in their attempts

to contain health care costs. Many of the modern western democracies have thought to find solutions in principles of the market, whereas others choose government to intervene.

This thesis will focus on analyzing different policy alternatives which are aimed at controlling national healthcare costs and/or increasing the sector's productivity. More specifically, I will attempt to describe and explain whether governments in Hungary, New Zealand and The Netherlands have managed to lower their healthcare costs by implementing new legislation and governmental structures aimed at the purchase and provision of medicines and pharmaceutical care. A research into regulating what is likely to be the most controversial and distrusted markets after the banks: the pharmaceutical market.

1.1 The choice for Medicines

THE CHOICE TO ANALYZE the provision of medicines and pharmaceutical care was mainly based on the unique characteristics of medicines. The medicines are considered merit goods[2]. Goods of which the effects are positive, but without government intervention would, and/or could, not be consumed by sufficient people. But unlike other merit goods, such as education, health care and museums, the development and production of the goods is done by the private market. This would not be a problem, if the market would offer these products at an affordable price, but what is seen in practice is that these companies often offer their products against extraordinary high prices.

The pharmaceutical industry makes up for a total amount of over 300 Billion dollars with profit margins of around 30%[3]. Governments partly finance these by reimbursing medicines. Multi-billion fines are given on a yearly basis for large scale frauds by the ''Big Pharma'', but the government remains in business with them, simply because they have no choice.

Though, some governments have shown that they do have a choice. A clear example is that of South Africa where the government decided to import patented AIDS-medicines from neighboring countries as they saw it as their only solution to make it accessible for its financially, and medically, troubled population. The patent market has caused inequitable access to medicines all over the world. Not only poor countries do not have access to some vital medicines, also in the Western countries problems start to emerge as they become limited in their capabilities to reimburse their current, and future, broad selection of medicines[4].

[2] Rodda, C. (2013)
[3] WHO (2013)
[4] Fisher, W. Rigamoniti, C.P. (2005) p. 6

Some scholars and politicians support the idea of increased government involvement in the development of medicines. To increase the efficiency and the effectiveness of their budgets, funding should shift from the national level towards a more innovative global approach[5]. However before looking at such options on a global level, we might first have a look at successful cost-containment attempts at the national level.

When it comes to pricing pharmaceuticals there are two major factors of influence. One is the earlier discussed patent protection, which gives private producers the power to temporarily monopolize their markets. The other is the fact that the price of a medicine is rather in-elastic, both for experts and patients, making it vulnerable to that other market failure: asymmetric information. Patients are not able to directly compare the benefits with the costs of a medicine. In some cases patients are simply dependent on them for survival, making them literally priceless. This goes together with the fact that it is not the patient himself who chooses his medicine, but their physicians who function as their agents[6]. As for the physician is not financially affected by the purchase of a medicine he, or she, may also be considered to be less vulnerable to the elasticity of the price. It is the government's role to try and rationalize the pricing.

1.2 Three Countries, Three Strategies

The selection of the case studies Hungary, New Zealand and The Netherlands is not a random one. All countries differ significantly from one another, and the rest of the world, in their regulation for structuring the pharmaceutical sector. Key aspect is how the countries determine the prices of their pharmaceutical care and medicines.

In New Zealand PHARMAC has been given the task of determining prices of medicines. PHARMAC is an autonomous agency operating within a budget set by the Minister of Health. In their efforts to lower prices, the agency uses various strategies and tools to negotiate with manufacturers. PHARMAC is considered to be rather successful as they managed to achieve some of the lowest price levels in the world with hardly any government interference in their actions. In PHARMAC's own words: ''Our work has meant that, since 2000, PHARMAC's activities have saved District Health Boards a cumulative total of more than $5 billion.''[7]

Unlike New Zealand, the Netherlands choose not to nationalize the procurement of medicines, rather they decided to ''marketize'' it by outsourcing the purchasing power to private, non-profit, health

[5] Moon, S. (2009) p. 1
[6] OECD, (2009)
[7] PHARMAC (2012) Annual Report, p 16.

insurers. The insurers compete with each other over attracting as many patients as possible by offering the lowest premiums and the best quality of services. Each health insurer negotiates prices with pharmaceutical manufacturers, signing contracts for distribution to their customers with those manufacturers that offer the lowest price. The Dutch preference policy may as well be considered a success, as it achieved a reduction of the prices on generic pharmaceuticals for up to 99% since 2006.[8]

In Hungary negotiation prices is performed by the National Health Insurance Fund (NHIF) which is part of the Ministry of Health. Since 2011 their strategy has changed, most of generics are now purchased through a process of blind bidding procurement. The manufacturers get the option to bid on the rights to supply the Hungarian market at the maximum level reimbursement. The introduction of the method has led to significant price drops in the recent years[9], but the question can be asked: who is paying for these reductions?

1.3 Research Objectives

Saving costs on health care does not automatically state it to be an improvement overall. A possible consequence of saving money is the decrease in quality. In this thesis I would like to analyze, compare and evaluate the different approaches followed by the three countries. Not only analyzing them on the basis of costs and benefits, but also judge them on the basis of quality. I question myself whether Hungary can learn from the alternative models for purchasing medicines and pharmaceutical care in New Zealand and the Netherlands, making the central goal of this research the following:

Aim of Research: *Analyzing and mapping the different Pharmaceutical Cost Containment regulations in Hungary, The Netherlands and New Zealand in order to make an objective comparison among these systems in order to find out what and how the Hungarian Government might be able to learn from the alternative approaches.*

To Analyze and map the different Pharmaceutical Cost Containment regulations in Hungary, The Netherlands and New Zealand in order to make an objective comparison among these systems to find out if, what and how the Hungarian Government might be able to learn from the others' regulations.

Central question for research will be the last part of the research statement; *what can the Hungarian government learn from the Dutch and Kiwis considering the implementation and development of their future pharmaceutical policies*? As for these possibilities, they do not just imply looking at the results of the policies. What might be of even greater importance is to analyze whether the Hungarian political, social and economic context is suitable for implementing alterations? The next chapter will explain more elaborately what concrete questions we should ask ourselves.

[8] Kanavos, (2012), p. 26
[9] Horvath, (2013)

1.4 Analytical Boundaries

On forehand it might be wise to note that this thesis is focused on the lowering the pharmaceutical expenses through government purchasing policies. Thereby it should be said that this does not involve the restrictions on patent abuse by the pharmaceutical industry. Although, these actions seem very interesting, this thesis will mainly focus on the purchase of pharmaceutical care and off-patent, so called generic-, medicines in which multiple suppliers have access to the market and in which patented monopolies are less likely to play a role. Government policies affecting the generics' market are therefor to be considered independent, pursuing different goals and using different means, from those targeting patent abuse.

There are multiple roles to be played in relation to the provision of medicines to the market. It starts with deciding whether a medicine is allowed to enter the market. For this it has to be elaborately tested on its safeness and efficacy. We may state that this control function is primarily in the hands of qualified governmental agencies. In Europe this role is executed by the European Medicines Agency (EMA)[10], whereas in New Zealand the government assigned this task to MedSafe[11]. The approval and evaluation function refers to both innovative as well as new generic versions of medicines.

Once the medicine is approved it is in the hands of the professionals (doctors, surgeons, specialists, pharmacists, etc.) to decide whether the medicine should be prescribed for treatment. Simultaneously it is for the government to decide whether the medicine should be reimbursed or not. For this, governments, or advising agencies, develop criteria, for it is understandable not all medicines are subsidized. Cosmetic treatments as well as medicines are less likely to be reimbursed than those medicines that help to cure serious and life-threatening diseases such as cancer and diabetes.

Consequently when a medicine loses its patent, another choice becomes available, namely the choice of which brand of the medicine will be reimbursed. In this thesis, this choice will be the main focus. The three countries which are taken into account all have their own structures to decide how, and who, makes this decision. Shortly stated, in Hungary they choose to give this power to the NHIF, in the Netherlands they gave this power to the multiple (semi-public) health insurers, whereas in New Zealand they decided to put matters in the specialized hands of PHARMAC.

[10] Ema.europa.eu
[11] Medsafe.govt.nz

Table 1.1: Focus of Research				
	The Netherlands	**Hungary**	**New Zealand**	In this Thesis
Approval/Evaluation	EMEA/ College ter Beoordeling Geneesmiddelen (CBG/MEB)	EMEA/National Institute of Pharmacy (GYEMSZI)	Medsafe	-
Reimbursement or not	Ministry of Health/CVZ/CFH	Ministry of Health	PHARMAC	+
Which manufacturer is reimbursed?	Health Insurers	National Health Insurance Fund	PHARMAC	++
What treatment/medicine is prescribed?	Physician/ Specialists	Physician/ Specialists	Physician/ Specialists	+
What are the tariffs for pharmaceutical care?	Health Insurers/Pharmacists (Fixed Fees)	Government (margins)	DHB's/Pharmacists (Fixed Fees)	+

++= elaborately + = shortly - = no

1.5 Structure

An attempt has been made to structure this thesis. Therefor I will start by explaining the theoretical framework which will serve as a guideline for my thesis by identifying the theoretical boundaries of my research. The theoretical framework is followed by a description of the methodology that was used in order to explain and justify the validity as well as the reliability of the results. This chapter will then be followed by the first part of analysis in which the quantitative results of the policies will be described into detail. The second part of the analysis will analyze the political, social and economic context of the policies to find out to which extent Hungary would be able to alter and learn. In the last chapter I will present my conclusions, including the answers to the main research questions and whether my research objectives have been achieved.

Table 1.2: Thesis Structure	
Chapter	**Content**
1	Introduction
2	Theoretical Framework
3	Methodological Framework
4	Quantitative Analysis: Impact Assessment
5	Qualitative Analysis Part I: Historical Backgrounds
6	Qualitative Analysis Part I: A Stakeholder Analysis
7	Conclusions/Recommendations
8	References

The chapters are also structured, starting off with a short introduction on what will be discussed, followed by the actual discussion and closing with a short summarizing paragraph on what has been discussed in that specific chapter.

1.6 Relevance to Society and the Academic World

There is no need to explain the value of savings in the current economic condition the EU is in now. If there is anything the Hungarian government can learn from, making their policies more efficient and effective, this will positively affect the Hungarian citizens. Every Forint saved in the pharmaceutical market, is an additional Forint to be spent, or less to be saved, in fields where they are vitally needed.

With this thesis I hope to make a contribution to the Academic field, by exploring the use and predictability of theories such as the principal agent dilemma, social learning and multiple streams. I will try to verify and learn from the assumptions given by theoretical foundations with regard to making reform possible and optimizing the performance of executing agencies. Furthermore I will try to contribute by developing my own comprehensive framework: the Policy Perceptions Model. I hope this model will contribute to making the field of Public Administration a little bit less complex.

2. Theoretical Framework

THIS THEORETICAL FRAMEWORK WILL function as guideline for this research. It helps to build the foundations for understanding the topic by discussing a selection of relevant literature. Besides giving guidance to me as a researcher, the theoretical framework also helps to justify my research[12]. It will explain to the reader why, and what, I choose to perform this research. In short, the theoretical framework can be summarized as ''the system of concepts, assumptions, expectations, beliefs, and theories that supports and informs my research. It identifies the main aspects to be studied, meaning the key factors, concepts, or variables and the presumed relationships among them''[13]

The conceptual framework can be summarized as ''the system of concepts, assumptions, expectations, beliefs, and theories that supports and informs my research. It identifies the main things to be studied, meaning the key factors, concepts, or variables and the presumed relationships among them''

This research will be focused on analyzing the policies that were established in New Zealand, The Netherlands and Hungary considering attempts that were made to lower pharmaceutical expenditure. The question that this research attempts to answer is why these policies succeeded or not, but to do this we must first understand how policies are established and changed.

This theoretical framework aims to give an overview of existing literature about the policy change. The framework consists of multiple different theories which help by providing their view on (parts of) the this process. The upcoming paragraphs are structured towards giving the reader understanding on when, how and who changes policies.

The first part of the chapter will be aimed at explaining reform. The questions will be answered what reform entails and how it differs from policy change. Consequently, the discussion is raised about how reform can actually take place. For that I will first elaborate on the possible barriers which could hamper reform, followed by discussing theories which help explain who and what facilitates it. In the end I will try to integrate the different theories and views into a single framework which will help me formulate a list of concrete questions for my research. The table (2.1) below shows a more detailed overview on what to expect.

[12] Maxwell (2004) *p. 33*
[13] Miles & Hubert (1994), ''Qualitative Data Analysis'', p. 18.

TABLE 2.1 - The Structure of this Chapter

Reform
- **What is reform**
  ○ **The Paradigm and its role**
  ○ **Organizational Structures and their role**

Barriers to reform
- **Paradigms**
  ○ **The Possible Paradigms**
  ○ **The role of Principal Agent theory**
- **Existing Policies/Path Dependency**
- **Existing Structures/Administrative Resistance**

Facilitators of Reform - **Multiple Streams: Politics, Problems and Solutions** - **Crisis and Mandates** - **Social Learning** - **Advocacy Coalitions**
Creating a Framework

2.1 The Concept of Reform

AS THIS MASTER THESIS looks for possible alternatives to the Hungarian pharmaceutical policies it might well be assumed that these alternatives would require the introduction of significant changes. To understand what these policy alternatives entail and how large these changes are likely to be, I choose to look at these alternatives as possible reforms. Discussing the concept of reform elaborately will hopefully make clear whether the policy alternatives are considered to be reform and what is likely to be of importance if they were to be introduced by the Hungarian Government. I will start by conceptualizing reform.

2.1.1 Conceptualization

The main aim of conceptualizing reform is to make clear how the concept relates and differs from the concept of (policy) change. To get an idea about what reform entails I will first introduce my readers to a small number definitions given by renowned scholars who went ahead of me in analyzing the

phenomenon. The overview will lead to the establishment and adaptation of a useful definition of reform, forming a foundation on which I will build further pieces of the theoretical framework.

According to Keeler, Reform is defined as a policy innovation manifesting an unusually substantial redirection or reinforcement of previous public policy. The reform is realized by a Reform Government: 'a government that manages to achieve, through sponsored legislation and/or other executive action, an unusually large number of reforms[14]'. Bannink & Resodihardjo define reform as 'a fundamental, intended, and enforced change of the policy paradigm and/or organizational structure of (an organization within) a policy sector'[15] . Where Keeler identifies reform as a possible reinforcement of previous policies, Bannink & Resodihardjo solely speak of reform when these previous policies are actually abandoned. The following paragraphs will more elaborately discuss the core features of the latter definition. Throughout the remaining of this research, the concept of reform will directly refer to this definition.

Reform *can be defined as 'a fundamental, intended, and enforced change of the policy paradigm and/or organizational structure of (an organization within) a policy sector'*

Fundamental

The assumption that reform is required to be fundamental refers to the actual impacts of the change compared to the status quo. Reform requires the means and goals of the newly implemented policies to be significantly different from those of the existing policies. If this is not the case the term reform should not be attributed, instead we might speak of just an incremental policy change. According to Streeck and Theelen there are four ways in which policy changes might take place. To make a distinction between institutional changes the two authors look at the way the change took place as well to how the impacts of the change affected the status quo[16]. A schematic reproduction of their ideas is shown in the table (Table 2.2) below.

[14] Keeler (1993) p. 433
[15] Bannink & Resodihardjo (2008) p.3
[16] Streeck & Theelen (2005)

Table 2.2 - Types of institutional change: processes and results

		Result of Change	
		Continuity	Discontinuity
Process of Change	Incremental	Reproduction by adaption	Gradual Transformation
	Abrupt	Survival and return	Breakdown and replacement

Source: Streeck & Thelen (2005)

Looking at the typologies that Streeck and Theelen distinguish we may state that reform requires a discontinuity of the status quo. Consequently one might ask whether this change should additionally take place within a short timeframe or whether this change can be gradual within a longer time span. The punctuated equilibrium theory tells us that reform can only take place if the former is the case[17]. These changes can be characterized as notable breaks or turning points. 'They embody far-reaching transformations of socio-technical structures and regulations, which had been stable over a comparatively lengthy period of time, and had, until then, influenced broad portions of the economy and society'[18]. Assuming this is true it leads us to placing reform merely in the right-bottom cadre of table 2.2. But as for is normal in science, not all scholars agree.

Other authors claim that reform may well take place according to the laws of gradual transformation[19]. In this case the reform is considered to be the result of gradual processes of adjustments to the existing institutional structures. They are to be considered answers to the environment in which innovative technological and knowledge developments require these structures and existing regulation to adjust itself to remain effective and efficient. Eventually, in terms of up to 30 years, the change in laws, structures and patterns of interaction appear to be radically different from when the gradual transformation process was put in to action. These gradual changes make abrupt reforms to become superfluous[20]. This theory of gradual change, allows us to place the concept of reform not only in the Bottom-right-, but also in the top-right square of table 2.2. But solely if the actual final results of this gradual change can be considered discontinuity of the status quo[21].

What type of change is likely to occur is strongly related to the actual political context in which the change is to occur. Later in this chapter we will take a closer look to what this influence of the political context exactly entails.

[17] Ibidem.
[18] Dolata, (2005), p. 5
[19] Streeck & Theelen, (2005).
[20] Dolota, (2011) p. 6
[21] Ibidem.

Intended & Enforced

By calling the reform intended Bannink & Resodihardjo aim at the fact that we should not be interested in the unintended effects which emerged from incremental changes, instead we should be interested in those effects which were actually expected, those effects the policy-maker aimed to achieve with the implementation of his or her policy[22].

Analyzing a reform means analyzing a policy that is actually implemented. Implementation of the policy is understood as the fact that the policy went past all of the stages of the policy cycle successfully[23]. Note that the definition of reform does not include any requirements about the actual quality of the results.

2.2 The Paradigm: How people think

Government and politicas are both tasked with attempting to solve social issues. In this attempt all actors are confronted with uncertainty which makes solving the issues difficult. There are multiple ways to tackle the issues, but none of the politicians or government officials actually know which way is the best or in which way an option is optimally designed and implemented. Instead, governments and politicians choose an option that is best for society in their (collective) opinion and within the borders of their available knowledge and cognitive capabilities.

Before I continue on this, it might be valuable to first deduct ourselves to the individual. The individual needs to make his or her choices. Can we predict this choice? According to the old neoclassical economists' rational choice theory we can. The prediction can simply be found by identifying the very best solution possible. The economists assume that the individual will make this very best decision for he is assumed capable to be fully informed.

This assumption led to the development of the 'public choice theory'. The rational decision maker was described as an individual who acts in his or her own best interest[24]. However, in practice this is not the case. In practice decisions are not so predictable; people do not simply choose the very best solution for they do not possess the abilities and the resources to become fully informed. Herbert Simon (1958) was one of the first to notice. As a reaction he developed the concept of bounded rationality which was part of his theory he termed the 'behavioral theory of choice'[25]. The theory made clear that people base their choice on what they are capable of knowing.

[22] Bannink & Resodihardjo (2008) p.3
[23] Ibidem
[24] Hill, (2009)
[25] Jones, (2002) p. 271.

The theory of bounded rationality was founded on the basis of four principles. The principle of (1) *intended rationality* assumes that people behave according to the goals they want to reach. In this case it is important for the analyst of this behavior to investigate in which way the decision-makers' 'cognitive and emotional constitutions concomitantly promote and interfere with goal directed behavior'[26]. The (2) principal of adaptation explains that humans behave differently the more they get to know their environment. It sounds logical if we were to say that people make different choices when they enter an unknown environment compared to the decisions they would make if they have spent time and get to know this environment[27].

A Paradigm is a framework, of ideas and standards which policy makers use that specifies not only the goals of policy and the kind of instruments that can be used to attaint hem, but also the very nature of the problems they are meant to be addressing.

The principle of (3) uncertainty refers to the fact that decision-makers are not fully informed about their environment. It is closely related with the fact that a decision-maker tries to predict the effect of the alternatives that are available to him. In this prediction the individual tries to calculate the risks and quantifying the likelihood of certain consequences from happening. Practice has shown however that people have troubles with working with probabilities leading them to act overconfident or too reticent. The last principle the behavioral theory leans on is that of (4) trade-offs. The principle refers to the fact that people are unable to compare goals, benefits and costs objectively. Instead people make a guess of the values that represent these vital parts of the decision to make[28].

The governments and the politicians can be considered as a group of individuals who collectively make their decisions. Just like the individual makes his set of preferences and his set of norms and values to guide his decisions, the politicians and governments make paradigms. The paradigm is closely related to the four principles that were discussed above. For as the individuals make decisions they search for guidance due to the limitations its bounded rationality. This guidance is given by the collectively set-up paradigm.

Just like the individual, groups cope with a lack of information and limited cognitive abilities. The individuals in the group find it hard to make a rational decision and therefor they turn their heads to

[26] Ibidem, p. 272.
[27] Jones, B. D. (2003) p. 397
[28] Ibidem

what has already been socially constructed about the phenomena and the environment. Just like already discussed in the principles of bounded rationality people adapt to their environment the longer they experience it. It is a process of learning, ones a person knows more, a person experiments more, that person learns from the results and repeats the cycle. Future attempts are intended improvements to the decisions that the individual made before and from which he analyzed and studied the consequences.

Hugh Heclo already discovered that the process that takes place on the individual level of decision making also takes place on the level of the group. In this case the government and the politicians can be identified as the group of people that has to make a decision. Heclo stated that ''Politics not only finds its sources in power but also in uncertainty – men collectively wondering what to do… Governments not only 'power'.. they also puzzle. Policy-making is a form of collective puzzlement on society's behalf… much political interaction has constituted a process of social learning expressed through policy.''[29] In other words, governments and politicians collectively learn from how they experience and tryout the environment. Their knowledge from experience is combined and shared into the paradigm for other to learn from.

Now, after describing the idea behind the paradigm, we might start searching for a clear definition. As I am not the first to analyze policy reforms, others have already thought about this. As I will later be discussing his work, I will here choose for the definition given by Peter Hall. *'Policymakers customarily work within a framework of ideas and standards that specifies not only the goals of policy and the kind of instruments that can be used to attaint hem, but also the very nature of the problems they are meant to be addressing. Like a Gestalt, this framework is embedded in the very terminology through which policymakers communicate about their work, and it is influential precisely because so much of it is taken for granted and unamenable to scrutiny as a whole. I am going to call this interpretive framework a policy paradigm.''*[30]

Now in this definition the paradigm is related to the policies, ideas as well as the instruments which actors use. More about these aspects is discussed in the upcoming paragraph in which I will deconstruct the different levels of a paradigm.

[29] Heclo, H. (1974) p. 305-306. Hall, P. (1993), p. 275-276, Baumgartner, F. (2012), p. 12.
[30] Ibidem.

2.2.1 The Paradigm: Levels of Beliefs

When we would like to identify a reform, one should make sure that a shift of paradigm took place[31]. That not every change of policy is referred to as a reform can be related to the distinction which can be made in level of beliefs. ''A belief is the psychological state in which an individual holds a proposition or premise to be true''[32]. The beliefs guide the individual in their choices as it gives him the assumptions about how the world works. Hall distinguished three different levels of believes, namely: core-, primary- and secondary beliefs. The different levels help to determine whether policy change is considered to be reform or not.

Within the Paradigm Hall distinguishes three levels of believes: Secondary, Primary and Core Believes. All dependent on how much ethical and emotional value they represent.

The primary and secondary beliefs mainly consider the use of policy instruments to achieve the goals that are determined by the paradigm. Changing the way policy instruments are used can be due to experience or the availability of new knowledge; this is considered to be a change on the secondary level. The actual goals and the instruments are not affected in this case, but the routines that surround, and determine how to use, them. The primary beliefs moreover focus on these actual instruments that are used. The goals, and also the policy itself remains the same, however the techniques to achieve these are changed. This is also caused by the process of gaining experience and the availability of knowledge which Hall himself identifies as social learning. This process will later be discussed more elaborately[33].

Table 2.3: Beliefs

Level of Belief	**Representation**
Core	The Policy
Primary	The Instruments
Secondary	The use of the instruments

The core beliefs are the actual grand guidelines and philosophies of a paradigm. When these are replaced we may speak of a paradigm shift and an actual reform. Hall refers to the radical shift which took place in Britain between 1970 and 1989 in which their macroeconomic regulation changed from Keynesian policies to more Monetarist-like solutions. The reform was marked by ''simultaneous switch of instrument settings, the instruments themselves as well as the hierarchy of goals behind policy''.

Hall states that reform is a case in which a paradigm shifts. How this happens will be discussed later, what it means we will discuss here. In relation to the beliefs, we may state that in case of reform, the actors let go of their core beliefs. As we will see later, this does not have to mean that all actors do,

[31] Bannink, P. & Resodihardjo, S. (2008).
[32] Schwitzgebel, (2006).
[33] Baumgartner,(2012), p.2

however it does mean that the decision making authority (the advocacy coalition) does. To make clearer what a reform is, it might help to state what it is not.

Policy change happens a lot more often than reform does. In case of policy change does not have to entail a shift of paradigm, Hall speaks of so-called first or second order change. In the case of first order change, changes take place in relation to the secondary policy beliefs. Changes on how instruments are used can be considered a case of secondary order change. Hall himself related the phenomenon of first and second order change to the concept of incrementalism which was identified first by Charles Lindblom in 69'.

According to Lindblom actors choose incrementalism, rather than reform, due to the complexity and risks that surrounds policy-making. Baumgartner agrees and stares: ''Essentially, any proposed change to the status quo represents a "risky scheme," which, while it may be well intentioned, risks upending a carefully constructed balancing act and may have far-reaching unintended consequences. Considering that most public policies are quite complicated and have diverse effects on a great number of constituencies, this is not a bad argument''[34].

According to Lindblom actors choose incrementalism, rather than reform, due to the complexity and risks that surrounds policy-making.

Instead of risking to make large and lasting mistakes, the policy maker decides to change only little and looks at the limited impact these small changes have. If the consequences are in line with the predictions of the policymaker he can continue with successive small changes[35]. Besides uncertainty and the risk of mistakes, actors are reticent to reform due to the fact that to make decisions they depend on others. In 1977 and 79' Lindblom already argued that incremental policy making does not offer the solutions which societies need. However, due to the pluralistic way in which decisions have to be made in modern democracies, decision makers choose incremental steps, not only to limit the amount of risks related to possible mistakes, but also to increase the chance of convincing opposition which is necessary for achieving the changes[36].

[34] Ibidem. p. 13.
[35] C. Lindblom, (1969) p 87.
[36] Sapru,(1994) p 78.

Example 2.1 - The Example of Stock-Trading – Levels of Beliefs

During this thesis I will try to make core-theories and concepts more clearly by giving an example related to stock trading. In this case I discuss the paradigm. In stock-trading a trader has two paradigms, on which he can base his decision to buy, or sell, a particular stock. Either he bases his decision on the base of Technical Analysis, or he can choose to follow the information provided by Fundamental research.

The technical paradigm looks at the movement of a stock. Consequently this movement is compared to identify patterns. These patterns can be based on the historical movement of the stock, Historical and current movements of other stocks, Historical and current movements of complete indices, etc. These movements are used to predict the future movement of the stock.

The trader for example can choose to use the movement of a stock as leading indicator (instrument) and the movement of the indices as a whole as a secondary indicator. He does not pay attention to the movement of competitors.

The fundamental paradigm does not look at movements; it merely focuses on the performance of a company. Decisions to buy, or sell, a stock are based on predictions on how the performance of the company will develop. Also here there are multiple instruments that can be chosen to give guidance. The trader can look at the performance of the sector as a whole, the economy as a whole, a particular competitor or, of course, the performance of the company itself. He may than rank these indicators just like the technical trader did with his instruments.

In this case we can identify the three different beliefs. The core beliefs are the actual paradigms: Technical or Fundamental. Within these paradigms the trader is limited to using only certain instruments. The selection on which instruments are his primary beliefs. Besides all this the stock trader has the ability to rank these instruments in order of importance. This ranking are his secondary beliefs.

The influences of beliefs and a pluralistic environment on the impacts and size of reform will be discussed in a later stage; first we will aim our focus on what hampers reform. In the upcoming paragraphs multiple barriers to reform will be discussed.

2.3 Barriers to reform

According to Bannink and Resodihardjo the existing literature lacks giving answer to the question which barriers should be overcome in order to make reform likely to take place. At the same time it does not provide an insight in which conditions are likely to (help) facilitate reform. They argue that it is important to analyze which circumstances help diminish barriers and/or help to create facilitators[37].

When analyzing the barriers, or constraints, to reform one has to consider two approaches. The first is identified as the calculus approach, which represents the rational choice and is based on analyzing formal structures which influence decision making. A government or a politician cannot make a

[37] Bannink & Resodihardjo (2008) p.12

decision on his or her own; there are formal state structures which limit their opportunities. These institutions make sure that the individual becomes dependent on others, having to convince more than himself. Examples of institutional barriers to reform are to be found in many forms, times and places. Structural barriers mainly take the form of formal procedures[38].

The cultural approach focuses on identifying sociological barriers. These barriers have more to do with how people think and whether reform is backed by people who think the same way. Key for the cultural barriers are concepts like ideas, preferences and behavior. The approach assumes people to act on the basis of a ''logic of appropriateness'', meaning that they consistently pursue that what they want[39]. We will start by discussing these barriers in the next paragraph.

2.3.1 A Paradigm as Barrier to reform

Earlier we discussed the concept of a Policy Paradigm. A policy paradigm can be a barrier for reform. As reform entails the shift of a paradigm, it sounds like a logical assumption. Just like the existing policies, paradigms are unlikely to change without outside interference[40]. The existing policy paradigm influence how actors behave as it determines the sociological boundaries within which they look at the phenomenon and its surroundings. The actors adapt their preferences to the paradigm they believe in. A simple example is the liberal who generally believes in distributional policies which give leeway to the market, where as a socialist prefers distributions should be coordinated by government intervention. However, considering the paradigm we should not always assume that a liberal votes against socialist ideas, or think the contrary of the socialist. Sometimes the context makes them decide against their ideas. It shows that a decision maker's paradigm can shift or be ignored.

2.3.1.1 Paradigms in the health care sector

As a paradigm can form a barrier to reform it is important for us to identify within which possible paradigms health care policies can be placed. For that I make use of the typology that has been presented by Esping-Anderson in his most influential book The Three worlds of Welfare Capitalism. He states that welfare states can be divided into four possible paradigms: a state based on Social-Democratic-, Corporatist- or Liberal Values or a state based on Charity. To determine to which paradigm a state belongs one has to look towards two aspects of its policies. One is to which extent the state centralized authority. The other is to which extent the state has

Welfare states can be divided into four possible paradigms: a state based on Social-Democratic Values, Corporatist Values and Liberal Values or a state based on Charity.

[38] Ibidem.
[39] Ibidem.
[40] Bannink & Resodihardjo (2008) p.6

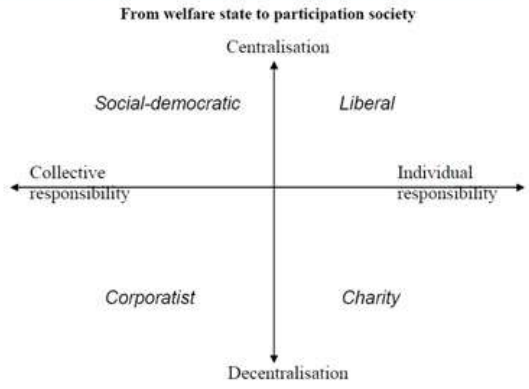
put the responsibilities related to their policies in their own collective hands[41]. (Also see figure 2.1 and table 2.3)

Table 2.3 Three Types of Welfare States

The three types of welfare states that Esping-Anderson developed were those based on the either the values of Social Democracy, Corporatism and the Liberal state. In a Social Democracy the government chooses to peruse a political ideology which is based on sharing. In this world the government plays a large role in distributing and redistributing resources by taking up a large amount of responsibilities. Government intervention is the key in reacting to those failures of the market such as poverty, inequality and dominancy of certain groups. The social democracy does not favor a free market, neither a completely government regulated market[42]. The social-democrats support the expansion of social rights, including elderly care, workers compensation, health care and education[43].

In a state pursued by conservative/corporatism the government focuses on dividing and running the state with corporate groups. The corporate state is marked by its approach to run affairs with corporations which are owned by the state. Communism and fascism were strong supporters of the corporatist state, but nowadays corporatism is also seen in a much more ''friendly'' and successful way. The Neo-corporatist state was first developed in the 60s as a response to the threat of recession-inflation[44]. Basic principle was the state to be founded on the basis of tri-partism which would include the existence of far going and instutionalized consultation between unions and state[45].

Figure 2.1: Paradigms of the Welfare States



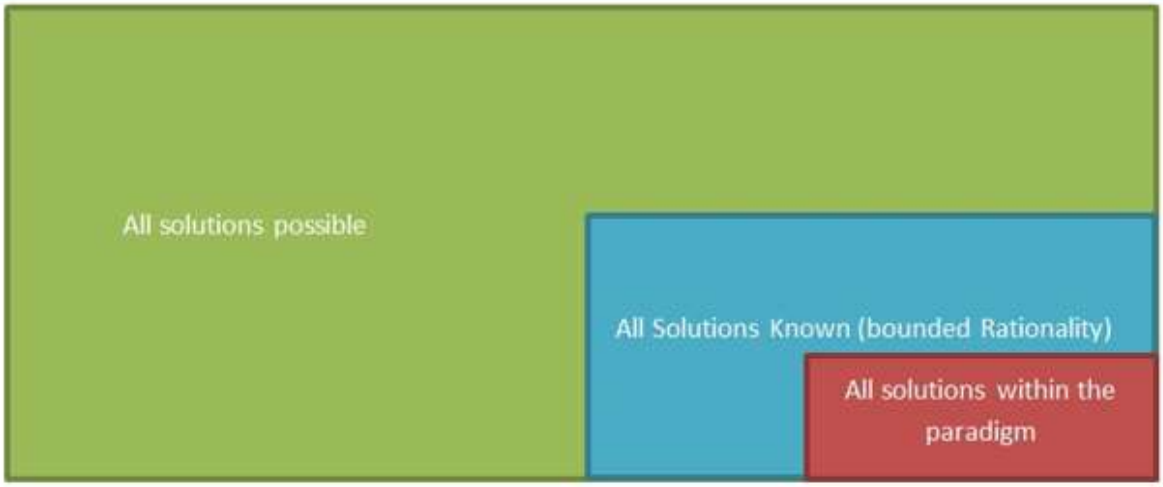
Source: Esping-Andersen (1990)

Lastly, the Liberal welfare state is characterized by its limited amount of collective facilities. Mainly the Anglo-Saxon countries are known for their liberal type government structures. The aim of the state is to intervene as limited as possible to ensure decent living conditions for those which can not suffice the basic needs without intervention. To acquire government support people must really be incapable of working themselves. The state assures only to the extent of minimal living conditions, different that those of equal condition as pursued by the social democrats. In a liberal state the markets distributes and the government is small. Taxes are low and government expenditures are small[46]. The state based on charity is about the same idea, however instead of having a centralized market to provide for distribution and care, the people themselves on a micro level have to take care for one another.

[41] Esping-Andersen, 1990
[42] Ira, C. (2012), p. 29
[43] Meyer, T. (2009), p. 59
[44] Jones, R.J. (2001), p. 243
[45] Ibedem.
[46] Wildeboer Schut, J.M. (200) p. 17

The different typologies are considered to be ideal types. It means that in practice they do not appear in their purest form. Rather can they be seen as a goal which governments try to achieve, but in practice they end up with hybrid forms, in which aspects from all ''worlds'' can be seen. Scholars have argued about the value of the theoretical model. Whether the model helps only with describing or also with explaining the things we see[47]. According to the author himself the answer is that model does more than just a describing an array of policies. The determination of the welfare state a country exhibits with its policy can be seen as an institutional force[48].

Figure 2.2: Bounded Rationality and The Paradigm limiting choice



His answer can be seen as confirmation for seeing a paradigm as a barrier to reform. The assumption is put forward that one's a welfare state is, or is being, built in a certain direction, towards certain ideal types, it will be hard to deviate from the path that is chosen. A corporatist like state is more likely to develop their policies the corporatist way, whereas the liberal state tries to solve its problems the liberal way. Simultaneously, we may state that if governments decide to change their direction, the new policies will significantly differ from the status quo. It's similar to the logic behind path dependency, a phenomenon I will discuss later.

2.3.1.2 The Regulatory State

In this thesis it will not be enough to identify the paradigm by looking at the organization of the policy. The questions which would be asked would be whether the policy is executed by the government itself and to which extent the executive layers are decentralized, whether the policies are executed by one, or more agencies, or whether the execution is done by the market. But asking these questions is not

[47] Arts, W.A., Gelissen, J. (2002)
[48] Esping-Anderson, 1994, p 712

sufficient. To fully determine the paradigm and its influence, we should also ask ourselves the question to which extent these actors have their own autonomy, i.e. decision making authority.

Levi-Faur describes the balance that governments try to find between being either a welfare- or a regulatory state. In the former, the government chooses to keep matters in their own hands; they collect public resources (Tax) and decide how these resources should be divided (Spend). During the early times of the rise of the welfare state, such authority was expanded. The government collected more resources and decided to provide more services. In later stages the welfare state became to be challenged. The costs for providing services started to rise, whereas the income from taxation started to decrease. Additionally, the environment became more complex, expressing the need for specialized personnel to tackle its challenges[49].

Governments started to give away more functions. Specialized agents, local and regional governments or market players were considered to be more efficient and effective in providing certain services. The governments gave away the rowing and remained to steer. However, over the years also the steering has been given into the hands of these specialized actors. Nowadays, the states are face with finding the right balance: what tasks to they want to keep doing themselves, what functions do they put in the hands of agencies or the market and to which extent do they give these agencies the authority to decide on these policies[50].

The question is how large is the cage in which the birds are allowed to fly. The bars of the cage are equal to the legislation which describes the functions of these agencies. It answers the question to which extent these agencies are free to fill in their functions; the higher the limitations, the bigger the regulatory state. In this thesis I will try to identify to which extent the national pharmaceutical policies can be typified as welfare state structures or regulatory states. Or as Levi-faur suggests: a bit of both.

2.3.1.3 The Principal Agent-Dilemma

Before, I would like to discuss a phenomenon which is strongly related to the neo corporatist approach and the regulatory state. As many of the countries have chosen to establish agencies as a mean for executing their policies I would like to investigate further on how the relationships between governments and these agencies can take shape.

Just like many other theories in Public Administration, the roots of the principal-agent theory are found within the science of business. Starting off with analyzing the problems which emerged between management and shareholders, Neo-Corporatism and New Public Management have brought the

[49] Levi-Faur, (2013)
[50] Ibidem.

theory straight into the public field. With the emergence of many autonomous government agencies, the study between the owners, and principals of the agencies (the government in most cases), and the management of the agency itself became of ever growing importance.

The main question which is to be answered is how the agencies are assured to act according to the will of the elected. According to Smith (1997) situation involving principals and agents identifies three phases: funding, transferring and spending. The first phase is most likely to be filled in by the central government accountable to the elected officials. The latter is executed by the health providers, the specialists, GP's, dentists, etc. For the second process an agency is often established in the Health Care Sector[51]. There are multiple ways in which the principal can increase his control over the agents' actions.

Problem

The model of Smith relates closely to that was developed by Niskanen in 74'. He identified that problems arise between bureaus (agencies) and sponsors (politicians, ministers), due to the interests and nature of bureaucrats (individual employees of the Bureaus). As for the sponsors, they have the absolute power over the supply of resources. This is caused by the traditional deviation of power which finds its foundation in Montisque's Trias Politica. However, the shortcoming of the sponsor is that he himself is not skilled enough to deliver public services in the most effective and efficient way. For that he needs the executive branch, consisting out of bureaucrats and bureaus. The bureaucrats are specialized in developing policies in particular fields. They possess the information the politicians are lacking[52].

Niskanen argues that 'the bureaucrats' critical advantage is their ability to propose new programs and expanded activities based on constituent information that is not available to reviewing sponsors'[53]. The interest of the bureaucrats causes them to abuse this advantage. According to Niskanen the bureaucrats are budget maximizers due to the fact that they pursue goals such as: 'higher salaries, perquisites of office, patronage, power, public reputation, output of the bureau, ease of making changes, and ease of managing the bureau'[54]

Pursuing these goals, the bureaucrats contribute to the interests the bureau as a whole is doomed to pursue; which is the maximization of its budget. After all, the goals of the bureaucrats require the bureau to attract more financial means to achieve their individual goals. Logically, this is not what

[51] Smith, P.C (1997), p. 1
[52] Blythe, E. L. (1983), p. 17
[53] Niskanen, W.A. (1975), p.27
[54] Niskanen, W.A. (1971), p. 22.

governments want to achieve with their pharmaceutical policies. The question is therefore how we can counter these bureaucrat interest, or maybe even better, make them of use. The literature gives us an array of strategies.

Competition

Lane argues that multiple agents can serve the principal in achieving control over his agents. The relation he finds corresponds with that of Anthony Down's struggle for votes by politicians in a multiparty system in which the agents (the politicians) adjust their preferences towards the preferences of their principal (the median voter). If multiple agents have to compete over the favor of their principal the principal may expect that his interests are served[55]. The negative consequence of implementing competition is that it eliminates cooperation between different agents[56]. Within pharmaceutical purchasing, this may mean losing the advantages related to scale.

Hierarchical monitoring

Hierarchical control is the most direct option for the principal. However, as the principal does not have the time or the knowledge to control the agent himself, he will need to hire a supervisor. This will mean that the hierarchy will at least consist out of three levels; a principal, and agent and an agent to control the agent. Miller stresses the principal to make sure that there is no cooperation between agent and supervisor. Strausz proved that a principal is always better off hiring a supervisor than trying to monitor the agent himself[57].

Involvement

Gailmar searches this control in the concept of Public Service Motivation. The theory suggests that, both on individual as on organizational, agents are more likely to act according to the policies of the principal, if they themselves are involved in making these policies[58]. ''When politicians reward expertise development in bureaucracies with an enhanced role in policymaking, agents who obtain utility from improving public policy will obtain unique benefits from public service, and self-select into it.''[59] In other words, the principal is better of involving the agent in the goal he sets. A practical example could be the establishment of institutional consultations between the agents and the principal.

[55] Lane, J.E. (2000), p.8
[56] Miller, G. (2005), p. 356
[57] Miller, G. (2005), p. 358, Strausz, (1997) p. 351
[58] Gailmard, (2010), p. 35
[59] Gailmard, (2010), p. 43

Bonuses

For decades bonuses were seen as the vital mean for ensuring the performance of employees. But the financial crisis has shown that these incentives have led to the neglect of long-term goals. The rationale behind bonuses is to link the achievement of the agents' goals to the achievement of the principals' goals. Agents are rewarded more of the resources they pursue as long as they realize more of the goals the principal pursues.

Discretionary budgets

Migue and Belanger elaborated on the budget maximizing behavior of bureaucrats. They made a distinction between budgets for output and managerial discretionary budgets. The former are the funds to realize the principal's goal, whereas the latter is open for the bureau to organize itself. The discretionary budget refers to the payment of staff and expenditures that are not related to fund the principal's wished output. The authors argue that it is merely this discretionary budget that the agents pursue want to maximize[60]. In order for the principal to keep close attention to the agent's actions, separation between the two budgets is of vital importance.

2.3.2 Path Dependency as Barrier to Reform

Besides the paradigm, previous policies can cause constraints for future policy development. Prado notes that, in practice, institutional reformers do not act freely, but rather they are bound by a context which consists out ''a complex set of context-dependent particularities'' which heavily influenced, if not completely, the historical development of the existing institutions. The existing institutions determine ''the nature and scope of feasible institutional reforms''[61]. The previous policies and institutional structures are the results of a (long) lasting period of policy-making within an existing paradigm. In this way they empower, enforce, guide and uphold this paradigm.

With this notion the concept of path-dependency is described. It simply says ''history matters'' when analyzing the policy making process. However, path dependency is not seen by all scholars as a theory. Elinor Ostrom argues that path dependency does not tell us anything about variables and relationships among them, like theories should. Rather, path dependency should be seen as an

Path Dependency: Decision-makers are bound by a context which consists out ''a complex set of context-dependent particularities'' which heavily influenced, if not completely, the historical development of the existing institutions. The institution determine ''the nature and scope of feasible institutional reforms''.

[60] Migeu, J.L., Gelanger, G, (1974)
[61] Prado et all, 2009, p. 349 -350

empirical category[62]. In this thesis I will consider path dependency as an important and influential theory which can help to find explanations on why governments did or did not reform.

Paul Pierson thinks so as well, he examined why path dependency has such an influence on governmental attempts to reform. Pierson concludes, like many scholars do about many social phenomena, that there is no clear and single-used definition about the concept of path dependency[63]. In an effort to clear the vagueness, Pierson analyzed multiple case studies to retrieve the mechanisms which go behind the influence of historical decisions.

As an answer Pierson finds himself developing the concept of ''increasing returns''. The concept is described by the fact that a decision maker is faced with (high) costs if he wants to implement his alternative policy idea due to fact that he has to stop with developing and using the existing policy. With it comes the fact that in most case, the longer a policy is already in use, the higher the costs are to abandon such a policy[64].

Example 2.2 - The Stock Trader and Switching Costs/Sunk Costs

The concept of ''switching costs'' can well be explained analyzing a stock buyer. Together with buying the stock come the transaction costs, let's say eight euros (Sunk costs). Ones the buyer acquires shares for 200 euro, he will have to pay an additional amount of eight euro's. Now after a month, the shareholder has seen his stocks drop in value to only 150 euros (severity of the crisis). He then realizes that his decision was not a right one. He develops the alternative, which is partly based on the advice given by his investment adviser and other investment managers (Size of mandate), namely to sell his stocks. However, when doing this he is confronted with the additional costs of eight euros of transaction costs. The transaction costs can be seen as his switching costs. When the shareholder now decides to not sell his shares due to the fact that he thinks the transaction cost of eight euros is too high, he made his decision on the basis of the ''switching costs'' remaining with the existing policy to keep his stocks instead of his own idea to sell them.

Policies require investments as institutions to implement, execute and enforce them have to be established. When a decision maker wants to exit the policy, with his decision the existing institutions

[62] Kay, A. (2005), p. 476
[63] Pierson, (200) 'Increasing Returns, Path Dependence, and the Study of Politics', p.252
[64] Ibedem.

will have to be lifted, be it reorganized, whereas new institutions will have to be established. The costs which are involved doing this can be considered the switching costs. Together with the switching costs come the possible ''sunk costs''. These are to be considered the costs of investment which were made implementing and developing the previous policies. As in the case of the shareholder, the transaction costs he paid for buying the stocks can be considered his sunk costs.

2.3.3 Institutions: The Existing Structures as a Barrier to Reform

A decision maker is obliged to follow certain procedures in order to implement his policy ideas. As I already showed before, the institutional structures surrounding policy-making are partly dependent on the ruling paradigm. In a regulatory state we speak of different institutional barriers compared to those in a welfare state. Procedures cause other actors to be involved in the policy making process, which requires the actual initiator of the policy to make sure that these actors agree with his ideas.

An example of a formal institutional barrier is that of constitutional control. In certain countries newly made laws are to be checked by the Supreme Court, or another independent institution, whether it does not conflict with the laws set up by the constitution. This procedure limits the decision-makers in their job. A decision maker has to take into account that his or her policy will fit inside the constitution if he or she wished it to be implemented.

Bannink & Resodihardjo refer to the phenomenon of veto points in the policy process when discussing the institutional barriers to reform. In this case a decision maker is bounded in his actions due the fact that other actors have the formal power to veto against the specific policy obeying the policy maker to make adjustments to his policy proposals. The role of structural barriers differs from country to country. Pollit and Bouckaert (2004) argue that countries organized according to the federal principles are likely to have more veto points than those which choose to maintain a much more centralized system[65].

The structural barriers to reform seem relatively easy to identify. The complex side of these barriers is to identify to which extent they really influence the policy-making process. Answering this question we might relate these barriers to the later to be discussed policy sub-systems identified by Sabatier and Peter Hall. Assuming that each structural barrier causes the decision maker to account for more actors to be involved, we may conclude that these actors are to express their opinion. The formal structures may be the perfect place for subsystems to emerge and more actors to join in.

For every veto point there is a chance that policies are stopped. This power attracts interest groups towards these stages in the policy process to influence those actors who have the formal powers to

[65] Pollitt, C., G. Bouckaert (2004)

achieve change. However, not only these actors but also time might cause actors to change their view on the policies. Structural barriers cause the policy process to slow down, giving the actors more time to gather information about possible effects or environmental changes related to the proposed policy. This will lead to more opportunities for actors to resist.

Mahoney and Thelen researched the effects of the veto possibilities and level of discretion on the nature of change which is likely to occur. With the level of discretion the authors aim at the capabilities of the administrative bureaucrats to influence the policy execution and implementation. Like earlier discussed by Niskanen the bureaucrats value their bureaus and the autonomy they have. They may be expected to try and protect it by resisting reform, if it endangers these values. If the bureaucrats have high levels of discretion, reform is harder to achieve[66].

This is also to see in the table below. The table was designed by Mahoney and Thelen and shows the type which is likely to happen if one analyzes the institutional context around the policy making process. As is seen reform is most likely to happen when administrative discretion is low and the number of veto points is small. Only in this case ''displacement'' is likely to happen[67]. In case of displacement ''existent power is undermined or discredited in favor of new paradigms'[68], saying nothing less but that radical reform takes place.

[66] Layzer, J. (2012), p. 23
[67] Layzer, J. (2012), p. 27
[68] Comodromos & Ferrer (2011), p. 333.

Table 2.4: Types of change & Institutional Context

		Characteristics of the political context	
		High level of discretion in interpretation and enforcement	Low level of discretion in interpretation and enforcement
Characteristics of the political context	Strong veto possibilities	Drift	Layering
	Weak veto possibilities	Conversion	Displacement

Source: Mahoney & Thelen (2010).

The authors also predict what is likely to happen if the external conditionals are not so favorable. Although, these will not be of great importance I will shortly discuss what is meant by these terms. ''Layering'' is the phenomenon in which politicians choose to place new policy on top of the others. If existing structures have proven to be too hard to abolish, politicians can choose to keep them in place, by implementing their new policies on top of them. The hope of this is that the new dynamics that emerge out of the two policies existing next to each other will eventually create a more favorable climate which will open the road to (transitional) reform[69].

The concept of ''drift'' is described as the change of goals and functions of the bureaus themselves. The bureaus (agencies) realized that they will have to change to fit in the environment. The policy, as well as the agencies, stays in place, but internally they change their strategies and focus on new goals. Although, drift is not to be considered reform, it can eventually be that spark that can start, or accelerate, gradual reform[70].

Lastly, ''Conversion'' is defined by Thelen as the process in which the goals and functions of institutions are changed. However, unlike drift, this does not happen naturally and/or by the institutions themselves. The change is implemented top-to-bottom. Conversion may involve the introduction of a new paradigm, in which new ideals are reached by the old institutions, which is likely to ultimately lead to transitional reform[71].

[69] Ibedem.
[70] Ibidem, p.334
[71] Ibidem.

2.4 Opening the Window to Radical Reform; Diminishing Structural barriers and Changing Paradigms.

Now we are familiar with the concept of reform we can continue with answering the question when it actually takes place. How can we overcome these barriers?

2.4.1 Kingdon: Multiple Streams Model

Kingdon asked himself the same question in 1984 and identified that reform could only take place when various constraints which before frustrated governments to pass through reforms would be diminished. The moment at which this diminishment reaches a sufficient value reform may take place as a so-called 'policy window' is opened.

According to Kingdon, for reform to take place there should a collision of three different streams. First of all there must be a Problem stream, a policy issue which is to be solved by the proposed reform. Besides there have to be options, the reform proposals/solutions stream, which are to be able to address, and solve, the policy issue. Lastly the politicians have to pay attention to the problem and the solutions, without their interest for solving the problem there will not be any support, and action, to implement reform.

Figure 2.3: Multiple Streams

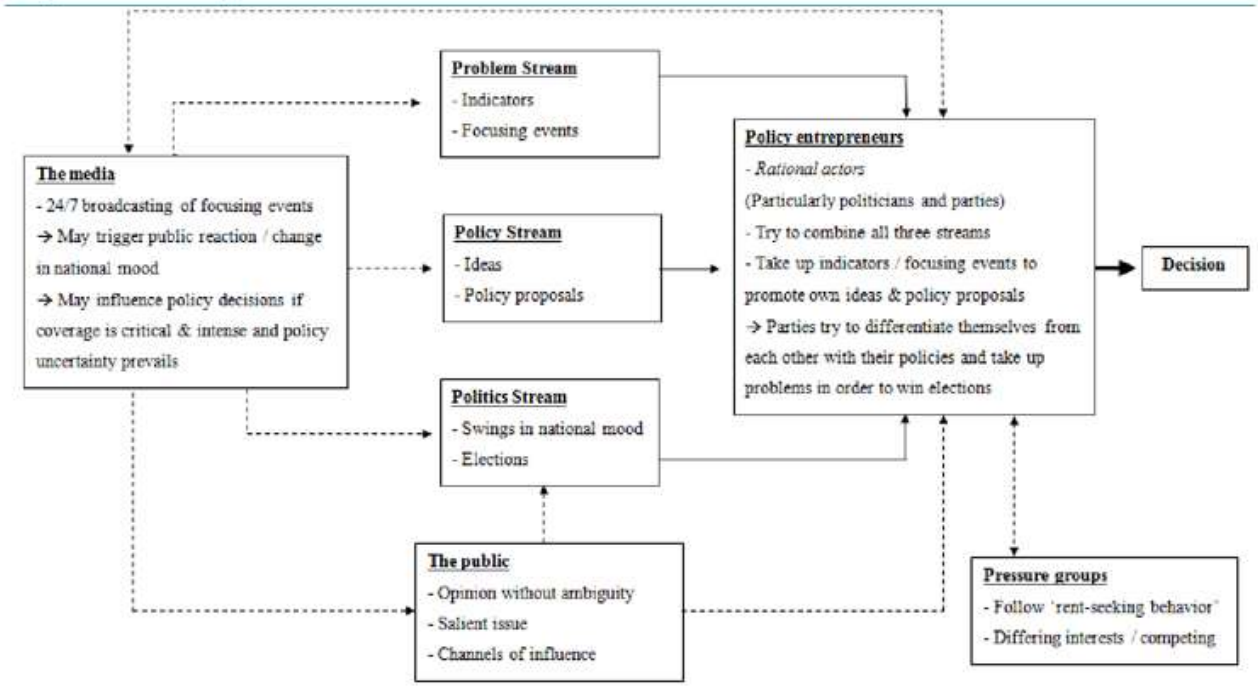


Figure 2.3 - Source: Henze, 2012

There are multiple variables which may influence the different streams. Figure 2.3 shows the most common ones. We can see the role of the media as a prominent variable which is able to influence all

three different streams. What is interesting to note is the nature of a problem. Problems can exist due to multiple reasons. The most obvious reason would be an actual problems, something which cannot be denied as ''being a problem''. An example could be an actual disaster or a war breaking out. In this case none would disagree that we speak of a problem. Problems may have also existed for longer than years but never been experienced as being a problem. In this case the media or maybe a whistleblower might be the ones to reveal and/or discover a problem.

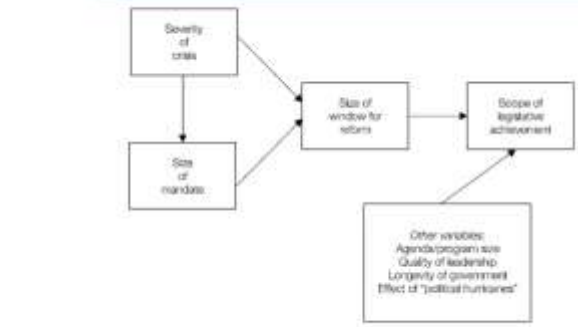
However, Problems can also exist without being problems. It may sound kind of strange but in this case it depends all on perception. People all have their opinions about problems and what causes them. If enough people agree on the cause of a problem it will likely end up that this cause is a problem. Even when in fact this causality is not proven. The same goes for solutions for solving problems. The actual effectiveness of a policy may not have been proven, but as long as people believe that it's the answer it is also considered as that. The media can play a decisive role in framing causality.

Keeler: two concrete variables which determine the appearance and properties of the policy window: a crisis (the Problem) and a mandate (the support for recognizing the problem and solutions).

2.4.2 Keeler: Mandate-Crisis Model

According to Kingdon there are two factors that determine if, when and how large a policy window appears: societal problems and political developments[72]. According to Keeler, these two factors can be transformed into two more concrete variables which determine the appearance and properties of the policy window: a crisis (the Problem) and a mandate (the support for recognizing the problem and solutions)[73].

Figure 2.4: Mandates & Crises



Source: Keeler, 1993: p. 230

Mandate

To start with the mandate side, Keeler identifies the political developments as shifts in the size of mandates governments have. The mandate can be defined as the amount of support governments

[72] Kingdon, J. (1984), p. 174, 182-184
[73] Keeler, J. T. S. (1993), p. 230

enjoy from the public and other stakeholders. Large, or a majority, support makes it easier for governments to reform. This relation between reform and mandate can be explained through multiple different mechanisms. Note that with the mandate we do not merely include the electorate, rather we speak of the support of all stakeholders involved.

The first mechanism which Keeler identifies is (1) the authorization mechanisms. A government's mandate creates the appearance that a government is authorized to make reform. Considering this aspect it is not important whether this is formally the case but mainly the perception of the public that it is. Vital concepts to this mechanism are legitimacy and credibility. (2) The empowerment mechanism actually looks at the formal side of power the mandate gives to the government. Normally speaking, a government that enjoys the support of the majority of the electorate has the formal power to create and implement policies.[74]

The last mechanism that Keeler identifies is the (3) party pressure mechanism. When a government enjoys a large electoral victory politicians may feel obliged to put forward reforms which they do not consider politically wishful. Especially in current times, in which populism plays a significant role in politics, promises during elections might go beyond reality. An example is that of Khrushchev during the Cuban Missile crisis. The Russian President, as for President Kennedy, were forced to find a solution to prevent the cold war from escalating. Both Presidents were bound by their electorate to keep a strong stance as they could not bear the consequences of showing weaknesses. Khrushchev was almost forced to continue provoking a war as retreating the Cuban Missiles would lead to Public Humiliation. Khrushchev was not lead by what he thought was best, but according to what his electorate forced him to do. Just to complete the story: In the end the presidents managed to avoid escalation of the conflict by a rather minor deal on the retreat of American missiles in Turkey in exchange for the retreat of the Russian missiles in Cuba[75].

The case shows that it could be that policies which politicians actually know are harmful, will have to be implemented due the pressure of the expectations they experience from their electorate. Populist promises are useful to practice the opposition role in the parliament and to gain support but at the same time hard to actually realize when practicing a coalition function.[76] Especially, charismatic leadership is viable to this rather dangerous influence.

[74] Ibidem, p. 234
[75] PBS, (2011)
[76] Keeler, J. T. S. (1993), p. 235

Crises

Societal problems develop themselves in a rather natural way. First, the situation exists in which certain information becomes visible to the public and policy-makers. As this information serves the interest of greater groups of people the public demand for action will start to grow. When the situation appears in which public demand is high, the politics will have to act by implementing new policies to answer the public. Keeler refers to such situation as a crisis. He himself uses the definition that is given by Flanagan for 37 this situation stating that this is a 'situation of large-scale public dissatisfaction, or even fear, stemming from wide-ranging economic problems and/or an unusual degree of social unrest and/or threats to national security'.[77]

A crisis can have an effect on the policy window according to two mechanisms. One way, can be through the effect a (1) crisis has on the political mandate. In this case the crisis indirectly affects the policy window. During the crisis the public demands alternative action, some form of action that deviates from what politicians have done before. The effects of the crisis mobilize the public to support alternatives. The politicians are then to respond to the public, trying to come up with the most popular solutions. In this way a crisis affects all streams: acknowledging a problem, demanding a solution and forcing decision makers to respond to the needs.[78]

A second influence of the crises follows through the (2) urgency mechanism. With this Keeler refers to the leeway a crisis give decision-makers to put forward change unnoticeable. During the crisis officials and public tend to lose their overview and control over decision-makers. A response is given by a package of measures, rather than a single reform. The decision-maker has the chance to present a package and with it include measures which might not be supported by his electorate at all. This mechanism is closely related to the (3) fear mechanism, in which people feel endangered and tend to agree with anything that answers their treat. I would see the attacks on 9/11 as example. As before the US was nowhere to be in for war, the newly used concept of 'terrorist threats' easily convinced both public to support two wars.[79]

Now if we look closely at the example (2.2, page) of the shareholder we can also identify the concepts which were identified by Keeler. Namely that severity of a crisis and the size of the mandate can determine whether a decision is made or not. The crisis in this case is the loss of value of the stocks. Each shareholder is willing to take a loss, however at some point they begin to lose their confidence, their losses are too high and they are forced to intervene. At the same time we also see that a size of

[77] Ibidem, p. 237
[78] Ibidem, p. 238.
[79] Ibidem.

mandate can be identified in the example. The shareholders are influenced by their fellow shareholders as well as the investment analysts. They give advice about the stock, now when the general opinion is that fellow investors and analysts believe the stock will rise, the buyer is also likely to buy the stock. Now in case when the stock starts dropping, analyst and fellow shareholders start to sell their shares. The shareholder now also thinks of following this strategy even though he has no certainty himself about how the value of the stock will change in the future.

2.4.3 Pluralism & The advocacy coalition framework

That policies are not just made by one person does not have to be explained. External factors might encourage decision makers to develop and implement reforms; however at the same time they do not give information about how multiple actors agree with one another on a certain policy. The multiple streams model and the model described by Keeler describe how and when certain policy issues end up on the agenda of the politicians. There are other theories that describe how the actual policy-making process takes place and when it is likely to succeed. In the following paragraphs multiple theories about the police process will be discussed, starting with discovering more about the concept of pluralism and positioning.

2.4.3.1 Pluralism and positioning

Anthony Downs (1957) realized that the economic theory on rational behavior could very well be applicable to the field of public choice. In his article ''an economic theory of political action in a democracy'' he analyzed and described how he saw political actors make decision in modern western democracies. Downs saw that ''every agent in the mode – whether an individual, a party of a private coalition- behaves rationally at all times; that is, it proceeds towards its goals with a minimal use of scarce resources and undertakes only those actions for which marginal return exceeds marginal cost'.[80] Downs predicted that ''political parties in a democracy formulate policy strictly as a means of gaining votes. Their social function – which is to formulate and carry out policies when in power as the government – is accomplished as a by-product of their private motive – which is to attain the income of power, and prestige of being in office''.[81]

However, prediction governments' decisions are not simply looking at the public's preferences. Instead, we would have to understand the view that political parties have about the electorate. According to the theory of down the parties express their preference on the basis of how many votes they will enjoy by choosing them. Analyzing the choices a government makes is not so easy; even though they are rational they are influenced by a process of political warfare between different

[80] Downs, (1957) p. 137
[81] Ibidem.

political opponents[82]. Downs sees the concept of politics as ''a marketplace in which leaders compete for votes''[83]. This phenomenon makes analyzing governmental decision making a complex task, but moreover it makes clear that a government is not just a simple single actor who decides. Instead governmental decisions may more likely be assumed to be a compromise, a result of negotiations between multiple actors.

2.4.3.2 The Advocacy coalition framework

But how do these actors behave, and how to they manage to get an agreement? This question has been asked by multiple scholars. Sabatier developed a framework for the analysis of plural decision making as he stated that before one can actually develop a theory for policymaking, one should first understand how the actors involved (governmental agencies, media, the public, interest groups) behave within the process. After extensive research Sabatier developed the Advocacy Coalition Framework (ACF) which was part of an academic movement which was to develop a new paradigm too replace the old paradigm based on the work of Anderson, Jones and Peters[84].

The framework can be considered a response to the shift of power in decision making away from just governmental institutions. Sabatier saw that to understand the policy process one should not only focus on a specific institution, or a specific actor, at a particular stage like the political scientist had been doing since World War II. Rather one should follow the road which public policy scholars had followed, meaning that it was important to look at all actors and at all stages of the policy process. The methodology of the public policy process was simply more complete and therefor more accurate. Sabatier blamed the political scientists for neglecting multiple aspects important to understanding the policy process, namely:

1. The importance of policy communities/networks/subsystems involving actors from numerous public and private institutions and from multiple levels of government;
2. The importance of substantive policy information;
3. The critical role of policy elites vis-à-vis the general public;
4. The desirability of longitudinal studies of a decade or more;
5. Differences in political behavior across policy types. (Sabatier, 1991, p171.)

The assumptions require us to take a closer look to some of the concepts which are used by Sabatier starting with the policy communities and subsystems.

[82] Ibidem.
[83] Hill, M. (2009) p. 52
[84] Sabatier, P.A., (1991) p. 147

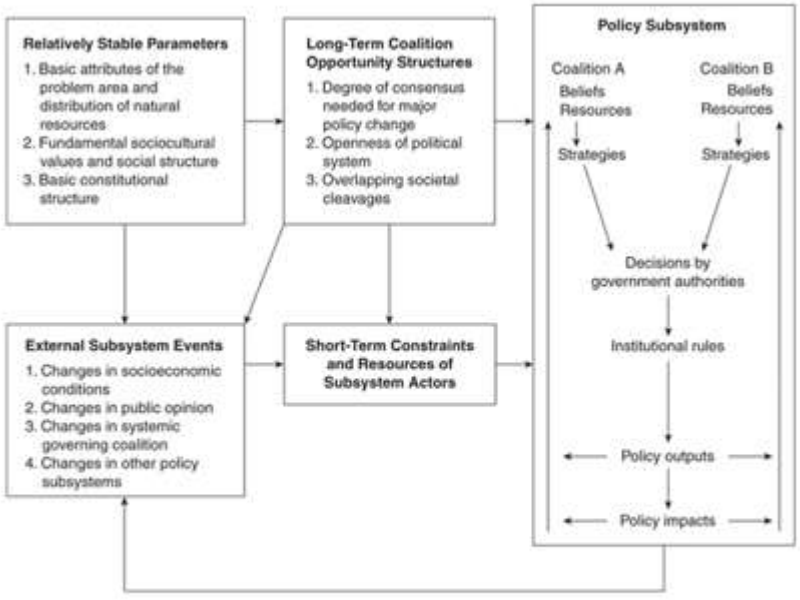
Policy communities, Networks & Subsystems

Sabatier refers to the lack of broadness in the perspective of policy research in the 50's and the 60's. After this period multiple scholars have demonstrated that policy development and execution involves a large number of governmental institutions, media, consultants, scientists as well as interest groups at multiple levels. 'Policy subsystems are defined by a geographic scope, a substantive issue, and a population of hundreds of active stakeholders from all levels of government, multiple interest groups, the media, and research institutions'[85]. In other words, Sabatier looks at all stakeholders who are involved in developing and executing the policy.

Sabatier: 'Policy subsystems are defined by a geographic scope, a substantive issue, and a population of hundreds of active stakeholders from all levels of government, multiple interest groups, the media, and research institutions'.

In an attempt to gain influence over the policy, the stakeholders seek coalitions and increase their support. The most influence is in the hands of the advocacy coalition, those that are able to uphold the policies[86]. 'Shared professional norms and ways of thinking are the glue that holds together a policy community, and ideas are at the core of Hall's explanation of policy change. When ideas are widely shared by an entire policy community, they can be called a paradigm. Some policy communities may well be dominated by a single paradigm, others may see competition, and others may see the replacement of one dominant paradigm by another.'[87]

Figure 2.5: The Advocacy Coalitions Changing



Source: Adapted from Sabatier, P. A., & Weible, C. M. (2007). The advocacy coalition framework: Innovations and clarifications. In P. A. Sabatier (Ed.), *Theories of the policy process* (2nd ed., pp. 189–222). Boulder, CO: Westview Press.

The stakeholders are in constant competition with one another to gain control over the public policies of their interest. They do this by working together in the policy networks. These policy networks are interactions between shareholders. The interactions may take place due to multiple reasons. First of all is due to the bounded rationality of actors. Just like as already discussed before, the world in complex and stakeholders do not know everything. Interactions take place in

[85] Sabatier & Jenkins-Smith, (1999).
[86] Weible, C.M., Sabatier, P.A. (2005). P.182
[87] Baumgartner, F. (2012) p.13

order to increase their knowledge of the policies at stake. With more information they are better informed and more convincing[88].

A second reason for interaction is to cooperate with other by exchanging personnel, financial resources or services[89]. Another reason can be to search for stakeholders that are willing to form a coalition, in an attempt to overthrow the ruling one[90]. Some actors seek interaction in an attempt to gain control over important means. In some cases this could mean that the actor lets go of his preferences in order to gain more power[91]. As for gaining support for your coalition, this can be done in two ways: either by exchanging favors or otherwise by convincing the other stakeholders. However, due to 'the sticky nature of ideas within policy communities: reframing an issue is not easy because you dealing with other experts within the community'[92]

[88] Ibidem.
[89] Ibidem.
[90] Salisbury, 1987.
[91] Weible, C.M., Sabatier, P.A. (2005). P.182
[92] Baumgartner, F. (2012) p.13

Example 2.3: Stock-trader and the Policy-Subcommunities

Also the process described by Sabatier I will try to make clear with a stock trade example. Imagine a large investment bank. This bank is ran by a board of directors who have decided to base their investment model on the basis of the paradigm of Technical Analysis. Below the board of directors there are multiple departments: the department buying stocks in energy, a department managing the stocks in food markets, another department focuses on technology, etc. In these sub-communities there are groups of analysts who try to increase the company's profit. The more profit they make, the more bonus they get.

Stock-trader A works on the department of energy stocks. He is not doing very well and one day he decides to try it another way. Instead of the technical analysis, he starts buying stocks according to the fundamental paradigm. After two weeks he starts making more profit than ever before. In order to increase the bonus his department gets, he wants to start convincing others to use the fundamental paradigm as well. Convinced by the results of stock trader A, his fellow department analysts start thinking fundamental as well. Profits start exploding now and the energy department is outperforming the others.

The fundamental paradigm seems such great success, that other departments want to use it as well. The board of directors starts to feel pressure. They can either choose to prohibit the department of energy's behavior and uphold their rules for using the Technical Paradigm, or they admit that their paradigm is inferior to the Fundamental and to change their rules supporting the new paradigm.

Choosing the latter makes this a great example of what Sabatier determines as the importance of sub-communities. The experts, bureaucrats or interest groups can convince coalitions on lower levels of their solutions, eventually getting enough support to pressure the top of implementing reform.

Change of Coalition: New Actors, New Beliefs

Actors actually changing their preferences are one way to manage reform and change a paradigm. However, there is also another way in which this can be realized. In this case, it is not the actual preferences of the actors that change, but the merely the actors themselves who change. Peter Hall does not take this into account when he talks about the social learning of policy actors, however Sabatier does in his ACF. He refers to a situation in which changes in the ''systemic governing coalition'' (Sabatier & Weible, 2007: 189-222) take place. Such a situation could be caused by elections. In this case, the actors are replaced, which could turn out to bring in a majority of actors following a different paradigm, or at least different beliefs.

The Political Environment
Reform as an answer to decreasing support or a change of actors

Otherwise, the advocacy coalition might change bottom-up. As for the general policy politicians decide, but as we saw before parts of a policy can be changed by different stakeholders who are involved in the policy in one of its subsystems. The stakeholders have two ways of achieving the change. One way is by gaining coalitions in as many subsystems as possible and changing parts of the policy to their wishes. Eventually these small coalition victories might lead the more general policy to require to reform. This is what we already saw when we discussed the concepts of drift and conversion. Logically, that this type of bottom-up transitional reform is more likely to be seen in political contexts marked by high levels of administrative discretion.

Another way is that the shareholders of the sub-communities immediately aim their efforts on the central authorities. They have to identify the processes trough which they can directly interact with central political leaders and convince them of their reform ideas[93]. Politicians often see bureaucrats', but also other stakeholders, as ''sources of creativity''. It is the aim of the stakeholder to use this status and convince central decision makers to form an advocacy coalition. The fact that the sub-communities have increasingly made use of these direct approaches, has caused the focus of scholars in comparative politics to shift from the formal decision-makers, like politicians and governmental institution, towards these communities of stakeholders when analyzing the process of reform[94].

2.4.4 Social Learning - Beliefs, Preferences and Interests

Now we know that particular actors have certain ideas. The question we can now ask ourselves is how these ideas change? Before we answer this question we might first start by explaining the difference between an interest and a belief. What first can be said is that both are variables that guide human behavior, rather than just ideas alone like Weber once told[95]. This view does not fit in with the rational choice theory, as it suggests that humans are purely guided by own interests. Instead we might state that the two concepts are interrelated with one another. Both are of influence, but which one comes first?

We already discussed the definition of a belief, but before we continue our discussion I would also shortly like to introduce the concepts of preferences and interests. The preferences of a person are based upon ones' beliefs. The preferences are the concrete wishes on how beliefs can be put to work. A liberalist believes in the power of the market, if he was to be asked on how high should be the levels for unemployment benefits, he would be likely to say as low as possible. This is due to the fact that he

[93] Walker, (1989) p. 8
[94] Baumgartner, F. (2012) p.13
[95] Goldstein, J. Keohane, O. (1993) p. 3-4.

believes that the market will take care that the unemployed will get work. Higher benefits will only cause the unemployed to not take any job the market gives them.

Now the interest is also based on the actual beliefs, however in this case there is also the influence of the context. A liberal may belief in the power of the market and together with this lower unemployment benefits and less government intervention. When the liberalist himself is unemployed, it would be more in his interest to want something else. This is also when the interest starts to differ from a preference. If the beliefs that you prefer do not lead to the maximization of what you actually want, you might want to choose to deny your preferences and start following your interests. In short, as I would like to explain it: the preferences are based on how you would like the world to work for everyone, while the interest is are based on the actual gains.

Goldstein and Keohane argue that the ideas are there to help an actor determine his or her interests. The beliefs, and ideas, help him to identify the causal relationships between ''goals and alternative political strategies by which to reach those goals''[96]. Simply said, the actors view the world through the glasses which consists out of their beliefs. He would like to see his goals achieved and therefor he chooses those interests which help him execute the strategy which he identified through his beliefs.

When actors are confronted with a clash between core interests and ideology, actors rarely chose to follow the latter and rather choose to pursue the former

However, Ideologies, or core beliefs can, and do, change. There are plenty of examples where actors switch from a liberalistic ideology to a conservative one due to changes in the environment[97]. Mahoney (2005) argues that when actors are confronted with a clash between interests and ideology, actors rarely chose to follow the latter and rather pursue the former. Huckfeldt repeat the assumption that the political behavior of actors is strongly influenced by the developments in the environment[98]. Now in this case we should not assume that the actual beliefs of the actor changes, merely does the actor neglects, be it changes, them for the specific situation as it is in his interest to do this. Now we know that believes can neglected as a result of interests, but these believes are also able to change themselves.

[96] Ibidem, p. 12
[97] Katznelson, I. Weingast, B.R. (2005) p.322,
[98] Epstein, (1997) p. 816.

Example 2.4: Stock-Trader example – Interest vs. Beliefs

The actual goals of a stock trader are to make profit. He tries to pursue this within his own paradigm. However, if this paradigm is not reaching his goals to the optimal extent, while a rivaling paradigm is clearly performing better, it is likely that the stock trader is prepared to let go of his paradigm and start to follow the other. This is an example in which his preference (or goal) of profit goes ahead of his ideal of following his paradigm.

According to Sabatier & Weible (2009:196-197) the main driver of human behavior in the policy process is the paradigm in which they believe. As long as the majority coalition believes in a certain paradigm, reform is unlikely to take place. The policy participants' thoughts are strongly influenced by their so called beliefs. These beliefs can change. The authors discuss how this change might take place. Just like discussed earlier, the actors in the policy (sub)-systems are guided by their preferences and, arguably, to a lesser extent by their beliefs.

Change in the beliefs could be the result of various causes according to Sabatier. In the ACF he refers to three of these mechanisms, although they all relate to influences from the environment. A first cause could be a change in socioeconomic conditions. In times of crisis or (un)natural disasters a government is often forced to (re)act quickly by pushing forward necessary policies which might differ radical from the existing ones. An example can be given after the bankruptcy of the American bank Lehmann Brothers. Although, at the time the paradigm in most modern western democracies was that of privatization and an open market related to the financial sector, the economic developments forced governments in some countries to support their banks by ensuring credit and in some cases even deciding to nationalize these financial institutions. During the time 'it was not credible to suggest that no changes were needed'[99]. The mechanism is very similar to that was identified by Keeler, who said that a crisis helps to enlarge a policy window.

The Socio-Economic Environment
Reform as an answer to a environmental changes

Peter Hall somewhat agrees with the critical path to a paradigm shift developed by Sabatier. He states that paradigms may shift as social learning takes place. Social learning involves a decision maker that learns from his or her environment by adjusting his believes to the context in which he operates. Hall seems to agree on the impact of the policy communities as he states: 'issues of authority are likely to be central to the process of paradigm change. Faced with conflicting opinions from the experts, politicians will have to decide whom to regard as authoritative, especially on matters of technical

[99] Baumgartner, F. (2012) p. 14

complexity. In other words, the movement from one paradigm to another is likely to be preceded by significant shifts in the locus of authority over policy'[100].

With this Hall also seems to refer to the importance of the advocacy coalitions. Whether a paradigm shifts is closely related to the position of those who have the authority to make the decisions. If this authorities shift, so is likely to be the case for the paradigm. The authorities who are empowered to make the decisions are what Hall identifies as 'venues'. The interaction between different venues helps to determine the 'image' that the venues have about the policy, their different beliefs. As the image of the venues changes, so does the legitimacy of who is to decide about the policy. The change of the image and the consequences it has on the policy and the balance of power can be entitled as the process of social learning[101].

Social learning can be seen as the reactions of the policy and its involved stakeholders make in response to the changing environment. What drives social learning is that which influences the image of the venues. Comparable to policy change, there are factors that stabilize the image, preventing change from happening, but also factors that facilitate changes to the image. Just like earlier discussed, social learning commonly takes place in incremental steps. The images that the venues have change slightly (only their secondary beliefs), as a reaction the venues decide to change the policy slightly (first order change), ultimately leading to minor changes in the balance of powers.

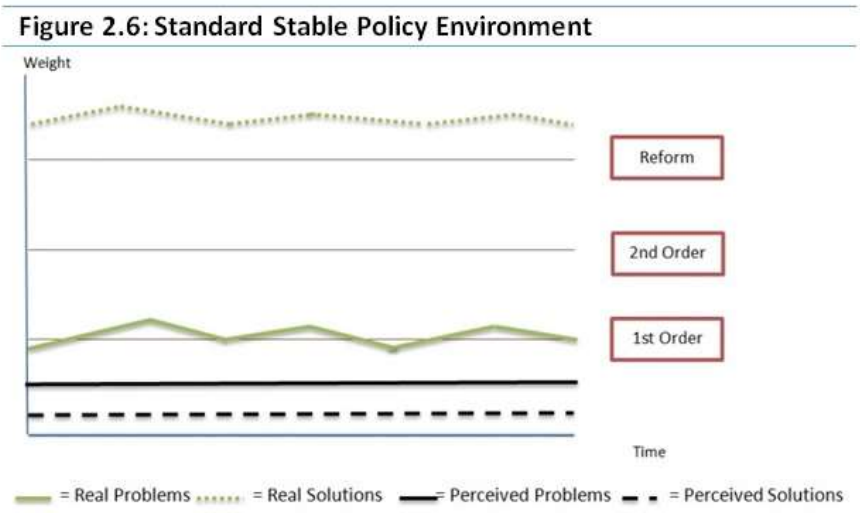
2.5 Synthesis: Creating the framework

After discussing all the concepts from paradigm to policy beliefs, social learning to advocacy coalition framework and barriers versus facilitators, I will give an overview of what was discussed and try to explain how I see all these theories related to one another. The result is that I developed a general framework which helps with analyzing policy change. The framework, which I call: ''the Policy-Perceptions-Framework '' (PPF), involves most of the core features of the variety of theories that have been discussed.

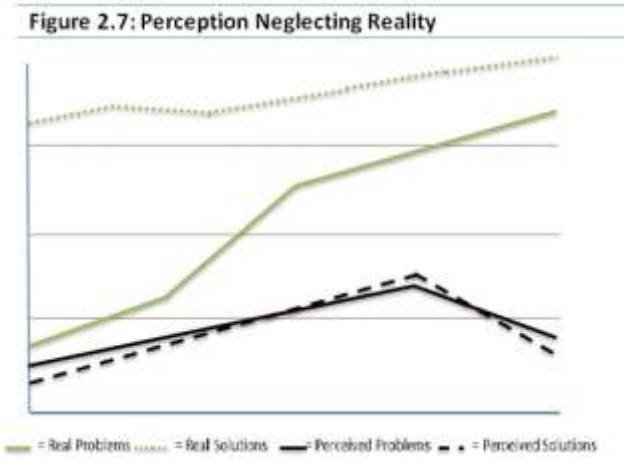
[100] Hall, P. (1993) p. 280
[101] Baumgartner, (2012) p.2

2.5.1 Policy Perception Framework

On the basis of the framework is the theory on the multiple streams which was developed by Kingdon. The PPF involves working from a model in which four main streams are present: the problem stream, the solutions stream, the perceived problems stream and the perceived solutions stream. The latter two replace the so-called political attention stream in the model of Kingdon and tries include the concept of the ''image'' the venues have, as identified by Hall. Besides this change, I also implement two determinants of the stream: the weight of the problems and/or solutions and the variable of time. In this way I do not see the streams as being randomly flowing in the political or institutional landscape. Figure 2.5 gives a graphic c overview of the foundations of the framework.

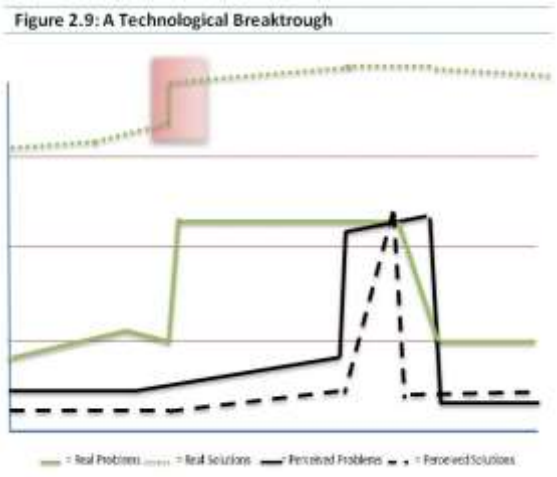


The red lines show the weight of the policy. The location of the lines which represent the real problems and solutions varies. The problem line is now located at the level that incremental changes of the first order, this means that the problems are relatively small and incremental changes could help lessen the problems. The solution stream is always high, as there are always an infinite amount of solutions possible. The perceived solutions is always at a lower level compared to the real solutions streams, as we should refer to what was discussed earlier that decision-makers are never to be considered rational, but instead considered to be bounded rational, due to the fact that they do not have the capabilities (time, brains and other resources) to identify all the solutions possible, let alone all of their effects.



Additionally, their perception is bounded by their beliefs. A decision-maker prefers to looks for solutions within his or her own paradigm, withholding him to consider those solutions that lay outside his beliefs. Lastly, his solutions are limited by the fact that many of them are not in his interest; it simply limits his gains, while he would rather prefer those solutions that do serve his interests. According to Downs, these interests for politicians are related to the votes and support he can gain by recognizing a certain problem and proposing certain policy-solutions. At a lower level, in the policy sub-communities, other interests are of importance. This may vary from financial interests like the budget expansion of bureaus to the advocacy coalition strategies which were described by Weible and Sabatier.

The same can be said for the real problems stream. Ones paradigm, interests and limited cognitive capabilities and resources makes a decision-maker want to 'choose' his problems. The judgment on whether a certain situation is a problem can be a normative one. A great example is that of extremely religious political parties in the Middle East opposed to those in favor of a secular state. Female oppression is seen by the latter as a serious problem and I think that we may agree that this is to be considered a real problem (stream). The extremely religious parties perceive this this way, due to the fact that it is their paradigm that guides them.

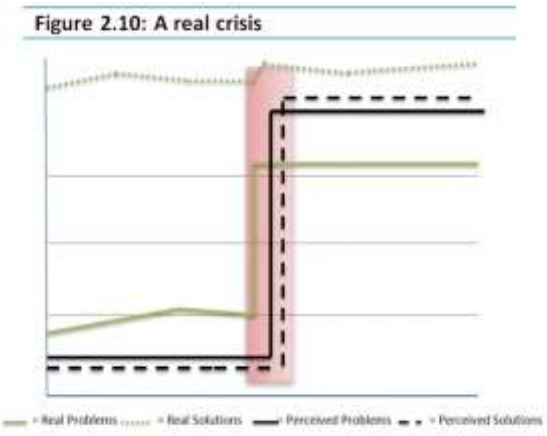


Here we also see the problem emerge that a paradigm can be a barrier to reform. Figure 2.7 shows the situation in which the paradigm makes decision-makers neglect real problems. The dark green line represents the real problems, in this example the violation of women's rights. The perceived problems and solutions lines do not see these violations as problems which need reform. In this case, they consider them problems which could be addressed by implementing only incremental reform. Figure 2.8 shows how this incremental reform takes place.

At moment 1 in the graph incremental reform takes place. The real problem stream does not have to be of influence in this, it is merely the perceived problems and solutions that matter and cause the first order change to happen. The decision maker recognizes that his policy is not optimal and requires third

order change. This change only happens if his solution stream exceeds the problems; at this point he realizes that a change of third order would solve the small problem which he identified. He implements that change, and the two streams, representing the perception of the decision-maker, drop down again to the levels in which no change is required. Figure 2.9 shows a similar situation in which the decision-maker realizes his policy can be improved by using the technological advancements that have taken place. Without adjusting the policy, it would not make use of these advancements, leading to a situation of underperformance (shown by the rise of problem stream before the 2nd order change took place in figure 2.9).

Figure 2.10: A real crisis

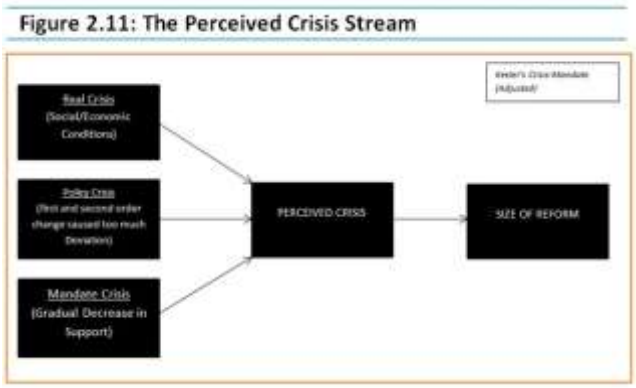


But do real problems not matter? Yes they do. Some real problems can simply not be denied due to their impacts. An example is the 9/11 attacks. Disasters require decision makers to act. Figure 2.8 shows the situation in which perception is consistent with the development of real problems. The rad cadre shows the real problems to grow significantly in very short time-period. Decision-makers are likely to quickly identify these problems.

In figure 2.10 I also tried to show the urgency- and fear mechanism which was described by Keeler. In the figure it shows that the perceived problems are far larger than the real problems. Now part of this can be nature of decision-maker, due to their bounded rationality they may tend to overestimate problems, however as we saw, it could also be in the interest of the decision-maker to exaggerate his perceived problems, due to the fact that people are less likely to be critical towards reform proposals, this way he can realize reforms, kind of ''unnoticeably''.

In this case I expressed this by raising the perceived problem stream, however it might also be an idea to add additional streams, namely the ''expressed perception of problems'' and ''expressed perception of solutions'' streams. This could cover a more detailed explanation for the use of framing methods to convince stakeholders of policy ideas.

Figure 2.11: The Perceived Crisis Stream



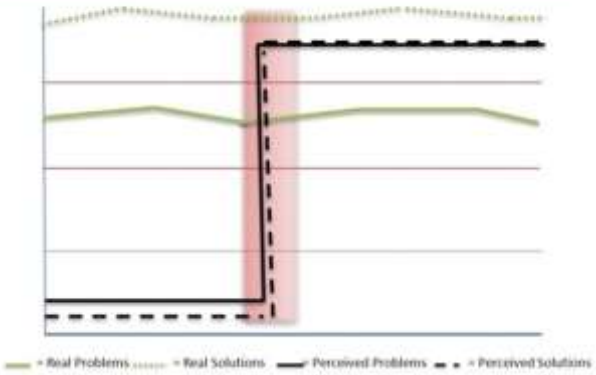
With the involvement of the stakeholders we may continue by discussing the mandate function as well. As Keeler talked about two variables which determine the possibility to

reform: the crisis and the mandate. At first glance, it looks as if only one of the variables is represented in the model, but this is not the case. The mandate function is included in the perceived problem stream of the model. I do not see the mandate function as a separate variable; rather I see it as part of the perceived crisis (Figure 2.11). It might best be explained by the fact that I consider the perceive problems not only as problems that could be related to the nature of the policy and the effects it has. The perceived problem stream also consists out of the political stream, to which a decision-maker will see himself forced to act strategically.

That the mandate function does not have influence on the real problem stream is shown in figure 2.12. The figure shows the case in which a landslide victory has taken place in a country. In this case it is an extreme example in which a new government, acting within a radically different paradigm compared to the previous government, takes over. The figure shows that the real problem stream does not change, as this stream is (largely) not determined by the political context, but rather by the economic, social and environmental context. The figure shows that a government with a completely different paradigm might see problems that need reform, whereas the old government did not recognize this as problems at all. From then on, reform is still likely to take place, even if the real problem stream does not require reform.

change is the result of a decision-maker's reaction to: (1) Perceived real crisis, (2) a Perceived policy crisis or (3) a Perceived mandate crisis or, most likely, a combination of these.

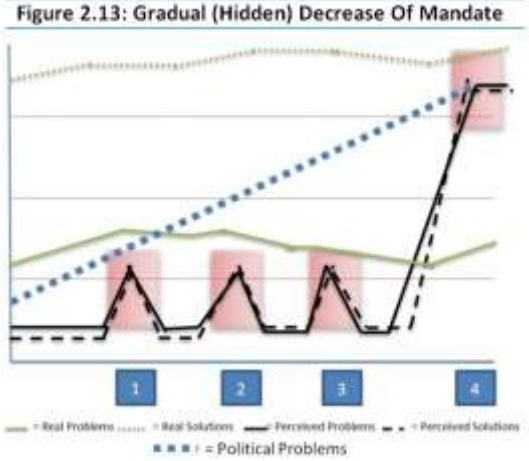
Figure 2.12: A Landslide Victory/Mandate Change



For what we have learned from the Advocacy Coalition theory, it is not necessary for elections to take place in order for change to take place. Especially, third order changes can be largely dependent on the actual behavior of the policy sub-communities on the lower levels. Eventually, the policy communities might realize reform with their efforts. This can be reached in two ways. Either by realizing enough third order changes to convince decision-makers to follow up with reform. A discrepancy between execution and general policy demands an adjustment from either one, in order to make the policy consistent again.

But stakeholders, even those who are not functioning as executing agents, may convince parties with decision-making authorities, on all policy levels, to start supporting their policy ideas. By creating and expanding coalitions they try and create a political problem, taking away the advocacy coalition of decision-makers', mandate. When the Advocacy coalitions starts realizing their shrinking mandate they are likely to react with change in order to regain their coalition strength. Whether this regaining requires first, second or third order change, depends on the strength of the opposing ''convincing''-coalition and the amount of time that has passed until the advocacy coalition acts. This could make it useful for opposing coalitions to try to expand their policies and support little by little, this way they keep their actions out of the decision-makers sight. Figure 2.13 shows the procedure.

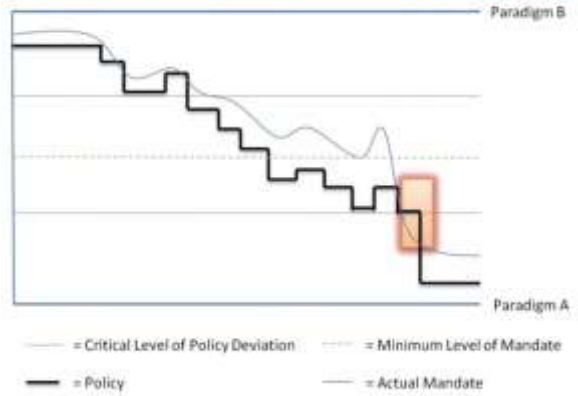
Figure 2.13: Gradual (Hidden) Decrease Of Mandate



The figure shows the additional stream of political problems. Political problems are related to the mandate that advocacy-coalition (the ruling decision-makers) have. Policy sub-communities can often realize small policy changes. The small changes are represented by the numbers 1, 2 and 3. These changes can either be in line with the ruling paradigm, but can also represent changes that are part of a different paradigm. The example could be the instruments that an agent uses in order to achieve the goals of its principal.

If the policy sub-community starts moving in another direction by implementing small reforms, or by starting to support different ideas, the bleu stream of Political Problems raises. Alternative incremental directions could cause the rationale for executing the policy to become significantly different from that behind the general policy. If the policy sub-communities start to more and more support these changes, the advocacy coalition may lose its majority support. Then it is up to the variable of time and the strength of the advocacy coalition's reaction to respond to the political problem of inconsistency and/or the political problems of shrinking support. At point 1 in time, the advocacy coalition recognizes the problem in time, being able to regain their support and/or diminish policy inconsistencies by incremental changes. If they do not notice the changes in time, and the blue line continues to rise, the decision-maker realizes that he has to respond in order to restore these consequences. Point 4 represents this situation, in

Figure 2.14: Gradual Policy Deviation/Incremental Changes



which the perceived problems remain low, while the political stream is in fact rising. At point four, the decision-maker realizes the stream, in which his perceived problems have become these political problems. In this case his only option is to respond with reform. Policy shifts have been caused bottom-up, expressing the importance of the policy sub-communities role.

In Figure 2.14 I try to show the influence of policy deviation by incremental reforms and the influence of mandate once again. The small vertical changes in the policy line represent incremental reforms. The two red lines on is the maximum extent a policy can deviate from its existing point until reform is the only option left. The decision maker enforced his paradigm, while the executing (sub-) communities are acting according to a new paradigm. At a certain moment the decision maker has no choice but to adjust his policy towards the attitudes of the (sub)communities on which he depends for effectively achieving his goals. This certain moment is what I identify as the 'critical level of policy deviation'; the moment at which the decision maker realizes that he is forced to adjust his policies towards the paradigm of the gradual developed new policies, as fit is obvious to him that leaving the paradigm would lead to better results.

We see the line of the political mandate change consistent with the line of the policy. This relation is likely to be seen, as more and more the stakeholders are realizing and supporting the new adjustments that have been implemented, especially if the gradual deviations are perceived as superior in relation to the previous policies of existing paradigm. To sustain a paradigm, the decision-maker will have to stay above the minimum level of support; the advocacy coalition has to remain dominant over the opposing coalitions.

The figure (2.14) makes it seem very simple, however as we have seen in an earlier stage, there is not just the forces of Paradigm A and B, in practice we see often multiple paradigms (Esping- Andersen's Welfare States) between which the policies and mandates can flow. A streak of incremental changes could be the result of so-called 'policy learning' which 'denotes the process by which policy makers and stakeholders deliberately adjust the goals, rules, and techniques of a given policy in response to past experiences and new information'[102].

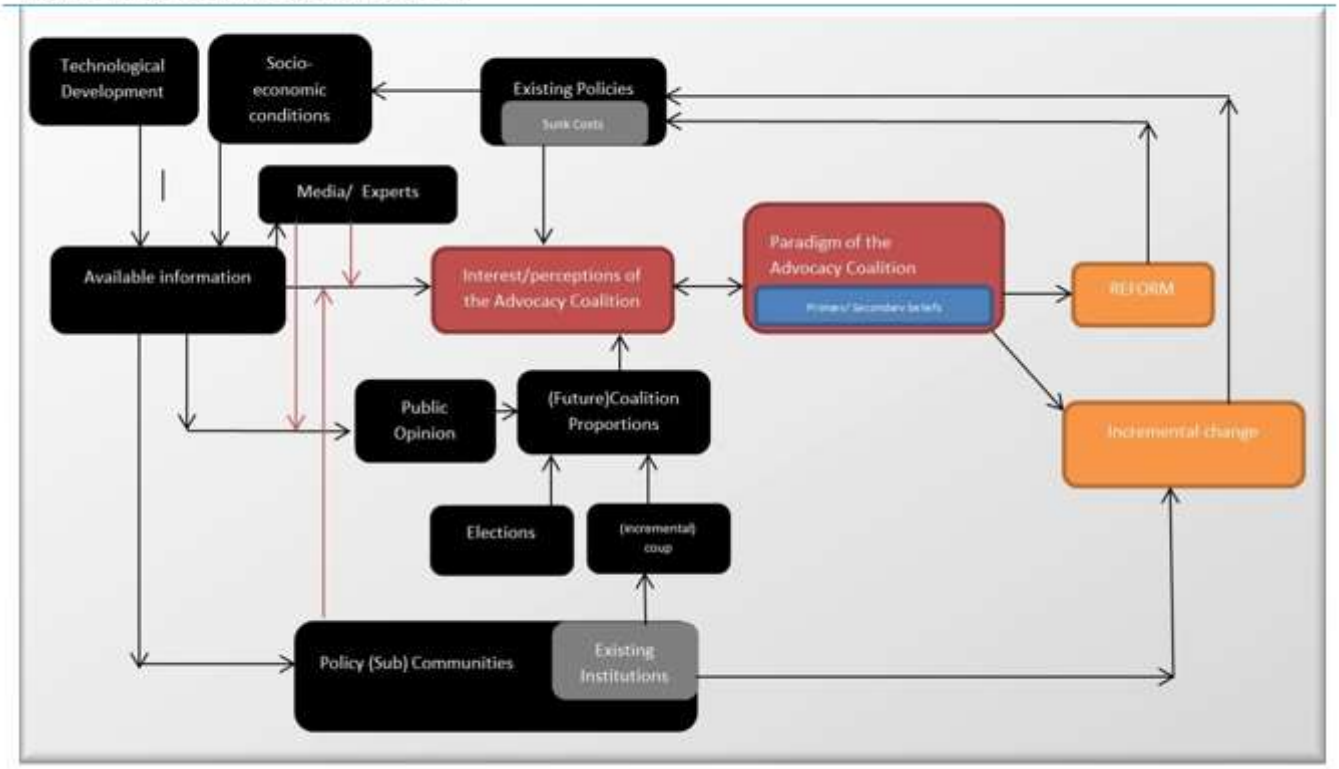
2.5.2 What influences the Perceptions?

So far I have tried to make clear how perceptions are of importance for policies to change (or remain the same). The question that is next is how the perceptions change. As we have seen in this chapter before, this is part of the process of social learning. In this way I would define social learning as the movement of the perceptions stream. As the decision-makers learn from their environment, they

[102] Helderman, J.K. et all (2005)

adjust their interest and, indirectly, the value they attach to their beliefs. In the figure (2.15) below I try to explain which factors and processes determine the interests of the decision-makers.

Figure 2.15: Variables to Reform.



At the foundation of the framework is the assumption that a decision maker is constantly struggling between his interests and his beliefs. Without changing both, no reform will take place, as is also to be seen in the framework. The question emerges which one of these principles dominates ones' choice. In answering this question I choose to follow Mahoney. When one is confronted with a clash between interests and ideals, most likely a decision maker chooses the former. However, for reform to take place, we saw that paradigms will have to shift, for change to take place we learned that beliefs will change also. As seen in the framework, reform will not take place if the paradigm does not change, as for incremental change does not take place if the primary and secondary beliefs do not change.

Whether an actor chooses to let go of his core, primary or secondary beliefs, he does this because it is in his interest to do so. These interests are influenced by multiple variables which have passed in review during the discussion of the multiple theories. As was stated before when we discussed the theory of Anthony Downs, politicians base their decisions on their self-interest of votes. This variable is shown in the framework as **Public Opinion** and the **Expected Proportion of the Coalitions.** At the same time these variables represent the theory of Keeler that mandate determines the chance of reform. Besides they represent the theory by Sabatier in his **advocacy coalition**, in which he assumes

that reform may be caused due to a shift in the systematic governing coalition. I argue that this can also be achieved when the advocacy coalition expects (perceives) a shift of governing coalition, as they want to prevent this, they would be willing to reform.

But the **Advocacy Coalition** can also change by gradual force which is started by the stakeholders in the **policy (sub-) community**. As they gradually increase support within the communities for their ideas, this might change the proportions of the coalitions, slowly leading to the opposing coalition, becoming more powerful, or they even might be able to become the **new advocacy coalition** (**coup)**. Once again, the advocacy coalition might act prior to this, by signaling their loss of support. They might respond to it by introducing first or second order change in an attempt to stop the coalition from shifting.

But the policy communities have more tools to reach reform. As I said before, they may also try a policy crisis. In this **case the policy community** uses the decision-making discretion it has in order to achieve as many **incremental reforms**. The incremental reforms express themselves in the **existing policies** which limit the options of the advocacy coalitions as we learned by discussing path dependency. The incremental reforms create a path that deviates from that of the original paradigm. If the advocacy coalition reacts in an early stage, they may be able to correct the deviation by implementing first and second order reforms back into their preferred direction. If they are too late, the advocacy coalition is too late and the deviation is too large, they have no choice but to reform their policies into the new direction that was set by the policy- communities and could mean a completely different paradigm.

And then there is also the last option for **the policy (sub)communities** which is to directly try and influence the interests of the advocacy coalition. This is represented by the arrow that connects the policy community to the arrow that is between the available information and the interests of the advocacy coalition. This arrow tries to make clear that the community tries to influence what the advocacy coalition perceives from the total amount information available. The community would like to see this perception of the advocacy coalition to be the same as their own.

The same goes for the **media and the experts**. One could argue that these are part of the community, but I would like to see them apart as they are also putting efforts to influence the perception that the public has about the world (the information that is available). That is why there are red lines directly connected to the lines between advocacy coalition and available information and the public and the available information. Key is that media, experts, communities and public get their information directly from their interpretation of the environment and that they all would like the advocacy coalition to have this same interpretation. The media, experts and communities do this by directly trying to

influence the decision-makers, whereas the public has the tool to do this with giving, or taking, their **electoral support (the decision-makers' mandate).**

Lastly we see the information of **technical developments and socio-economic crisis** these naturally change the information that is available. They change the size of problems and the array of solutions, it is up to the actors to perceive and act to these changes.

2.6 Research Questions

As the theoretical framework is created to give guidance to my research it will be wise to formulate a list of key questions which need answering. The questions will contribute to answering the central research question which was put forward in at the end of the previous chapter.

1. *What existing policies and what institutions are in place?*

Answering this question I will analyze the existing institutional system which is built around the pharmaceutical policies. Goal is to identify to which extent the institutional system of Hungary would have to adopt in order to implement the alternative options. Assumption is that the more change is necessary the more difficult reform will be. Especially, due to the fact that the existing institutions will try harder to keep their place and meaning, more resistance may be expected.

2. *What are the results of the existing policies*

To take into account the process of social learning, I will try to analyze the results of the existing policies. The rationale behind this is that social learning is likely to occur when the results of the existing policies are perceived as negative. In this case governments are more like to search for, and adapt, new alternatives. The effects of the alternatives may be seen as a form of new information on the basis of best practices.

3. *What paradigm is in place?*

To answer this question I will use the welfare states that were identified by Esping-Anderson as well as the regulatory- vs. welfare state distinction put forward by Levi-Faur. In general I will identify the paradigm which lies behind the general Health Care Policies. Consequently, I will try place the existing pharmaceutical policies within the welfare state spectrum and identify how these specific policies relate to the general Health Care Policies. The assumption is that countries with similar paradigms which are close each other are more suitable to take over policy alternatives from one another, than countries with alternatives which are located in completely different paradigms.

4. *How was the paradigm established?*

To answer this question I will put efforts into research the historical backgrounds of the general health care- and pharmaceutical policies in the three different countries. The idea is to identify the developments and overall trends in the health care policies. The assumption is that previous made policies determine the possibilities for future policies.

5. *Who are the stakeholders in the existing policy? What is their view on the policy? What is their influence? How do they execute the policy?*

These three questions refer to the earlier discussed advocacy coalition framework. The idea is to identify the stakeholders and what role they play in the existing policies. The public will be included in this analysis as well as the media. Simultaneously, I will research the mandate they represent as well as the institutional pathways they are able to follow in attempt to influence the policy process. The assumption is that in a system where there are many influential opposing parties with many abilities to influence policy making, it will be much harder to realize reform in the form of the policy alternatives of New Zealand and The Netherlands.

6. *What is the relationship between the Government and the Actors who execute the policies?*

In line with the discussion of the Principal-Agent theorem, I will analyze the relationships between the government and its intention regarding the existing polices and the relation it has with the actors who execute the policy. As we saw earlier principals have multiple strategies and tools to structure their relationship with the executing agencies in attempt to keep control over policy processes and results.

7. *Is reform needed? How can changes take place?*

The last question is a question which combines all the information from the previous question. It involves finding out whether reform is possible, but as well whether it is needed. If there is not option for reform, could the existing policy in Hungary learn from the policy alternatives from the two other countries by making possible incremental adjustments?

3. Methodological framework

THE METHODOLOGICAL FRAMEWORK GIVES answers to the concrete questions on: how, Who, When, And where this research will take place. This chapter should give the researcher the answer what methods should be used in order to give the best answers to the research questions that are set, which ultimately leads to achieving the research objectives.

3.1 Two parts: Quantitative and Qualitative

As earlier already discussed in chapter one, this research will be split into two parts. The first part will cover a comparative analysis of the quantitative results and requirements of the different policies, whereas the second part will entail further research into the foundations, developments and environments of the policies. The following paragraphs will start by explaining why this research is split apart.

3.1.1 The concept of best practices

In the qualitative part I will try to find out if a policy is feasible for implementation. A policy can be very efficient and effective in a particular country; this does not mean it would also do well in another country. To implement best practices one has to look at a countries context and time[103]. Best practices are relative[104] which makes it complicated to find the right ones[105]. Culture is of major influence to whether a best practice, or public policy, is effective or not[106]. Over the years Public administration has managed to identify a large amount of methods which can help us to compare and rank different policies on the basis of the results; however many times these rankings forget to explain to which extent these results rely on favorable environments[107].

In short: what is a best practice is determined by the performance of the policy and the context of the country that wants to implement it. De Vries identifies the concept of best practice as ''processes and activities that have been shown in practice to be most effective, efficient, democratic or whatever goal intended[108]''. To which these goals are achieved is highly dependent on the countries context.

That brings us to two objectives. The first one is to identify whether the different alternatives have proven to be best practices in their own countries. Secondly, we have to answer whether these alternatives could also be implemented in the Hungarian context, whether they are likely to perform just as well. The First objective will be aimed to fulfill by the Impact Assessment, a quantitative

[103] M.S. de Vries (2010), p. 2
[104] Löffler, (1999), Andrews, (2008), M.S. de Vries (2010), p. 2
[105] M.S. de Vries (2010), p. 2
[106] Löffler, (1999)
[107] M.S. de Vries (2010), p. 4
[108] Ibidem. p. 3

description of the policies and their results. The second will be fulfilled by the qualitative exploration of the political, institutional, economic and social contexts of all three countries.

3.1.2 Data Collection: reliability and validity

In order to perform a RIA there will be a need for data. The necessary data will be searched in literature and databases. Important for research are the requirements of reliability and validity. The former involves that the research can be repeated, with similar methods, without getting different results. To make sure that this is the case, the researcher has to make use of reliable data from trusted sources[109]. To make my research out most reliable, I have solely made use of renowned databases. Most of the information comes from the OECD, Eurostat or World Health Organization; large independent research organizations with reliable reputations. For data that was more specific of kind, I choose to make use of government supply. Ministries and government agencies have provided me this data.

The validity concerns whether the used data gives answers to whether the research 'measures really that what is intended to be measured'[110]. Using the right methodology can assure the researcher that his results are valid. Proven methods and objectivity can make sure that the results that are gathered also reflect the truth. In this sense validity requires the research to be reliable to begin with[111]. According to Patton improving the validity of research can be achieved by combining multiple methods of research, instead of using only one. "Triangulation strengthens a study by combining methods. This can mean using several kinds of methods or data, including the use of both quantitative and qualitative approaches"[112]. By combining both types of research in this thesis, I have tried to maximize the validity of research.

In the remaining of this chapter I will elaborate on which methods I used to perform my research. Starting with discussing the procedures related to performing the impact assessment for the quantitative part. I will consequently discuss on the methods I used to complete the second and qualitative-like part.

[109] Golafshani, (2003), p. 598
[110] Joppe, (2000), p.1
[111] 't Hart, H, Boeije, H., Hox, J. (2009)
[112] Patton, (2001), p. 247. Golafshani, (2003), p. 603

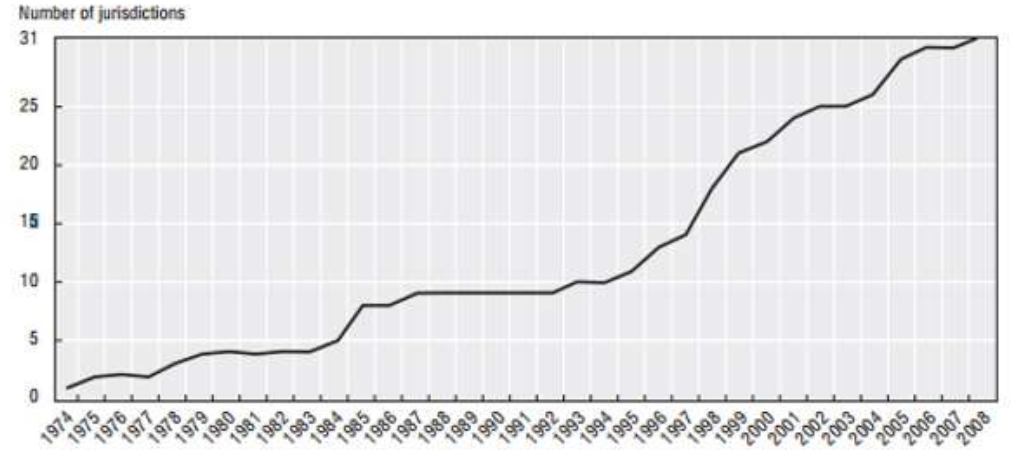
3.2 Quantitative Research: What are the results?

The first part will be of quantitative nature. The quantitative approach it is central to find characteristics in which groups differ from one another. To do this, the approach makes mainly use of numeric data. This data makes it easy to measure results and compare different groups with one another[113]. The results of the quantitative analysis will be presented in the next chapter.

3.2.1 The Regulatory Impact Assessment

The Regulatory Impact Assessment (RIA) is a widely accepted tool for comparative policy analysis. In the last thirty years the use of the RIA has grown exponentially (see figure 3.1) whereas in many countries the use of the tool has been formally required by law. The figure below shows the results of research efforts performed by the OECD stating the number of jurisdictions within their field of research which adopted the use of RIA as a formal requirement in public policy process, which includes the planning, implementing as well evaluation of public policies.

Figure 3.1: The use of RIA over the years



Note: This represents the trend in the number of OECD juridictions with a formal requirement for regulatory impact analysis (beyond a simple budget or fiscal impact).

(Figure 3.1, OECD 2010)

Although, the idea of the Regulatory Impact Assessment is single-minded: comparing multiple policy alternatives, in practice the incorporation and execution of the RIA has shown to differ among countries as well as institutions[114]. Between 2002 and 2005 the European Union has started with the institutionalization of the tool among its intuitions. Starting with the introduction in 2002, when it was to replace single-Sector type assessments, it identified the consequences of new European laws and policy designs in the fields of environment, society as well as economy. In 2005 the EU adopted a

[113] 't Hart, H, Boeije, H., Hox, J. (2009)
[114] OECD, (2009), p. 15

''common approach'' for all its institutions stating a list of so-called ''traffic rules'' to which execution of the RIA by its institution should comply in order to maintain a coherent legislative process[115].

How to perform RIA?

As a result of the growing popularity of the RIA multiple methods have been developed to perform it. In this thesis I will make use of the common approach which was adopted by the EU consistent to the guidelines which were prepared by the commission in 2009. The document states that in order to perform a thorough comparison through RIA one is advised to structure his or her research according six analytical steps (See table 3.1).

Table 3.1: Steps in the Regulatory Impact Assessment

1. **Defining the problem**
   - **Define key actors**
   - **Defining the nature and extent of the problem**
2. **Define the objectives**
   a. **Defining the parameters**
3. **Define the different alternatives and the status quo**
4. **Analyze the impacts of the different policies**
   a. **Economic**
   b. **Social**
   c. **Environmental**
5. **Compare the options**
   a. **Rank the options**
   b. **Identify the preferred option**
6. **Outline policy monitoring and**

Source: based on EU Commission model

Ex-post vs. Ex-ante

The Regulatory Impact Assessment was institutionalized by the EU as formally obligatory in policy development process. This means that the RIA is considered to be an ex-ante policy tool, in which policy alternatives are compared in terms of predictions of possible impacts. Much can be said however that the impact assessment can much be based on alternatives of existing policies as well. In fact, might one state that RIA always shares a part of ex-post in it as it determines the effects and impacts the status quo inflicts if it was to be upheld.

In this thesis I will perform an ex-post impact assessment as I compare different policy alternatives which are already implemented in various countries with one another. In this case the assumption is made that the impacts a certain policy inflicts in one country would have similar potential

[115] European commission (2008)

consequences in the other countries. This assumption lays on the foundation for the fulfillment of a most-similar case-study design.

Most Similar Case-Study and other explanatory variables

The ''Most Similar System'' design is a commonly used method by social scientist in comparative analysis. A most-similar design is based on the assumption that ''systems as similar as possible with respect to as many features as possible constitute the optimal samples for comparative inquiry…Common systemic characteristics are conceived as ''controlled for'' whereas inter systematic differences are viewed as explanatory variable… The number of common characteristics sough is maximal and the number of not shared characteristics sought, minimal' '(Prezwoski, 32-33).

The question is whether we can speak of a most-similar case-study if we compare the countries of The Netherlands, New Zealand and Hungary. The answer to this question would be logically: 'No'. We may state these countries are similar to the extent that they are fairly to well-developed western democracies. The consequence of this lack of similarity is that it will be my task to identify the factors that could eventually influence the impacts of the alternatives. Some of these impacts will be elaborately discussed.

What is of key importance is to identify to which extent pharmaceutical polices can contribute towards lowering medicines. This means structuring the pharmaceutical market. However, just like with many products there are more variables which determine prices. In the end, price is largely determined by the effects of demand and supply. Larger quantities would be expected to help achieve lower prices. Table 3.2 shows the variables that may contribute to lower pharmaceutical prices, but for which the effects are not researched in this thesis.

Table 3.2: Explanatory Variables Outside this Research			
Variable	**Hungary**	Netherlands	New Zealand
Economic Indicators			
Total GDP (Billion)[116]	197,7	702,6	130,2
Total Population (2009)[117] **(Millions)**	10,11	16,53	4,368
GDP Per Capita (2010)	19.555	42.478	29.813
Total Public Health Expenditures %of GDP	7.8	9.5	8.3
Average Wage U$D[118]	1.374	3.035	2.283
Indices of Price Levels (OECD = 100)	61	108	106
Health Indicators			
Total People aged over 65 (2010)[119] **(% of population)**	16.8	15,5	13,0
Doctor Consultations (per capita)	11,7	6.6	2.9
Smokers (% Population)	26,5 (2009)	23,3 (2008)	18,1 (2007)
Alcohol Consumption (Litres per year,2008)	11,5 (2009)	9,7	9,7
Overweight (15 years and older, % of total population)	61,6	47.2	63,0 (2007)
Obesity (% Of total adult percentage)	19,5[120] (2009)/28.5 (2009)	17%[121]	27,8% (2009)

Sources: [116],[117],[118],[119],[120],[121]

The hypotheses behind these variables

Population: The size of the population might influence the prices. As larger amount of people, demand a larger total amount of medicines, the advantages of scale could be significant.

Average Wage, GDP per Capita and Price Indices: As wages go lower, there is less money available to spend. This leads to lower overall prices. The price indices help show the average price levels of a variety of products. It could be that the prices of medicines behave in a similar way.

[116] OECD, (2012) Country Statistics Data
[117] OECD, (2012) Country Statistics Data
[118] Statista.com, (2012) Average wages around the world, adjusted by purchasing power
[119] OECD, (2012) Country Statistics Data
[120] OECD, (2012) Country Statistics Data
[121] OECD, (2012) Country Statistics Data

The health indicators: The hypotheses here is that societies with a lower health status (higher levels of smokers, obesity, alcoholics, doctor visits, etc.) will have a greater demand for medicines, making them buy medicines on a larger scale.

Life expectancy: as people grow older they become more dependent on care, as well as on medicines. Countries with higher life-expectancies have also a higher demand for medicines, giving the government the task to reimburse and purchase more medicines. Here again, more demand, means greater savings per medicines due to advantages of scale.

Scarcity: In the above hypotheses, I did not assume the medicines to be scarce. As we will see later in this research, in some case medicines can be scarce and influential to the prices.

Issues related to the use of RIA

Probably the most heard criticism on the (formal) use of RIA is that it often lacks objectivity. This problem is mainly caused by conflicting interests of the agent. Its primary goal is to satisfy his or her principal, the one who appointed the job of performing the job. Besides, its goal is to give an objective and independent analysis of the proposed policy options. Practice has shown that in many cases the primary goal overrules the second. This translates itself in to practices such as only testing just the expected costs and benefits of a proposed law, like they were suggested by the legislator (principal) himself. The result of these practices is that many performed RIA lead to just a justification of the expectations which the legislator hoped to achieve with its policies (OECD, 2009: 17). The issue of objectivity will not be of any threat in this master thesis as it does in no way conflicts with any interests for it is just an informative piece of work.

Another issue related RIA is that of the reputation it might develop over time. The OECD (2009) summarized the issue as RIA becoming victim of a so-called ‘’check-in’-the-box’’ approach in which it lacks meaning as well as dept. The practices shows that RIA is mainly performed for policy proposals targeting a single issue leading them to miss investigating problems related to coherence within the existing political and policy framework. The lack of depth may exclude researching many contextual factors for which it is aimed to do, legitimating the legislator to neglect this aspect of political governance in the policy process at earlier and later stages. In this sense, the RIA is intentionally used to frustrate interest groups the access into the policy process (OECD, 2009: 18).

Jonathan Wiener(2006:33) identified this issue already at an early stage in 2005. He suggested the EU was ensured to create a culture in which the performance of a RIA is based on principles of ‘’analysis of full variety of impacts and tradeoffs’’. So far however, it is argued that such culture does not yet exist to the fullest, still leading to practices described in the previous paragraph(s).

One of the more important shortcomings of the RIA policy tool is that it neglects to, sufficiently, take political feasibility and -context into account. The argument refers to the fact that a best practice is not only to be identified by its remarkable results, moreover one should take into account to which extent the successful execution of the policy depends on the context in which it takes place. The second part of this thesis will therefor focus on this aspect.

3.3 Qualitative: what is possible?

The theoretical framework serves as major guidance for performing the qualitative part of this research. This part will focus on exploring the contexts of all three countries in order to identify whether (parts of) the policy alternatives, which have been analyzed in the Impact Assessment, would be suitable for implementation within the Hungarian context.

3.3.1 Historical Analysis

In the first part of the qualitative part I will study the historical backgrounds of the paradigm. My main focus will be on analyzing literature on how the paradigms behind the different health care systems have changed. Key will be to identify the main changes that took place in the last thirty to forty years. The key moments in time will be placed within the typology of welfare regimes as described by Esping-Andersen. The goal of the historical analysis will be to discover patterns of path dependency and what influence they might have on the possibilities for future policy developments. The rationale behind the historical analysis will be to identify the historic trend of pharmaceutical policymaking. Policy improvements which do not, or to only to a minor extent, require decision-makers to deviate from this trend, are most likely to be feasible for implementation.

3.3.2 The Stakeholder Analysis

Part of the contextual analysis will be a stakeholder analysis. Schmeer states that a ''Stakeholder analysis is a process of systematically gathering and analyzing qualitative information to determine whose interests should be taken into account when developing and/or implementing a policy or program''[122]. The concept of a stakeholder was already shortly discussed in the theoretical framework. I would like to elaborate on the concept by giving a clear definition. Schmeer reckons that stakeholders are those actors that have a vested interest in the policy which is to be implemented. The stakeholders can be found in different categories: legislators, officials and agencies, the private sector, NGO's, unions and associations, civil society and consumers/patients[123].

[122] Schmeer, K. (2000) p. 3
[123] Ibidem.

The goal of the stakeholder analysis is to find out the different attitudes of the stakeholders towards the policy. Knowing this qualitative information can help the policy-maker to interact effectively, but moreover increase his mandate. What was already discussed before, it is important for the decision-maker to keep the support of his political (sub-) communities as he is dependent on their cooperation. The stakeholder-analysis helps to detect policy deviations and shifts of the advocacy coalitions. A policy that connects with the wishes of the stakeholders is likely to be more sustainable, compared to one that lacks this connection[124]. In this case, the stakeholder analysis serves to judge the sustainability of the different pharmaceutical policies and help to predict what changes are to be considered acceptable by the different stakeholders.

The stakeholder analysis consists out of 8 major steps; however some of the steps have already been performed during the Regulatory Impact assessment.

Table 3.3: Steps in the Regulatory Impact Assessment

Step	Actions
Planning the process	- Defining the purpose - Develop a plan and timeline
Select the policy	- Define the policies
Identify the key Stakeholders	- Identify and describe the roles of the different stakeholders
Adapting the tools	- Develop interview questionnaire
Collecting and Recording Information	- Review Existing information (literature) - Plan and perform interviews
Fill in the Stakeholder Table	- Determine the positions of the stakeholders in regards to the policies
Analyze the stakeholder Table	- Determine advocacy coalitions - Determine possible stakeholder strategies
Use the information	- Draw conclusions

(source: Schmeer, 2000)

In the second part of my analysis I will predominantly focus my efforts on successfully performing the last four steps. On the development of the questionnaires I will come back in the next paragraphs. What is of importance to me is to identify clearly the roles and the attitudes the different stakeholders have towards the pharmaceutical policies and in which way they would like to see them, or at least allow them, to change. Key is to identify what goals they have and their beliefs on how the pharmaceutical policies could best be developed to reach these goals. The preferences will be closely linked to the different orders of change and how they are likely to be influenced along the possible routes, as I identified in the Policy Perception Model.

[124] Ibidem.

3.3.3 The use of Literature

In the following chapters I will discuss the tools how I will gather the actual data which will be studied in order to give an answer to the research questions which were discussed earlier. The first tool will be the analysis of written documents. The literature studied in this research involve: statistical databases, academic journals, policy papers, position papers, political archives, newspaper articles, evaluation reports, white papers and many more. With the selection of documents I have tried to acquire my resources from reliable sources. Statistical databases involve those of independent organizations such as the OECD, The World Health Organization, Eurostat and National Statistical Agencies which is some case specifically target data-collection about pharmaceutical policies.

In some case data has been provided by stakeholders, which might increase the risk of using biased information. Personally I think, that if information from stakeholders is used this is clearly expressed. The use of literature can be recognized by the use of references by means of footnotes. The complete reference list can be found at the end of this paper.

3.3.4 The use of Interviews

A lot of information can be found in documents, but most of the times this information might be out-dated and not able to answer the specific questions that arise during the research. As an alternative this information can be found within the people that are close, or even perform, in the pharmaceutical sector. In total 9 interviews have been conducted. The interviewees all represent actors in the field or can be considered independent experts who are very familiar with it.

Table 3.3 – Interviews with whom?

Person	From	Organisation	How	Style
Ivan Vermeulen	The Netherlands	Dutch Health Authority (NZa)	Face-to-Face	Semi
Tim Riesebosch	The Netherlands	Representing Organisation Dutch Pharmacies (KNMP)	Face-to-Face	Semi
Ferry Visser	The Netherlands	Achmea Health Insurance	Skype	Semi
Said Zarroy	The Netherlands	VGZ Health Insurance	Face-to-Face	Semi
Tony Ashton	New Zealand	Professor Health Economics, University of Auckland	Skype	Semi
Lisa Williams	New Zealand	PHARMAC New Zealand	Written	Semi
Ann Privett	New Zealand	Pharmacies Guild	Written	Open
Beatrix Horvath	Hungary	Ministry of Human Resources - Dep. Pharmaceutical Resources	Face-to-Face	Semi
Brendan Melck	UK/Hungary	IMS Health – Dep. Central Europe	Written	Open

As a method I have mainly made use of so-called semi-structured interviews. In this style of interviewing, not all questions have been determined before the interview. The idea is that a list of topics will be discussed, which will consequently lead to the emergence of questions which seem fit. In some cases I also made use of the open-interview style. In these interviews I started by asking the interviewee a single question, from this starting point I started to ask further questions[125]. The open interview style may be considered more as an ongoing discussion. More than half of the interviews have been conducted Face-to-Face. Due to the geographical distance, other interviews have been conducted through skype or written correspondence.

3.4 Chapter Summary

In this chapter I have tried to explain what methods I use to achieve answer the research questions. I have also explained why I choose these particular methods. What became clear is that this research is split into two parts: qualitative and quantitative. The quantitative part involves performing an Impact Assessment, whereas the qualitative part is guided by the theoretical framework. The first part will make use of predominantly numeric data found in documents and databases. The qualitative part will make use of methods like interviews and literature in order to try and identify the personal views of actors in the field.

[125] Reulink, N., Lindemand, L. (2005) p. 13

4. Effectiveness and Efficiency: Impact Assessment

IN THIS CHAPTER WE will cover the Impact Assessment. As already said, the impact assessment makes up for the quantitative part of the thesis. The assessment aims to identify and describe the different pharmaceutical questions and by following all the steps (table 3.1) of the common approach impact assessment, we will try to identify the key results of the three different policies in order to get an idea of the relative quality. In short this chapter gives answer to two of the research questions: *What existing institutions are in place? A*nd: *what are the results of the existing policies?* To make things easy, the chapter has been divided into six parts, consistent with the identified six different components of the common approach.

4.1 What problem do we want to address?

With analysis of the pharmaceutical policies of New Zealand and The Netherlands I would like to find out whether these are best practices compared to the policies in Hungary. Financing the Hungarian Health Care sector has been one of the major challenges for governments to deal with ever since the first wave of reforms between 1989 and 1993[126]. The Hungarian health system is ranked 26th out of 27 within the EU. There are high differences in the quality that is brought to the patients in relation to the geographical area they live in. Similarly there are quality differences among specializations and equity of accessibility[127].

This chapter gives answer to two of the research questions: *What existing institutions are in place?* and *what are the results of the existing policies?*

Hungary copes with a large amount of trained specialists migrating abroad as the wages of medical personnel within the Hungarian borders are significantly lower than those in other EU countries. Overall the Hungarian Health Care system is coping with dozens of challenges including: incomplete and unbalanced Hospital Infrastructures, staff shortages, cost-effectiveness and efficiency. The system itself is unwieldy, largely decentralized and lacks transparency[128].

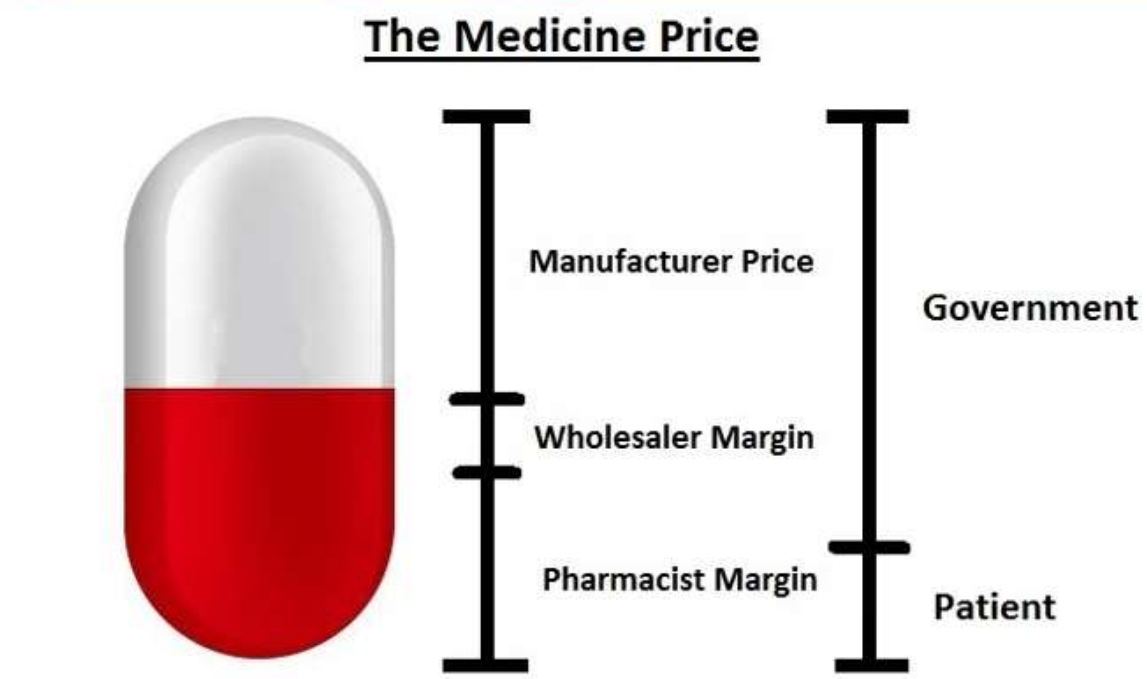
By analyzing the Pharmaceutical policies in Hungary, New Zealand and The Netherlands I will attempt to find policy alternatives for Hungary to decrease the costs of medicines and pharmaceutical care. In the Impact assessment I would like to find out whether the Dutch and New Zealand's pharmaceutical policies could serve as such alternatives by analyzing the economic results of the policies.

[126] Gaál, P. Et all. (2011), XX
[127] Ibidem, XXI
[128] Ibidem, XVIII

4.1.1 Defining the stakeholders

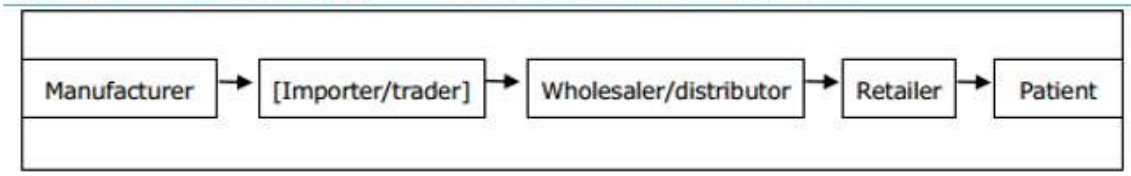
If we would like to define the stakeholders in the pharmaceutical sector we might best start looking at the actual market. We can ask ourselves the question who determines (agent) the prices and who pays (principal) for these medicines. In the figure (4.1) below an idea is given about who is involved in the pharmaceutical market.

Figure 4.1 – Who receives (left)? Who pays (right)?



Likewise, the supply chain for the provision of medicines shows a similar representation of actors.

Figure 4.2 – Traditional Supply Chain for Medicines in the Private Sector[127]



Source[129]

Looking at the figures we can identify five stakeholders directly: the patient, the government, the pharmacist, the wholesaler and the manufacturer. Besides the actors in the actual market, I will have a look at those that are responsible for prescribing medicines and I will also briefly discuss the position of the health insurers.

[129] Ball, (2011)

Patients

The patients are probably the most important as well as the most obvious stakeholder considering medicines and pharmaceutical care. As for a great amount of cases patients can simply not survive without, it is in their interest that the pharmaceuticals remain affordable and accessible, just like the health care sector as a whole. Besides, it is of importance that their health care provision is of highest possible quality.

Pharmacists

The pharmacist is a very old profession. Where it once started with shamans developing medicines for their tribes, it later developed to become the pharmaceutical market. During the industrial revolution pharmacies became indispensable to the people as it was them who provided the people with innovative medicines. Nowadays this innovation function has largely floated away to large pharmaceutical companies and the pharmacies have become to be primarily the distributer of the medicine. Besides they deliver pharmaceutical care; giving the patient guidance on how to use their medicines correctly.

The pharmacists depend on pharmaceutical policies as they determine a large part of their living. Their profession and their income are directly related to the profitability of the medicine market, as well as the profits they can make on pharmaceutical care. The distribution of medicines is seen as probably the most obvious part of this pharmaceutical care, however as we will see later, this kind of health care involves much more than just delivering medicines prescribed by physicians.

Producers

Considering the manufactures of medicines we can distinguish two types. The first one is the innovative industry that focuses mainly on the production of patented single-source medicines. For these medicines physicians, pharmacists and patients have no alternatives to choose. In most cases a patent expires after a certain period making it legal for generic manufacturers to freely produce the medicine and bring it to the market. From this moment on the product becomes multi-source. Generics manufacturers focus on selling these multi-source medicines without (patent). As they are not the only sellers, competition in these generics' markets, can assumed to be fiercer than is the case in that of of single-source products.

It should be mentioned that a single-source medicine might also have to compete, as there could be other medicines that work just as well or even better for similar treatments. In this case it is up to a specialized agency or the physician to analyze which medicine should be appointed for a particular treatment. This research however, will primarily be focused on regulating the purchasing of generics.

Government

The government acts as the agent of the people. They are responsible for purchasing medicines (If the medicine is chosen to be reimbursed). The people rely on the government to do this as efficient and effective as possible: keeping costs low and the quality high. Every penny the government is able to save, is another penny that the government is able to use realizing and/or improving other public services and goods.

Physicians

The physicians are the ones who have the responsibility to prescribe the medicines. With the term physician this research will include medical specialists such as: surgeons, specialists, general practitioners and dentists. Understandably, it would be efficient if these physicians are well aware about the savings generic alternatives give and take this into consideration when they prescribe medications.

Health Insurers

Now the Health Insurers are surely considered to be stakeholders, however there is a difference to which extent. The difference in extent will come clear by taking a closer look at the different styles of health care structuring in the three different countries.

4.2 What goals do we want to achieve?

In this case I refer to the goals which governments should want to achieve with their pharmaceutical policies, rather than the goals that I personally would like to achieve with this research. The goals of the policy are those variables from which the results can be measured. Most obviously the goal would be the lowering of the prices of medicines, however there are more variables such as the costs of the policy itself and more generally the costs of the pharmaceutical sector as a whole, of which the expenditure of medicines is only a part.

4.2.1 Selection of the variables

As state, lowering costs for pharmaceuticals and pharmaceutical care is one of the major goals. Lowering these costs would directly lead to helping contain health care expenditure. As to expect, the variables that are selected for research directly relate to this goal. However, at the same time it is important to note that the actual quality of pharmaceutical care should not be decreased, rather we would see the contrary, seeing the quality increase with the introduction of alternative options. In the following paragraphs the variables which will be measured in order to value the different policy alternatives are discussed.

Expenditures

In figure 4.1 I showed out of which components the medicine price exists: (1) the price of the medicine itself, (2) the margin the wholesaler receives and (3) the margin that the pharmacy receives. If a government wants to lower the prices, they will have to target all three of these components.

The medicine price exists out of three components: (1) the price of the medicine itself, (2) the margin the wholesaler receives and (3) the margin that the pharmacy receives. If a government wants to lower the prices, they will have to target all three of these components.

For the price of the medicine I turn my focus on the purchasing process. The question to be answered is how the governments try to keep manufacturers prices as low as possible. I will start by giving an elaborate description on how the different policies are structured. Consequently, in an effort to retrieve the quality of the policies, I will start by comparing the different policies on a macro scale. This first stage will involve comparing national *pharmaceutical expenditures* and the *expenditures on medicines* specific. Also I will take a closer look on a micro level of actual prices of individual medicines. Hereby I made a list of *34 common generics medicines*. For all the generics I have retrieved the manufacturer prices. A comparison of these prices will help me determine which of the governments is most successful in lowering their expenditures.

I will then continue by looking at the margins the wholesalers and the pharmacies make. The assumption is that the government can control these margins as well. However, in doing this, the government is rather limited to the efficiency of the market. I will therefor also analyze how centralized these markets are. The rationale behind this is that in a more central market, with fewer distributors (wholesalers and pharmacies), smaller margins will suffice due to advantages of scale.

Costs of the policy

Just like in any policy the cost aspects plays an important role. Efficiency refers to achieving the highest gains combined with the lowest costs. Not reimbursing any medicines at all might be the least expensive option, but simultaneously the least effective one. Costs are inevitable when establishing new policies; however different policies entail different cost levels and consequently different efficiency levels. What may be interesting to find out is to not only compare the results of the different policies in the different countries, but also the financial and human resources necessary to establish and maintain these policies.

Accessibility

An important goal of the pharmaceutical policies, as can be said for the total Health Care System, is the assurance of accessibility for the patients. The accessibility consists out of three components: the distance to-, the amount of- and the levels of out-of-pocket payments for pharmaceutical products and -care. The former can be geographically determined; this I will take into account briefly in the next

chapter. The second refers to the idea to make the policy as efficient but at the same time as effective as possible. Meaning that with the least amount of money the government will try to get the highest amount of services simultaneously at the highest quality. The last aspect refers to the costs an individual has to pay to make use of medicines and pharmaceutical care. Out of pocket payments can be used to lower costs, but they should not cause patients to be excluded from products and services. If out-of-pocket payments are high, the rich have better access to pharmaceuticals compared to the poor, most governments aim to ensure equal access for everyone.

Expectations

The data which is presented only gives an overview of the results that have been booked. With the discussion of this last variable, I will try to find out how much more potential there is for the near future. In some cases it might be that policies have only recently been introduced, which makes a judgment based on historical results, less valuable, considering that the real results of the policy are still to be booked. In this case, predictions would be of better value. To make my predictions I will make use of additional information which is provided by actors in the field. Moreover I will consider a last parameter: the total share of the generics market.

Replacing innovative medicines with generic substitutes can give significant reductions to pharmaceutical budgets. However, there are maximum levels to which generics can substitute. To see the potentials of government policies, I will therefor take a closer look at the current levels that have already been reached in Hungary and compare these to the shares which can be identified in the other two countries.

4.3 What do the different alternatives entail?

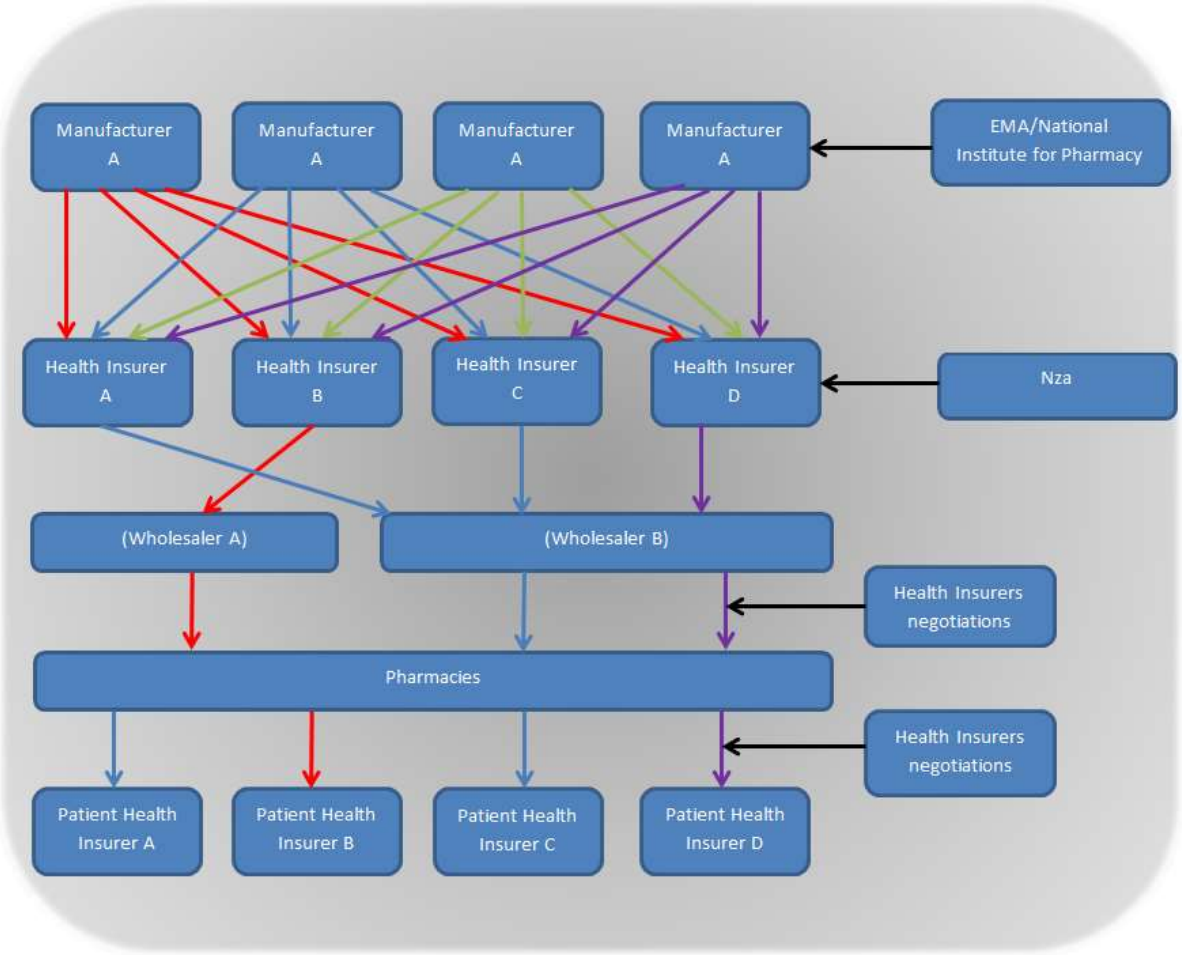
In the following paragraphs I will describe the three different pharmaceutical policies. This will give an idea to which extent the policies and related institutions are alike one another. In chapter five I will come back on this when I discuss the paradigms behind these policies.

4.3.1 The Dutch Preference Policy

The Dutch preference policy was introduced in 2006 together with the more general Health Insurance Act, in an attempt make pharmaceutical care and medicine provision more effective and efficient. With the introduction of the policy the Health Insurers were given the responsibility to directly negotiate the prices of medicines. Later, this task was expanded by also given the insurers the power to negotiate the prices of pharmaceutical care. The policy fits well within the existing health policies in which health insurers negotiate with the providers of healthcare about the quality and price of their services (Also

see chapter 5.1.1). Before these policies the role of the health insurer was to passively reimburse the costs of medicines and health care which were being declared by physicians and pharmacists[130].

Figure 4.2: The Dutch Preference Policy



Blind Bidding

The figure above shows how the provision and purchase of medicines take place guided by the preference policy. The procedure starts with a public tender set out by the health insurers. The manufactures are in direct contacts with the different health insurers giving them the lowest price at which they are willing to sell. The health insurer then compares all the bids he received on the procurement.

After comparison the health insurer decides on which brand of generic it is willing to reimburse, this medicine is the preferred brand. The health insurer informs the pharmacies about the brand and the price it prefers. The pharmacist then acquires the medicines from the manufacturer so he or she can provide the preferred medicine to those patients that are insured with the particular health insurer.

[130] Maarse, H. 2009: 1-2

Over the years different health insurers have developed new strategies to determine the prices they are willing to pay for medicines, these will be discussed in a chapter six.

Public Price List

The so-called Z-taxe is a general pricelist for all pharmaceuticals in the Netherlands. The prices are based on the input that is given by health insurers, pharmacists and other health providers. The list gives guidance to the multiple actors and some (smaller) health insurers have based their reimbursement prices on these listed prices[131]. In the recent years some health insurers have stopped providing the price information, as they think it gives them the ability to negotiate lower prices (also see chapter 5.2.1).

Claw-back

Additionally there is a claw-back margin to the price of medicines. The claw-back rule was introduced by the Dutch Health Autorithy (NZa) as a reaction to the generous bonuses and rebates which were negotiated by pharmacies before the preference policies. The claw-back policy forced pharmacist to pay a certain percentage (6,82%) of their sales to the government with a maximum of 6,80 euro per delivery. Although the Claw-back tax is formally abolished, the levy remains to exist within price contracts[132].

Pharmaceutical Care

As already shortly said before, since 2012 the Dutch government introduced the policy on 'free prices' for pharmaceutical care. The result of the new policy is that the tariffs for pharmaceutical care are, just like the pharmaceuticals, topic for negotiation between the health insurers and pharmacies. Before, power on tariff setting was in the hands of the Dutch Health Authorith (NZa). The health insurers have expanded the list of service performances which pharmacies can deliver. For each service a certain subsidy is applicable. The original list was designed and already used by the NZa before the introduction of 'free prices' policy. Negotiation is meant to take place directly between health insurers and pharmacies, there is no institutional body. The insurers are also in charge for negotiating the tariffs for distribution with and for wholesalers.

Control

The NZa is in charge of monitoring the execution of the preference policy and its effects. All the prices which are negotiated by the Health Insurers are known to the NZa[133]. The NZa fulfills the task of Market Regulator in Care. The NZa has an advising role towards the Minister of Health and represents three

[131] Z-index.nl (2013)
[132] Riesebosch, 2013.
[133] Zarroy, Visser & Vermeulen 2013

different public interests: transparency, accessibility and affordability[134]. The NZa monitors the behavior of the health insurers and providers in order to create and sustain a market in which consumers can rely that all the actors act according to the law. If the market is disrupted the agency has multiple tools to enforce legislation. The tools include determining budgets, tariffs and performance requirement in the health care sector, but wherever this is possible, they leave this task in the hands of the hand insurers and health providers themselves. The execution of these tools is realized by formal and informal measures.

Informally the NZa can use: consultations, written correspondence and press releases. Formal instruments are: the imposition of fines, administrative coercion, guideline-setting and the imposition of a cease and desist[135]. Important to note is that the NZa does not monitor the quality of health care. This task in is the hands of the Health Care Inspection (IGZ). The IGZ is under direct ownership of the Ministry of Health and enhances public health trough the effective monitoring of the quality of care, prevention and medical product. The IGZ advises the ministers and has the policy instruments to formally adress, and where necessary use administrative coercion towards, health providers. The IGZ judges on the basis of expertise and acts independent of any political color[136]. The health insurers are obliged by the formal Health Care Obligation (HCO) to deliver the best quality care at the lowest possible price; shortly said: the NZA checks the prices, the IGZ the quality.

4.3.2 The New Zealand Kiwi Model (Also see figure 1 from the Appendix)

In New Zealand the government chose a different strategy. Instead of giving the purchasing power to the pharmacists or the health insurer, they gave this power in the own hands of a specialized agency. As a reaction to the growing expenditures in health care, and more specific pharmaceutical care and medicines, New Zealand decided to establish the governmental agency: PHARMAC. The agency is responsible for funding the New Zealand Medicine System. After new medicines have been approved to access New Zealand's market by the governmental agency Medsafe, PHARMAC starts with determining the price of the medicine and to which extent the medicine will be reimbursed. According to the agency itself PHARMAC serves the ''Kiwis'' by ensuring that everyone has equal access to medicines, that they can be sure of the best quality of medicines and that they use the medicines in the most optimal way[137].

The agency is under direct responsibility of the Minister of Health and, like is common in democracies, the minister of health is accountable to New Zealand's' Parliament. PHARMAC's budget is fixed and

[134] NZa (2013)
[135] Ibidem.
[136] IGZ (2013)
[137] PHARMAC (2013)

decided upon trough consultation between the Minister of Health, the agency itself and the input of the District Health Boards. PHARMACS budget is capped, this is of vital importance as it forces the agency take into account the opportunity costs of the decisions it makes. Subsidizing one medicine or treatment means saving on another. It makes PHARMAC more conscious about choosing the best value for their money. Besides it supports PHARMAC by giving them a stronger argument for the negotiation process with manufacturers, as they can refer to their actual limits.

Example

PHARMAC choose not to reimburse COX-2 inhibitors, instead they choose to fund 18 other pharmaceuticals, which they calculated saved 437 ''statistical lives, additionally gaining 4231 QALYs in the first year as well as budgetary savings for Hospitals[138].

If a manufacturer wants to sell its products, be it patented or be it a generic, they will have to apply at Medsafe. This agency checks whether the medicine is allowed to enter the market on the conditions of safeness and efficacy. To get their medicine subsidized the manufacturer will have to apply for reimbursement at PHARMAC. For a thorough analysis of the subsidy request, PHARMAC has established a Committee of Experts. This committee (PTAC) gives advice to the agency whether they consider the medicine fit for reimbursement and to which extent. PHARMAC then decides whether it follows this advice[139].

In determining the value of a medicine compared to other possible expenditures, PHARMAC uses the QALY as measurement. The Quality-Adjusted-Life-Years are a measurement to quantify the expected effectiveness of a possible expenditure. The system for exactly calculating the relation between QALY's and costs is done by an elaborate method involving a Cost-Utility-Analysis[140]. A detailed version of this can be found in the appendix (Figure 1). Shortly I can state there is a threshold of Costs per QALY, when the proposed medicine or treatment hits a value below the threshold it is seen as a worthy investment. The assumption is right that in this case not always the medicines with the highest potential health gains are covered, rather those with the greatest health gains per dollar[141].

PHARMAC uses multiple tools and strategies to determine and lower the prices and value of medicines.

For generics PHARMAC uses a system of sole-supplier, meaning that only the cheapest brand of a specific medicine will be reimbursed. The winner of a competitive public tender will be allowed to exclusively supply the whole country's market. PHARMAC gives the opportunity for suppliers to ''enlarge the pie'', they may add extra offers to the deal. Examples for this are risk-minimization by offering expenditure caps, meaning that if too many units of the medicines are needed, the manufacturer takes over the

[138] Grocott, 2009, p. 183
[139] Cummings, 2010, p. 1224
[140] Grocott, 2009, p. 183
[141] Detsky, 2007. P. 1223

costs by offering rebates, or full refunds, of this unexpected higher demand. Also are manufacturers free to come up with multi-product agreements, in which a higher price is paid in exchange for rebates on other products delivered by that manufacturer[142].

Additionally, PHARMAC uses other tools and strategies to realize savings, such as reference pricing, in which PHARMAC compares proposed prices with those in other countries. Also common is the use of targeting criteria, in which the reimbursement is restricted to patients with only certain qualifications instead of to the whole medicine's target group. This makes patients outside the target group more likely to try other cheaper products first. Result of this strategy is that manufacturers offer lower prices during negotiations in exchange for de-restricting their medicines in this way. Lastly PHARMAC gives sole-suppliers of patented medicines and generics the option to prevent a medicine from being tendered in the future, by lowering the prices in advance[143].

Pharmaceutical Care

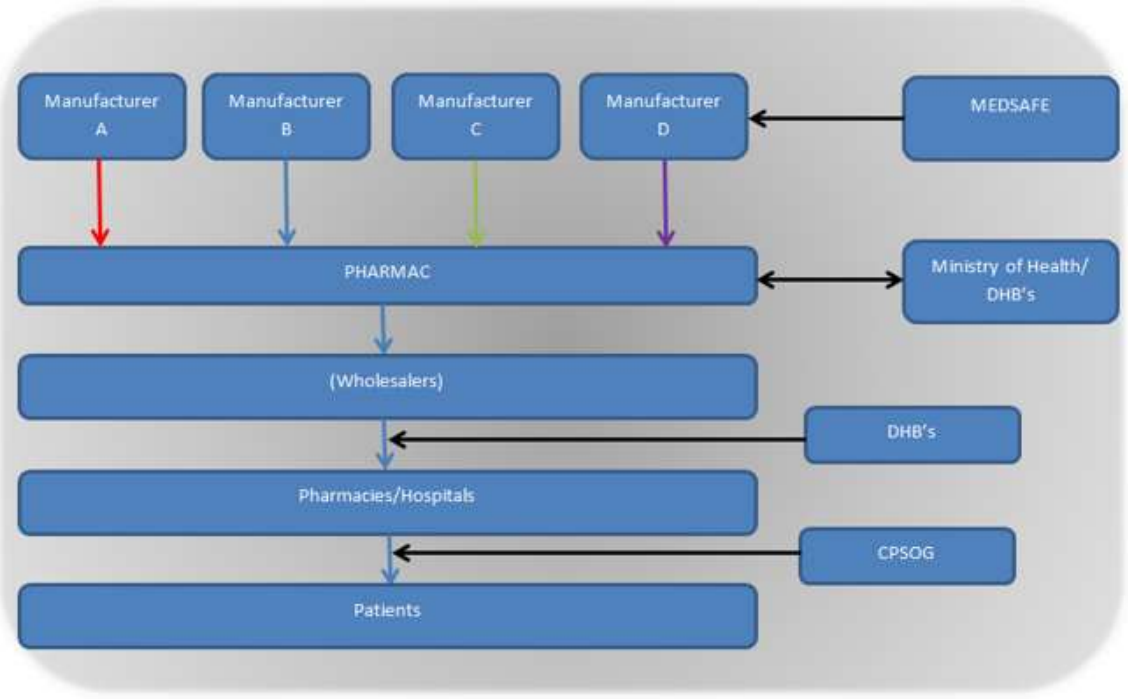
The tariffs for pharmaceutical care are determined by consultations between the pharmacies and district health boards (DHB's)[144]. To facilitate these negotiations, the DHB's and Pharmacies take seat in the Community Pharmacy Services Operational Group (CPSOG). In this group are four representatives of the DHB's, seven representatives of the Community Pharmacies, two representatives of the Ministry of Health, a strategic director, one person representing primary care, another representing secondary care and lastly a representative of the consumers[145]. These fees are paid by the government. Dispensing is done by community pharmacies. Besides dispensing, the DHB has put forward a list of other specific services, each with their own fees of refund.

Control

Unlike the Dutch model there are no independent agencies, such as the NZa and the IGZ in the Netherlands, to keep control over PHARMAC. Neither can we speak of a mean of competition in order to assure PHARMAC's loyalty to its principals' interest. Instead the Ministry of Health and the District Health Boards have intensive consultations with their agent. As PHARMAC's budget is set, the organization's only interest is to be as efficient and effective as possible. This budget has never been overspent as it is put forward by the agency itself. The fact that the governments interest are served is mainly due to the alignment between goal-setting and realistic forecasting which are the result of close communication between them and PHARMAC.

[142] Grocott, 2009, p. 185
[143] Ibidem, p. 186
[144] Williams, (2013)
[145] Centraltas.co.nz, p. 1

Figure 4.3: The Kiwi Model



4.3.3 The Hungarian Status Quo

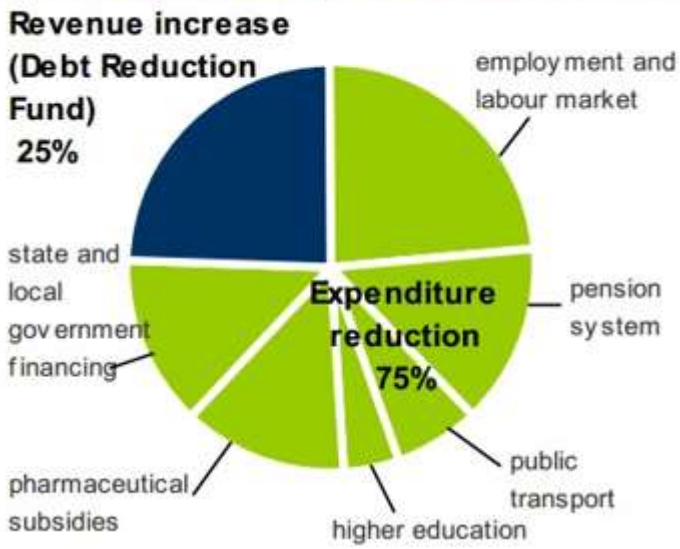
As I already stated before, the OECD ranked the Hungarian health care system 26th of the 27 European Union member states. The question remains whether this also involves the performance of the pharmaceutical system. As I will show, the pharmaceutical sector in Hungary has been a dynamic environment in the last three to four years. Key cause for this is the introduction of a comprehensive savings program: the Szell Kalman Plan. I will start by discussing the content and effects of this plan.

The Szell Kalman Plan

The Szell Kalman Plan was designed and presented in 2011 aimed to stabilize Hungary's national expenditures. The plan involves numeral structural reforms aimed to reduce the government's yearly deficit below the 3% which is required by the European Commission. One of the measures that were taken involved a significant reduction of the government expenditures on prescription drugs[146]. This decrease was to be achieved by the transforming the national system for subsidizing medicines leading to a total saving of 120 billion HUF in a three year time period[147].

[146] Ministry of National Human Resources, (2012)
[147] Kormany, (2011), p.22

Figure 4.4: Szell Kalman Plan Target Savings[145]

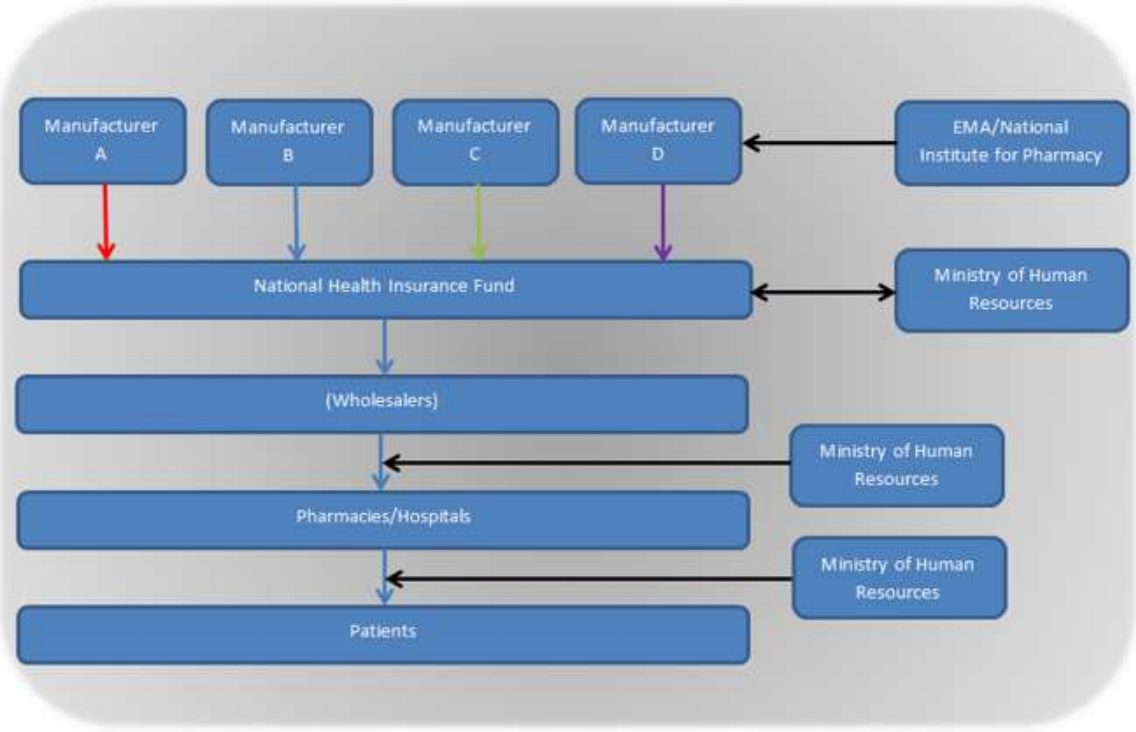


The measures involves increasing taxes on promotional activities of pharmaceutical manufacturers, an increase in the taxation levels related to the sale of reimbursed pharmaceuticals, a decrease of tax exemptions of R&D expenditures of related to pharmaceuticals[148] and the introduction of a more elaborate system of blind-bidding. This last measure refers to a system in which pharmaceutical manufacturers have to bid on the right to supply the Hungarian market at the highest percentage of government reimbursement. The winning bid allows the manufacturers to supply for a time period of six months at the maximum level of reimbursement, after which a new round of bidding starts[149].

The Blind Bidding system is now the main strategy used by the NHIFA to purchase medicines. The system is very similar to that of the Dutch Health Insurers; different manufacturers bring in their offers to supply a certain medicine at the lowest price. The cheapest manufacturer becomes the reference drug. This drug is reimbursed to the maximum extent which is determined by the government. There are four different levels of reimbursement: 80%, 50%, 25% and 0%[150].

[148] Cotarcea, R. (2011)
[149] Torok, E. (2011)
[150] Oep.hu

Figure 4.5: The Hungarian Pharmaceutical Policy



Pharmaceutical care and distribution

The tariffs on pharmaceutical care and distribution are set by the government. These tariffs depend on the price of the medicine. The margins of wholesalers vary from 8 percent for the cheapest prices, to 4.4% for medicines which cost more than 7 euros (2000 Forints). The margins of pharmacies vary from 27% for the cheapest medicine to around 3,25 euros (990 Forint) for the most expensive medicine. There is no direct communication or consultation between the government and the pharmacists/wholesalers. The government seems to irregularly respond to the reactions it gets from the market, as well as the quantitative data it gets from the NHIF and the advice coming from the National Ministry of Human Resources. In the recent years, the government has responded to the market, by raising the fixed tariffs and percentages of pharmacists, simultaneously lowering those of the distributors[151].

Control

The control on the quality of Hungarian health care is rather fragmented. The two most important organizations for monitoring the quality for health care are the in 2011 founded National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI) and the National

[151] Gyemszi, (2013) | IMS, (2013)

Public Health and Medical Officer Service (ANTSZ). The former operates nationally, whereas the latter also consists of regional departments. Both offices work under the governance of the Ministry of National Resources, to which they report their findings[152].

4.4 The Results of the Policies

In the following paragraphs I will elaborately discuss the results of the policies according the preset indicators. I will start by discussing expenditures, followed by the costs of the policy, the accessibility and the future predictions.

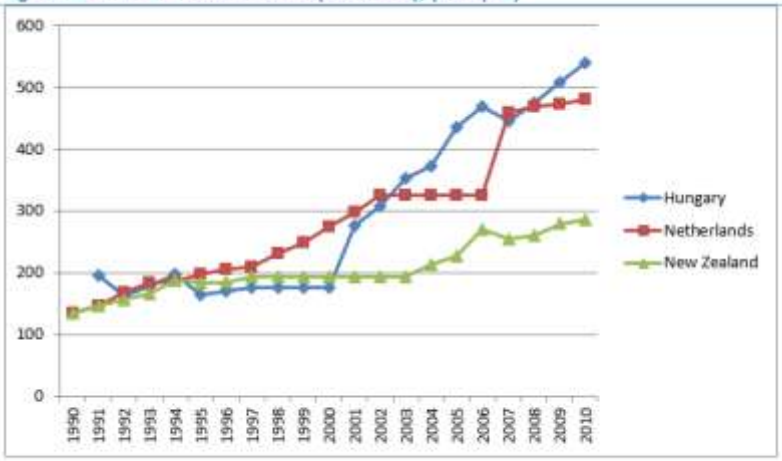
4.4.1 Expenditures

The expenditures are measured by multiple variables. First I will have a look at the expenditures on national level, beginning with the total government expenditures in the pharmaceutical sector.

Total Pharmaceutical Expenditure

The aim of all policies is to reduces the costs, or at least contain, their costs on pharmaceuticals. The OECD keeps track of the pharmaceutical expenditure levels of the countries within their research field. A comparison of these budgets may not be missing in this research. The graph below shows the expenditures on pharmaceuticals by New Zealand, The Netherlands and Hungary up to 2010 (figure 4.6). To make the expenditures easy to compare I choose to quantify them in terms of amounts per capita.

Figure 4.6: National Pharmaceutical Expenditures ($ per capita)

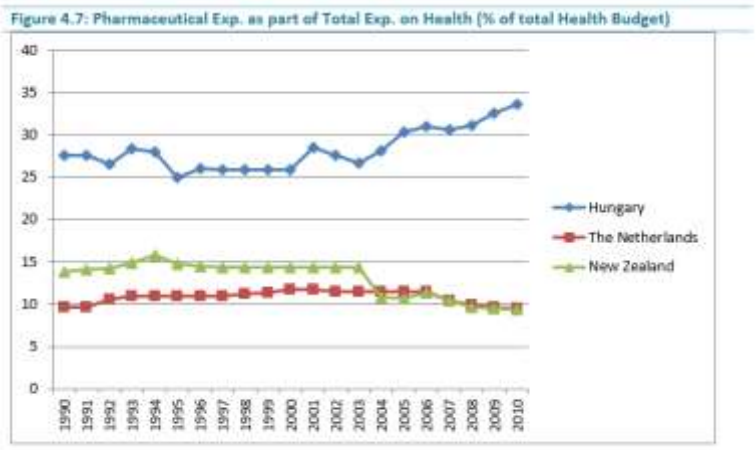


(Data: OECD Health Data, No data for: NL 2002 – 2006 and NZ 1998 to 2003 and Hungary 1998 – 2000)

The numbers indicate that New Zealand performs significantly better in containing their pharmaceutical expenditure compared to the Dutch and the Hungarians. What might be interesting is to put these numbers into perspective. In the graph below one can see what share the expenditures above demand form the total budget that goes to health care in the different countries.

[152] Gyemszi.hu (2013), antsz.hu (2013)

At first glance, the share of the Hungarian expenditure seems relatively high. However, in absolute terms this is not the case. The reason for this difference is in the fact that the remuneration of medical personnel in Hungary is significantly lower than those in the other countries. Wages make up a large share of the total health care budget in developed countries, as for the fact that this share in Hungary is significantly smaller; the share of pharmaceutical expenditure becomes automatically higher.



(Source: OECD Health Data)

Total expenditure on medicines

An indicator that gives a more detailed view on the actual costs of medicines is the actual expenditures spend on medicines. Now note, that the pharmaceutical expenditure, which was shown in figure 4.7, gives an indication of the total pharmaceutical costs, including pharmaceutical care. The actual expenditure that goes to medicines is only a part of this. The table below shows the developments in the expenditure on medicines per capita over the last five years. Unfortunately the Hungarian Ministry did only provide the OECD with data on 2010.

Table 4.1: Expenditure Per Capita on Medicines

Country	2004	2005	2006	2007	2008	2009	2010	2011
Hungary							516,5	
Netherlands	338	351	371	403	406	409	417,3	422
New Zealand	212,2	190,2	229,1	218,1	224,1	239,8	245,4	

(Source: OECD Health Data for *Hungary and New Zealand,* Stichting Farmaceutische Kengetallen for *Dutch* Data).

What can be noticed is that the expenditure per capita in Hungary, in 2010, is significantly higher than those in the Netherlands and especially New Zealand. With an expenditure of only 245 USD per capita New Zealand spends more than half as much on medicines compared to Hungary. What might be interesting is the trend which can be discovered in the expenditure on medicines. As for New Zealand, the expenditure has been relatively stable within the range of 210 and 250 USD between 2004 and 2010. What can simultaneously be concluded is that since 2007, with the introduction of the general preference policy, the Dutch have managed to successfully stabilize their expenditure on medicines.

With only an increase of 19 USD per capita compared to an increase of over 27 USD in New Zealand. In percentages the discrepancies are even larger.

However, these trends should also be seen in perspective to the maturity of the policy. As in many policies, the size of the additional impacts of a policy tend to decrease as for the longer the policy is in use. This correlates with the fact that medicine prices reach bottom-price levels after a while and side effects become more visible to the stakeholders.

The costs of pharmaceuticals: comparison on the micro level

After giving a clear idea about the macro level statistics concerning national expenditures it might be even more interesting to look at the actual prices of the medicines. To find out I compared the prices of 34 common generic pharmaceuticals in the three different countries. What should be noted is that for the cases of Hungary and The Netherlands I choose to only take into account the cheapest medicine available. In practice the Hungarian Government in some cases reimburses medicines which are priced within a certain margin of the cheapest option available. In the Netherlands the prices of different Health Insurers may vary, in this case I have only taken into account the cheapest medicine available, even though some patients might get refunds for higher priced medicines due to the fact that their insurer has negotiated a higher price for a certain generic. Taking into account only the cheapest price I hope to compare the actual potential of all the policies.

Table 4.2 shows all 34 generics with their lowest prices. The prices that are shown are manufacturer's prices. In the case of The Netherlands the actual prices the government has to pay are about 6.82% lower, as this is the earlier explained percentage of the Clawback rebate which is paid by the pharmacy. The prices exclude any margins, or fees, that wholesalers or pharmacist receive for distribution and handling. Additional data is shown in Figure 4.8 and Table 4.3.

Table 4.2: Manufacturing prices of 34 common generics. (Prices in €)			
Medicine	**Price Per Piece Holland**	**Price Per Piece New Zealand**	**Price Per Piece Hungary**
Metformin	0,020006	0,01212	0,015948
Captopril	0,017313	0,012	0,018448
Amlodipin	0,014984	0,0159	0,021494
Pantoprazol	0,02061	0,026357	0,021921
Metoprolol	0,015187	0,0282	0,023414
Captopril	0,020654	0,0144	0,025586
Enalapril	0,016649	0,007133	0,029885
Pantoprazol	0,027842	0,033	0,029926
Atorvastatine	0,019686	0,0168	0,035287
Enalapril	0,012487	0,0088	0,037356
Amlodipin	0,016705	0,0249	0,043755
Lorazepam	0,034018	0,06702	0,044368
Atorvastatine	0,030373	0,0278	0,045977
Naproxen	0,025331	0,0255	0,048391
Captopril	0,026627	0,021	0,051724
Simvastatin	0,011699	0,009333	0,062069
Enalapril	0,013274	0,011467	0,066092
Amoxycillin	0,073504	0,0318	0,068144
Simvastatin	0,014287	0,013	0,071724
Metoprolol	0,035098	0,0484	0,074943
Tramadol	0,024299	0,0297	0,082876
Amoxycillin	0,119995	0,019416	0,086207
Naproxen	0,039647	0,0534	0,09184
Quinapril	0,071996	0,030933	0,098851
Quinapril	0,054335	0,022933	0,106782
Omeprazol	0,025311	0,0194	0,133498
Gabapentin	0,039992	0,069	0,141276
Gabapentin	0,049002	0,0885	0,176138
Atorvastatine	0,04601	0,0488	0,177816
Pravastatin	0,027336	0,1088	0,182529
Simvastatin	0,019799	0,0212	0,185057
Pravastatin	0,044548	0,1856	0,248851
Omeprazol	0,023624	0,0252	0,289885
Total Basket	1,052228	1,177812	2,83805

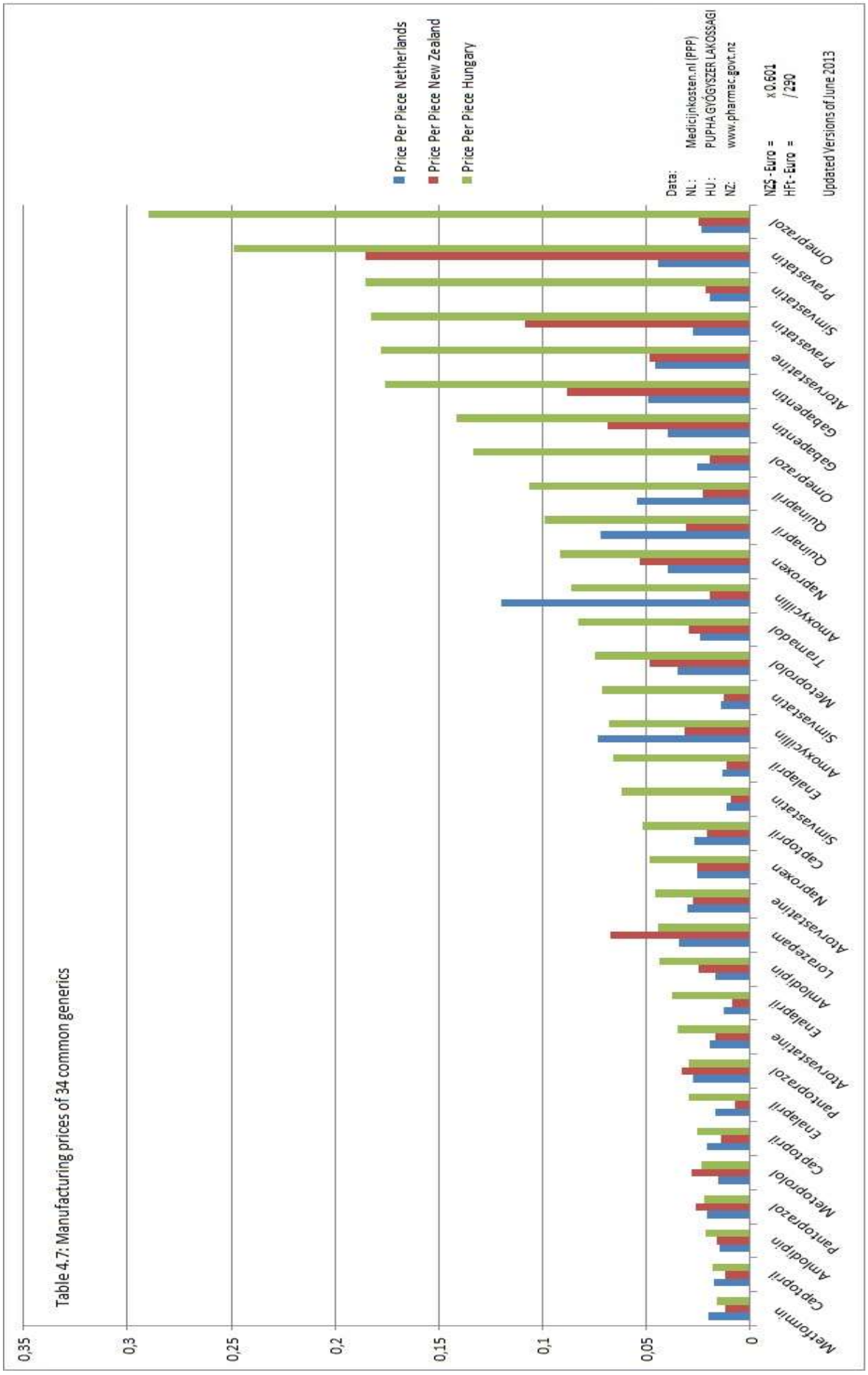

Price Per Piece Netherlands
Price Per Piece New Zealand
Price Per Piece Hungary
Data:
NL: Medicijnkosten.nl (PPP)
HU: PUPHA GYÓGYSZER LAKOSSÁGI
NZ: www.pharmac.govt.nz
NZ$ - Euro = x 0.601
Ft - Euro = / 290
Updated Versions of June 2013
Table 4.7: Manufacturing prices of 34 common generics
0,35
0,3
0,25
0,2
0,15
0,1
0,05
0
Omeprazol
Pravastatin
Simvastatin
Pravastatin
Atorvastatine
Gabapentin
Gabapentin
Omeprazol
Quinapril
Quinapril
Naproxen
Amoxycillin
Tramadol
Metoprolol
Simvastatin
Amoxycillin
Enalapril
Simvastatin
Captopril
Naproxen
Atorvastatine
Lorazepam
Amlodipin
Enalapril
Atorvastatine
Pantoprazol
Enalapril
Captopril
Metoprolol
Pantoprazol
Amlodipin
Captopril
Metformin

Table 4.3:Price differences between countries				
Medicine	**Dosage**	**HU/NL**	**HU/NZ**	**NL/NZ**
Atorvastatine	10 mg	179,25%	210,04%	117,18%
Atorvastatine	20 mg	151,37%	165,38%	109,26%
Atorvastatine	40 mg	386,47%	364,38%	94,28%
Simvastatin	10 mg	530,53%	665,02%	125,35%
Simvastatin	20 mg	502,03%	551,72%	109,90%
Simvastatin	40 mg	934,68%	872,91%	93,39%
Lorazepam	2,5 mg	130,42%	66,20%	50,76%
Tramadol	50 mg	341,06%	279,04%	81,81%
Captopril	12,5 mg	106,56%	153,74%	144,27%
Captopril	25 mg	123,88%	177,68%	143,43%
Captopril	50 mg	194,25%	246,31%	126,80%
Quinapril	5 mg	196,53%	465,62%	236,92%
Quinapril	10 mg	137,30%	319,56%	232,75%
Amlodipin	5 gm	143,45%	135,18%	94,24%
Amlodipin	10 mg	261,92%	175,72%	67,09%
Amoxycillin	250 mg (Caps)	71,84%	444,00%	618,02%
Amoxycillin	500 mg (Caps)	92,71%	214,29%	231,14%
Naproxen	250 mg	191,03%	189,77%	99,34%
Naproxen	500 mg	231,64%	171,98%	74,25%
Metoprolol	50 mg (NZ = 47.5 mg)	154,17%	83,03%	53,85%
Metoprolol	100 mg (NZ 95 mg)	213,52%	154,84%	72,52%
Metformin	850 mg	79,72%	131,59%	165,07%
Enalapril	5 mg	179,50%	418,95%	233,40%
Enalapril	10 mg	299,17%	424,50%	141,90%
Enalapril	20 mg	497,89%	576,38%	115,76%
Gabapentin	300 mg (Caps)	353,26%	204,75%	57,96%
Gabapentin	400 mg (Caps)	359,45%	199,03%	55,37%
Pravastatin	20 mg	667,72%	167,77%	25,13%
Pravastatin	40 mg	558,62%	134,08%	24,00%
Omeprazol	10 mg	527,43%	688,13%	130,47%
Omeprazol	20 mg	1227,09%	1150,34%	93,74%
Pantoprazol	20 mg	106,36%	83,17%	78,20%
Pantoprazol	40 mg	107,48%	90,69%	84,37%

The price differences are significant. Comparing the Dutch prices with those of New Zealand the prices are rather even as in the sense that differences are small. Most of the differences are within the range of 0.75 to 1.5 times the price. Amoxyllin and Enalapril show to be outliers with prices reaching up from two and a half to six times higher as those in New Zealand. Then again, Pravastatin, Lorazepam and Gabapentin are up to four times cheaper in The Netherlands.

The average prices in Hungary seem significantly higher than those in The Netherlands and New Zealand. Especially the prices of the common generics: Simvastatin, Tramadol, Enalapril and Omeprazol, show to be up to 12 times higher in Hungary than those in New Zealand and The Netherlands.

The pharmacists market

In Hungary, fairly large amounts of the prices of medicines are made up by the margins that wholesalers and pharmacies receive. If these markets are efficient, the government saves costs. At the moment, the margins on medicines vary from 4.4% to 8% (of ex-factory price) for wholesalers, with a maximum of 2000 forints, whereas pharmacies could receive up to 990 forints for distributing medicines. Besides the margins there are no fixed fees for the pharmacies and wholesalers[153].

In New Zealand and The Netherlands there are fixed fees for pharmacists. The fixed fees are between 4 euros to 5,50, for just distributing, to much higher fees for specific services. However, I would not like to compare these fees, as wages differ among countries, so do pharmacist and wholesaler remunerations. Instead I will look at the efficiency of the markets with the assumption in mind that: the more middlemen that are involved, the larger the margins they will have to get to sustain themselves.

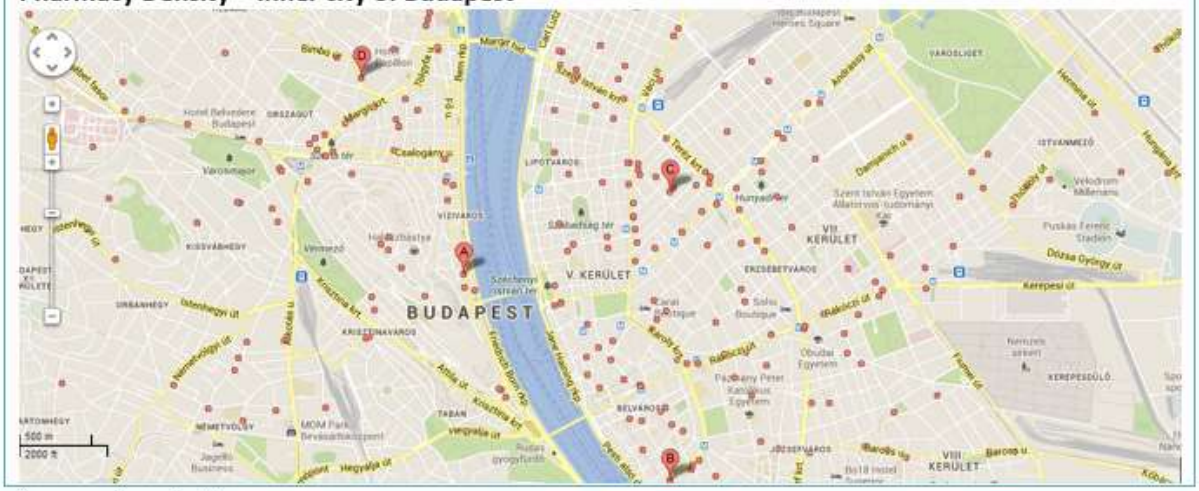
I will start off with rather remarkable images of the city center of Amsterdam and Budapest. Figure 4.9 shows the density of pharmacies in the two different cities. The total area that is shown is equal in size.

[153] OECD(2008). P.47

Figure 4.9: Pharmacies in the Inner cities of Amsterdam and Budapest

Pharmacy Density – Inner city of Amsterdam

Pharmacy Density – Inner city of Budapest



Source: Google Maps

The results shown in the image might not directly be generalized, but it gives an indication of what might limit the Hungarian government to further lowering the margins that are paid to pharmacists. More reliable statistical evidence is given by the numbers of pharmacists that are actually active in all three countries. Table 4.4 shows an overview of the total Pharmacists executing and practicing their profession. Due to the fact that the differences between The Netherlands and the two other countries is rather extreme, I choose add other OECD countries in order to be able put the numbers into perspective. We see that the Netherlands, with only 20 practicing pharmacists per 100.000 capita, is remarkably efficient. With 58 pharmacists Hungary is doing above average. We can also see that New Zealand is doing rather poorly.

Table 4.4: Pharmacists per 100.000 cap		
Country	**Practicing (2012 or latest)**	**Professionally active (2012 or latest)**
Austria	68	-
Australia	110	-
Belgium	116	-
Czech Rep.	59	-
Slovenia	55	88
Hungary	58	72
Slovak Rep.	-	63
Germany	62	73
The Netherlands	20	25
Portugal	75	113
France	105	113
Denmark	59	59
Italy	-	95
New Zealand	-	75
Poland	68	71
Spain	96	120
Sweden	76	81

(source: OECD, Health Data)

The low amount of pharmacies is not a result of the preference policy, the amount of pharmacies has always been low. Fact is that since two years the amount of pharmacies has started to decrease. In 2010, a total of 46 pharmacies closed down, whereas only 9 had opened. In 2011 these numbers were respectively 92 and 21. The amount of pharmacies in Hungary and New Zealand has remained rather stable in past five years.

Wholesaler Market

The wholesaler market will be excluded from research. This decision I made on the fact that the wholesaler market in Hungary is already relatively centralized with three wholesalers making up for over 90% of the market: Phoenix Pharma (41%), Hungaropharma (37%) and TevaMagyarország (15%).

4.4.2 Costs of the Policies

So fare I have only discussed the benefits that are gained by lowering the prices of medicines. But besides gains, there are also costs involved. On the one side the costs of implementing and running the policy and on the other side the costs of abandoning the previous ones. In the next paragraphs I will briefly discuss the costs of the three alternative policies. In these costs I will not directly look at the actual costs, for here again, differences in living standards among the countries are highly influential.

Looking at the set-ups of the policy we may conclude that the Hungarian option entails the lowest costs. No separate organization is established, the function for purchasing policies is placed under the authority of the National Health Insurance that already exists.

New Zealand's policies are most likely to be relatively advantageous regarding the cost. PHARMAC itself is a relatively small organization. The organization counts 62 full time jobs spread among a 69 strong staff.

The Dutch system entails the highest costs. Multiple Semi-Public health insurers will have to be funded. This is mainly done by the collection of premiums. Out of this public contribution the staff has to be paid. As the health insurers each purchase, and negotiate, the medicines themselves, the same actions are performed alongside each other by each health insurer separately. Normally in public administration this is not what one wants to achieve, as it seems rather inefficient.

I would also like to address the nature of competitive organizations. As they achieve their efficient results through competition, they also remunerate their employees ''competitive''. In the recent years there has been elaborate discussion on this topic, but what we may state is that the salaries in these semi-public organizations are significantly higher than those remunerations in state ran organizations. Not all of the health insurers are transparent on their remuneration policies, but looking at VGZ alone, the personnel in their organizations is rewarded rather generous, with 10 directors and managers earning an average of around 270.000 each[154]. With the budgetary discretion the health insurers have, it looks like Niskanen's theory seems plausible in explaining the extraordinary high salaries.

The lack of budgetary control of the government over the health insurers has been topic of discussion. In 2013 the health insurers all together made a total profit of 1.4 billion euros. In 2011 this was a profit of 500 million. In the end 100 million was used to lower the premiums[155], in 2012 again the health insurers stated that the profit would be mainly used for expanding their financial buffers[156]. The minister believes that she does not need to force health insurers to lower the premiums; she states that if a health insurer chooses not to do so, other health insurers will. Competition will correct this balance, ultimately leading to the market forcing the health insurer to use the money to increase competitiveness and lower the premiums[157].

[154] VGZ (2013)
[155] Trouw (2013), Riesebosch, (2013)
[156] Zarroy (2013), nu.nl (2013), Visser (2013)
[157] Trouw (2013), nu.nl (2013)

4.4.3 Accessibility and Freedom of Choice

The accessibility to medicines is hard to measure. In first instance I have tried to find data on the actual consumption of medicines, however most of this consumption is measured in value, rather than daily doses. Besides, the figure would only to a minor extent represent the effects of the actual policies. As for the Dutch National Health Authority, they measure accessibility by means of the prices of medicines and the amount (and distance) to pharmaceutical care providers. These variables have already been measured.

A variable that could be considered part of accessibility is the choice patients have. As I showed, the prices of pharmaceuticals in all three countries have dropped significantly, however in most cases this involved selling the right for supply to an individual manufacturer. Not only this causes full dependency on that manufacturer, it also limits the choice that patients have. This freedom of choice can be seen as a positive factor, although the concrete value of it to the patient is hard to express in terms of financial value.

Looking at this freedom we may state that Hungary gives patients the most choice in their medicinal use. Citizens have the choice to purchase any pharmaceutical that is within the range of ten percent of the (by state) appointed cheapest medicine. These medicines will be reimbursed against the maximum tariffs. All pharmaceuticals within a range of 10 to 50% above the appointed medicine are reimbursed equal to the concrete amount of the preferred medicine -15%[158].

In the Netherlands patients have no choice but the medicine which is appointed by the health insurer. In some cases, health insurers offer patients free choice in exchange for a higher premium. If patients would like to have a certain medicine, under full reimbursement, they do have the choice to change to a health insurer that does consider the particular medicine (brand) as preferred[159]. Besides, health insurers are obliged to reimburse alternatives if there is a medical urgency. This entails situations in which specialists confirms that the patient is dependent, or allergic, to a specific brand[160].

In New Zealand patients have no choice in fully reimbursed medicines. PHARMACS pharmaceutical price schedule determines which medicine is solely reimbursed and dispensed by the public pharmacies. Alternative medicines are only available if there is medical urgency, similar to the system the Dutch use[161].

[158] Gyemszi, (2013)
[159] ONVZ, (2013)
[160] Visser, (2013) | Riesebosch, (2013)
[161] PHARMAC, (2013)

Table 4.5: Freedom of Choice for Medicines (what is maximally reimbursed?)		
Hungary	**Netherlands**	**New Zealand**
Cheapest + Any medicine within a margin of 10% (& medicines within 10 to 50% above preferred price receive an amount equal to the value of the cheapest, minus 15 percent, as reimbursment)	Cheapest only (Unless you choose a more expensive Insurance)	Only the medicine chosen by PHARMAC

I did find further results on the accessibility of medicines, but this data does not represent actual numbers. Instead the accessibility is measured by the experience of the stakeholders in terms of shortages and exclusion for reimbursement. More on accessibility can be read in chapter six, in which I present the results I found during the performed stakeholder analysis.

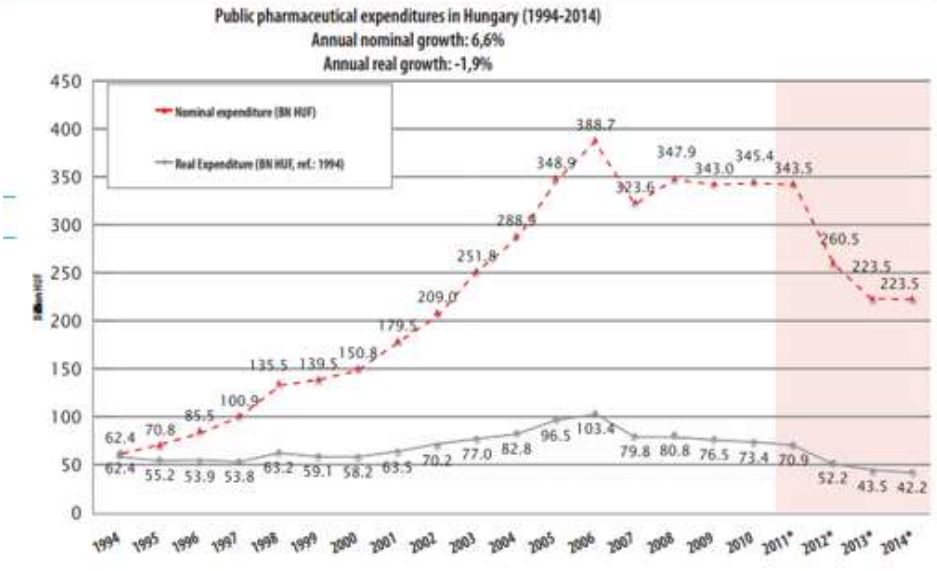
4.4.4 Predictions for the Future (Also see figure 2 from the Appendix)

Before I make a judgment on whether the results of the alternative pharmaceutical policies in New Zealand or The Netherlands can bet considered superior compared to those in Hungary, I will first put the results in the perspective of time.

Macro Level

The information that is discussed in this chapter, on the macro level, has mainly focused on the time period between 1990 and 2010. However, the real results of the Hungarian policy have been booked in the last three years. Looking at the data of the alternatives we may state that the Dutch and the New Zealand policies are reaching their limits. Margins have decreased significantly and prices have become so low, that actors are starting to experience

Figure 4.10 Pharmaceutical Expenditure in Hungary & Predictions



negative effects (See Stakeholder Analysis in the next chapter). The current prices seem to be the bottom for both countries; negotiations will probably not reach much further.

As we have seen the prices in Hungary are significantly higher compared to those in the Netherlands and New Zealand; however in the last three years the prices have started to decrease rapidly. The Szell Kalman Plan expanded the blind bidding procedure to most of the medicines and with it came the results. Figure 4.10 shows the expectations of the government before the introduction of the Szell Kalman Plan.

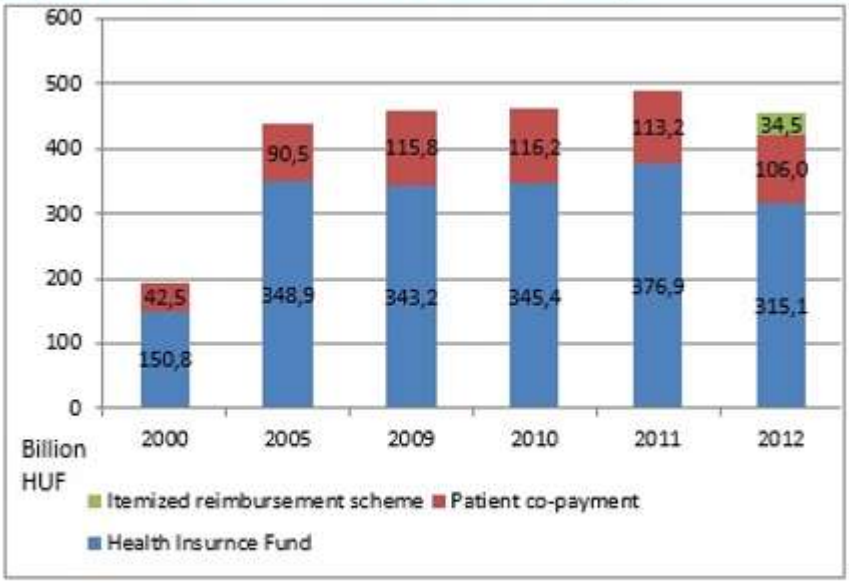
Table 4.6 Pharmaceutical Expenditure in Hungary

(millions Ft)	2007.	2008.	2009.	2010.	2011.	2012.
Pharmaceutical expenditure in support	299 982.5	309 563.4	328 510.5	342 213.4	360 613.5	295 987.0
Special categorized purchased drugs	18 049.3	9 528.1	9 637.0	9 832.5	9 742.9	9 977.9
Pharmaceutical Care Provision	0.0	0.0	0.0	0.0	0.0	0.0
Issue of fairness drug assistance	5 607.2	6 628.8	5 027.2	5 159.8	6 495.8	6 464.6
Pharmacy benefits					0.0	2 700.0
manufacturer payments	27 830.8	38 487.6	43 477.4	50 892.1	59 710.5	75 087.0
Health budget balance	**295 808.2**	**287 232.7**	**299 697.3**	**306 313.6**	**317 141.7**	**240 042.5**

Source: Ministry of Human Resources, 2013.

According to the latest data, the figures of 2012, a similar downward trend can indeed be identified. Table 4.6 shows a decrease of almost 25% in 2012. As shown, most of the savings are due to a gradual increase in the contributions from the manufacturers. The contributions are the result of a significant increase in the tax burdens on the industry. If we would like to get insight of the actual savings which are realized by the price cuts of medicines, we should exclude these contributions. In this case we see that the dropped

Figure 4.11 : Breakdown Structure Pharmaceutical Savings



Source: Baji & Gulacsi (2013)

from 376.9 billion (Health Budget Balance + Manufacturer Payments) in 2011 to 315.1 billion in 2012. This remains to be a total saving of 62 billion forints, equal to 16.5%.

Baji & Gulacsi did further research into the numbers and concluded that not all of these savings are to be contributed to the prices of medicines. The authors state that a large share of the savings, namely 34.5 billion, was realized by itemization of costs. By renaming the costs, they decreased the pharmaceutical budget merely on paper. 'The implementation of a blind biding mechanism of pricing and reimbursement of generic drugs resulted in savings of 35 billion HUF (7 billion HUF as co-payment and 28 billion HUF as NHIF drug budget) in 2012.'[162] This brings the total savings of the government as a result of the blind bidding system on a total of 7.4% (28/376.9), which is still a significant amount.

Market shares generics

One of the indicators which shows the effectiveness, but moreover the potential, of generic pricing policies is the division of market share between generics and innovative medicines. As for an efficient market generics should make up for as high market share as possible in terms of volume whereas at the same time their market share in terms of value can be considered the lower the better. Countries in which generic drug market penetration is high tend to gain significantly more cost benefits on medicines that those countries in which generic drug market penetration is low[163]. The table (4.7a & b) below shows the distribution of market share of the generics in comparison to the total market.

Table 4.7a: Generics Market Share % Volume Total Medicine Market								
Country	2004	2005	2006	2007	2008	2009	2010	2011
Hungary							45.4	51.1
Netherlands	46,6	49.8	53.7	54.1	56.2	57	60.6	63.3
New Zealand					64.2	66.8	70.3	72
Table 4.7b: Generics Market Share % Value Total Medicine Market								
Country	2004	2005	2006	2007	2008	2009	2010	2011
Hungary							28	
Netherlands	19.1	20.4	22	21.3	15.3	11.7	10.9	10.3
New Zealand					27.3	28.2	27.4	27

(Source: OECD, 2013)

The table shows that Hungary is lacking behind. This is negative for the currenty situation, but at the same time positive for the potential of its policies. The numbers show that there should still be leeway for profits to be gained in efforts to change the proportions of generic and innovative

[162] Baji, P. Gulacsi, L. et All (2013)
[163] Dylst, P. (2011)

medicine shares. The increase of generics used by the market can be achieved in two ways. First the government may decide in only reimbursing certain generics and this way stimulating the use of these types of medicines. On the other side there lays a responsibility with physicians who should be encouraged to prescribe the generics.

The micro level

Also on the micro level the expanded blind bidding policy has showed significant improvements in the prices of generics. In the appendix (figure 2) I added the data of the National Secretariat of Health stating the prices of the forty most prescribed medicines in Hungary. Changes can be notices up to 52%. On average, these forty medicines were bought by the government at a total savings percentage of 10.4% in 2012 compared to the year before. According to a more recent statement of the NHIFA, in April 2013 alone, it managed to cut the prices of over 700 medicines by an average of 14.2 percent, after a large round of blind bidding[164]. The numbers confirm the trend as described above in which the Hungarian prices of pharmaceuticals are showing a significant decrease.

4.5 Ranking of the alternatives

In the previous parts I have given an elaborate description on what the different policy alternatives in Hungary, New Zealand and The Netherlands entail and what economic performances these policies have shown. In the table (4.8) below I summarize the economic impacts the policies have in terms of cost and benefits for the governments.

Table 4.8: Ranking the Alternatives

	Pharm. Expenditure	Expenditure on Medicines (macro)	Prices of Medicines (micro)	Pharmacist Market	Costs of the Policy	Patient Choice	Future Expectations
Hungary	+/-	+/-	+/-	+	+++	-	+++
New Zealand	+++	+++	+++	+	+++	--	+++
The Netherlands	+++	++	+++	+++	+/-	---	+++

What we may conclude is that the Hungarian policies at the moment underperform compared to those in The Netherlands and New Zealand. Looking at the differences, there is still a significant amount of potential for the Hungarian policies and due to the fact that they are in a relatively early stage, their current policies may perform equally to the alternatives in a later stage. The recent trend does show a significant drop in the prices, however we must also notice that the Hungarian government might have less potential for decreasing prices, due to the fact that they already increased the level of taxes on

[164] MTI, (2013)

the manufacturers' other business activities of pharmaceutical manufacturers, such as promotion, sales and research.

I would like to state that out of these results we may assume that the alternative policies in The Netherlands and New Zealand could be entitled best practices. Whether these best practices are also applicable to Hungary will become clear at the end of the next chapter. On the basis of these figures I do not yet base any conclusions on whether Hungary is better off radically replacing its policy by one of the two alternatives. What I would rather like to take into account is the stability of the current policies in Hungary. As the results so far have shown that Hungary is significantly lowering its costs for pharmaceuticals it might be wise to ask ourselves the question:

Instead of reforming its current working policies, how can Hungary make sure that it can continue its current policy in order to continue achieving the results of decreasing prices?

If the government was to reform, New Zealand would be the most likely option, for its structural design is relatively similar to that which already exists in Hungary. Due to the structure of the Dutch policy, the costs are significantly higher. As there is need for competition and health insurers are not allowed to combine their efforts in negotiating prices they all have to do the same actions. Where in New Zealand and Hungary there is only one purchaser, in the Netherlands that job is performed seven times. With it comes the fact that the Dutch government loses control over their agents and how they spend their public money. Result is that salaries, especially for the management, seem to be significantly higher than that in the government agencies such as the NHIFA and PHARMAC.

4.6 Chapter Summary

What has become clear from this quantitative analysis is that each of the four policies has its own design. New Zealand and Hungary are relatively alike, whereas the Dutch structure is radically different. The results in The Netherlands on the prices of medicines on the micro level seem to outperform New Zealand by an average of around five percent, whereas Hungary remains to be at a considerable distance with an average price level almost double as high.

Still we must conclude that the Hungarians are catching up as their prices are showing a more rapid decrease than those in The Netherlands and New Zealand. The Hungarians have only expanded their 'blind bidding' system since 2011, we may speak that their policies are still in a premature stage with the performance improving over time. In the second part of the analysis more insight will be given about the social consequences of the different policies.

5. Qualitative Analysis Part I: Analysis of the Historical Backgrounds

IN THE PREVIOUS CHAPTER I gave an elaborate overview of the results of the pharmaceutical policies in The Netherlands, New Zealand and Hungary. Overall, we may state that the former two clearly outperform the latter at this moment of time. However, the most recent results have shown that Hungary's choice to adopt the liberal 'blind bidding' procedure since 2011 has worked out very well in terms of medicine prices. In this second qualitative part (chapter 5 and 6) I will try to find out whether the results of the policies in The Netherlands and New Zeeland could also be achieved in Hungary. The main question I therefor answer is how Hungary can sustain its current policies and what they can learn from Dutch and the Kiwis from how they managed to keep their policies stable.

In the theoretical framework I have discussed how change may be achieved, however in this part I will try to answer the question how to avoid large changes. For this I will analyze the variables which were identified in chapter two which influence the stability of a policy. These variables were identified as possible factors which could lead to a decision-makers' perception of crisis. One, or a combination of these types of perceived crises, could lead actors to act and change their policies. In the following two chapters I will try to focus on identifying the following variables:

- *Previous policies*: does the current policy fit within the historic trend of pharmaceutical policies?
- *Existing policies & Structures*: does the policy fit, and remain to be fit, within the context of surrounding policies and institutional structures?
- *Mandate*: the support/opposition for the policy
- *Social/Economic implications*: do the results of the policy support continuation with the policy; could, and if so which, changes improve these social-economic results of the policy and enforce the stability?
- *Technological developments*: does the policy make optimal use of the technological developments that are available?

The chapter will be structured along the core questions that have formulated by means of the theoretical framework. As for question 1 and 2, they have been answered in the previous chapter. The chapter gave answer to what the economic implications of the policies are in terms of concrete costs of pharmaceuticals. In this chapter we will start by researching the paradigm and its history. Therefor I will start by giving the historical background of the surrounding health care systems and a description of the current paradigm. Consequently I will more specifically look at the pharmaceutical policies and the recent developments they have undergone. The goal is to map the history of the paradigms and

discover trends in order to judge whether continuation of the current policies fits well within these trends.

Answering the third question involves a stakeholder analysis, to try and find out the roles of the different stakeholders, their views on the current policies and how they would prefer them to develop. The analysis includes investigating the relation between decision-maker(s) and stakeholders (including the executing agencies). I aim to identify the opposition and supporting coalitions to the policies and what their arguments are and whether these arguments are similar to those experienced in all countries or whether they might be inherent to the specific country. The stability of a policy benefits if the opposition is small. Following this logic, arguments of the opposition might form challenges for the Hungarian government to overcome and might already have been experienced in the cases of Netherlands and New Zealand. I will conclude by summarizing the information that is gathered to make a judgment on which (parts of) the alternative policies could be effective for implementation in the Hungarian system.

5.1 The Historical Backgrounds

Policies do not emerge out of the blue. As I showed in the theoretical framework, history matters in the development of paradigms, from which policies derive. In the upcoming paragraphs I will make an analysis of the historical backgrounds/trends of the paradigm changes which form the foundations of each country's health care sector policies. Before I start with my discussion on the Dutch health care sector I would like to make clear what the division *between Funding, purchasing and providing health care entails.*

With the funding of health care I aim at the collection of funds, premium and taxes, and the allocation of these funds to the general health care sector. I aim with this at the central function for budget setting. Subsequently, agencies or governments are the ones to divide these resources; in this case I speak of purchasing health care. I speak of the specific fees and remunerations that are given to the health care providers. The purchasers are the ones to decide which medicines, treatments and health services will be reimbursed and to which extent and which health providers are allowed to offer them. The health care providers are, like the name states, authorized to provide the health care: dentists, hospitals, pharmacists and general practitioners. In some case these providers are independent and/or private actors, in other cases they may be owned by the (local) state authorities.

5.1.1 The Dutch Health Care Sector

As is in most countries is the case, the health care sector is one of the biggest expenditures of the Dutch Government. The system finds its roots in 1905 when the Dutch government started to get involved by giving poor people the opportunity to insure themselves against low costs. Before this

period, the poor were dependent on their families, the church[165] or labor funds that were established by and for the laborers. Later these institutions were followed by employers and renowned doctors who realized health insurances could be profitable both economically as well as for their reputation[166].

The system knew many shortcomings. As to be expected of the profit seekers, severely ill people were excluded from these initiatives as they would be too expensive to cover. Furthermore, there were the doctors and specialist who strategically choose to which insurance initiatives they would associate themselves, making it impossible for patients of certain funds to be treated in certain cities as for the funds did not have any medical personnel at those places under their coverage[167]. The Royal Dutch Company for Health Sciences (RDCHS) was founded in 1905 giving people the first opportunity, be it to a very basic extent, to insure themselves for health care provision covered by the state.

The foundation of the system from which the current system has developed itself, started in 1941 during World War II under German Occupation. The system was the result of the ''Dutch Sick Funds Agreement'' signed by the Dutch Government in August 1941. It should be stated that the decision was not made voluntarily but commanded by the Germans. It stated that from November 1st 1941 around 4.5 million citizens who earned less than the so-call ''sick funds-border'' were obliged to join with one of the acknowledged sick funds. The people earning above this border were free to insure themselves be it with one of the state's sick funds or a private health insurance[168]. As was to be expected, the system was based on the German Health Insurance system, the so-called 'krankenkassen'. The intention of the Germans was not just to increase the quality the Dutch health care sector, it merely might have served to give the German occupation a more social reputation attempting to gain the support of the occupied[169]. The German sick fund structure would stay into use in The Netherlands until 2006.

During this time (1941-2006) however the system did change significantly. As stated, the system was built upon three types of insurances. The compulsory collective sick fund, the voluntary collective sick fund and the private health insurance. The entrepreneurs and retirees were allowed to voluntarily join the collective insurance organized by the state's sick funds whereas the people with earnings above the sick fund border relied upon the private insurers[170]. In the years after the war and the introduction of the sick fund system the government addressed different goals.

[165] Schäfer, W., et al (2010)
[166] Nos.nl (2005)
[167] Ibidem.
[168] Kenniscentrumhistoriezorgverzekeraars.nl, (2013).
[169] Nos.nl
[170] Schäfer, W., et al (2010)

Stimulating Growth and Accessibility

In the first period, the government's main interest was to bring more equity into the system. The first major change was made in 1964 by the introduction of the mandatory Health Insurance Act(ZFW) which replaced the old Sick Fund Act. The Act came in a time of economic prosperity and growth, and the same idea came to the minds of the government and the people considering health care. The idea was that with the economy also the coverage and the quality of the system should grow. The Health Insurance Act was aimed at enhancing the accessibility to the system by expanding the package of services of the collective insurance, giving employees with earnings below the sick fund border access to a wider range of care[171]. In addition to the old system, a compulsory social insurance scheme with income-related contributions for severe medical risks, covering the entire population was added[172]. Another expansion was added with the introduction of the Exceptional Medical Expenses Act (AWBZ) in 1966 which was to cover the costs of long-term care for all citizens[173]. In short, between 1945 and 1965 the government Health Care policies were focused on expanding the range of the system considering services and population groups.

Controlling Costs

In the seventies the systems started to show some defaults. Whereas earlier new medicines and medical treatments were quickly picked up under the coverage of the health the system had to be reviewed after the Softenon disaster. The prescription was thought to be of use to pregnant women but in fact led to birth of disabled newborns[174]. The disaster caused society and government to rethink the acceptance of unbridled expansion of medical technology. Simultaneously, the economic prosperity started to slow down. The government, but also employers who had to pay almost a quarter of the cost of social health insurance for elderly, started to realize that development thus far would not be sustainable[175].

This turning point led to a change of focus of government policies. Accessibility and Quality would remain key goals in the Health Care sector but additionally the government was aiming at higher (macro) effectiveness of their resources and policies. The change of focus led to the introduction of the Health Care Charges Act (HCCA) in 1982 and the Hospital Provision Act (HPA) in 1971, both acts targeted regulating the prices and public budgets in the Health care sector. It might be interesting to state that during this time these policies were just not chosen by the government. During this time

[171] T.E.D. van der Grinten, J.P. Kasdorp (1999): 107
[172] Schäfer, W., et al (2010)
[173] T.E.D. van der Grinten, J.P. Kasdorp (1999): 107
[174] Kennislink.nl. (2013)
[175] Schäfer, W., et al (2010)

Netherlands was ever more characterized as a neo-corporatist bureaucracy considered to have the approval of almost all actors (patient organizations, unions, advisory agencies, hospital organizations, etc.) involved. The new policies were effective but not sufficient.

Enhancing the efficiency

In 1987 the parliament appointed a commission to investigate possible further changes to the system. The committee was named after its chairman, Wisse Dekker who was chief director of Philips at the time, who was requested to lead the investigation by Prime Minister Lubbers[176]. The committee ultimately presented the Dekker-Proposal ''Willingness to Change'' in 1987 presenting a uniform basic insurance for the whole Netherlands, based on market competition[177]. The idea of competition was expressed by making the different actors more dependent from one another. From now on the health care providers were to convince the health insurers to contract them, whereas the health insurers were to convince the actual consumers to choose their insurances. The proposal came to change the role of the consumer, from now on they were one of the principals to the insurance providers. Insurers were to adjust their health care supply to the wishes of the consumer. The negotiations between providers and insurers were to be guided by regulations and anti-trust laws[178]. The idea was that the decentralized Insurers would be much more efficient in purchasing health care (controlling supply side) than the old policy instruments that gave this power to the centralized institutions of the government[179].

The idea of Dekker fitted well within the political paradigm of New Public Management which clearly was in favor of marketization of government policies. However, realization of the plans did not get much further than it being promising plans. Marketization of the health care sector remained to be a thorny issue. Even though the plans themselves received full political support and a secretary of state for health deriving of a policy proposal[180] the labor unions feared income effects, employers feared cost effects and health insurers feared loss of influence[181] ultimately leading to the stranding of the reform attempt. The secretary of state stepped down in 1993 disillusioned about his failed efforts[182].

In 1994 a new social-liberal coalition came to power and the plan to introduce a general insurance scheme for the whole country was dropped off the agenda[183]. During the nineties no real reform took

[176] A.J. Dunning, 2001
[177] Schäfer, W., et al (2010)
[178] Krikman-Liff, (1989).
[179] Rutten, (2004).
[180] Helderman, J.k, et all (2009): 198
[181] Schäfer, W., et al (2010)
[182] Helderman, J.k, et all (2009): 198
[183] T.E.D. van der Grinten, J.P. Kasdorp (1999): 107

place. The Minister of Health chose a strategy of incremental changes, partially derived by the failed Dekker proposals of marketization. Examples of these changes are, the possibility for people to change insurance funds, harmonization of tariffs for privately insured and sickness fund insured persons, allowing funds to operate nationwide and make physiotherapeutic care tariffs freely negotiable[184]. The incremental strategy was to be considered successful as the opposition did not stop it[185].

In 2001 the social-liberal coalition was replaced by a more central-liberal coalition. As the problems with financing of the health care sector grew, so did the actual demand for reform. In 2003 the policy paper 'a question of demand' was presented guiding the new government under the lead of Prime Minister Balkenende to develop new reforms. The reforms were largely based on the Dekker-proposal of 1987 including the replacement of the old dual private and public insurance structure[186]. The new Health Care Law (Zvw) was proposed and approved in 2006 leading to the implementation of the health care sector as we know of today[187]. The system was meant to give the citizens more choice in health care provision, making health providers more competitive in order to get the patients' favor. The policy was to make more use of the latest technologies like the internet, also meant to keep the system transparent to both government and citizens. Accessibility was ensured by providing premiums to those lower incomes unable to cover the full premiums.

Change and reforms over the years

As earlier discussed in the theory there are multiple possible paradigms to be followed by countries and their governments considering the structuring of their welfare state. Main characteristic to be identified for this paradigm is to look who has the responsibilities of implementing, changing and executing the new policies. As we have seen in this chapter the responsibilities in the Dutch Health Care system have shifted multiple times. The table 5.1 below gives a general idea about how the Dutch welfare state shifted in the last era.

[184] Ibidem , 21.
[185] Helderman, J.k, et all (2009): 198
[186] Schäfer, W., et al (2010)
[187] Exter, A.P., et all. (2005)

Table 5.1 Historical developments of the Dutch Health Care Paradigm			
Time-period	*Ruling Paradigm*	*Types of Change*	*Agent/Legislation*
- **1900**	Charity	None	
1900 - 1940	Charity (Corporatism)	Layering	RDCHS
1943	Corporatist/Liberal (Funding/Purchasing)	Displacement	Sick Funds & Private Health Insurers
1945 - 1969	Corporatist/Liberal (Funding/Purchasing)	Layering/Drifting	Sick Funds & Private Health Insurers
	Social-Democratic (Funding/Purchasing)	Layering	AWBZ
1970 - 1994	Corporatist/Liberal (Funding/Purchasing)	Drifting	HCCA & HPA
	Liberal	Failed Attempt	Dekker Proposal
1994 - 2003	Corporatist (funding/Purchasing)	None	Sick Funds & Private Health Insurers
	Liberalization (Funding/Purchasing)	Conversion	Incremental
2003 - 2006	Liberal (Purchasing/Providing/) Liberal/Social Democratic (Funding)	Displacement Conversion	Private Health Insurer (Zvw), Premiums and Subsidies

As we already described in the previous paragraphs, the system around 1900 can be typified as a system of charity, a Rhineland Model, in which the main responsibilities for providing health care and financial support is in the hands of the families themselves. Collective responsibility only excited by means of the church and labor unions and other local institutions. From 1905 the government started to slightly get involved by introducing the Royal Dutch Company for Health Sciences, shifting the situation slightly more towards a social-democratic typical model.

It would be with the introduction of the Sick Fund Act by the Germans that the Dutch Health Care sector could significantly be considered to shift towards a more collectively organized system in which the government takes almost full responsibility of the Health Care provision. The remaining options for private insurance do give the situation a slightly liberal character as well. In the years to follow the state focused mainly on expanding the health care sector, that is why we can find the fifties in an even further corner of the Social-Democratic quadrant.

In the seventies the government started to aim at limiting the growth and the cost of the Health Care Sector, as the welfare state became typically know as a corporatist model so did the actual Health Care Sector. The Health Providers, insurers, employers and citizens got more influence, by their intermediary role, on the model and the actual policies leading to a changing model more towards the left bottom quadrant[188].

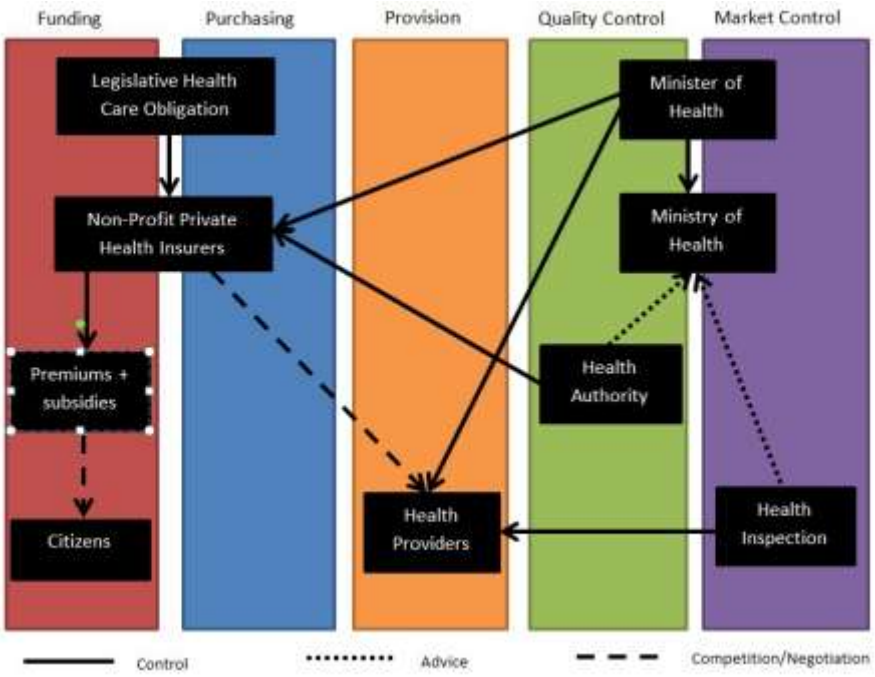
[188] Lieverdink, (2001)

The Dekker proposal came up with a more market type or Anglo-Saxon solution by implementing competition and letting the market lower the costs of the sector. With the actual introduction of the New Health Care law, giving everyone the same insurance with a voluntary option for private additions we might say the Social-Democratic structure made a comeback. Together with the introduction of the market-principles and competition among health insurers and health providers we may add an important turn towards the liberal quadrant as well.

5.1.2 The Current Situation in the Netherlands

Figure 5.1 shows the health care system in The Netherlands as of today. The figure shows that the (non-profit) private health insurers are in charge of funding and purchasing the health care provision. Funding is done by premiums, which are directly paid by the citizens who are obliged to get basic coverage from one of the health insurers and who can choose to get coverage for additional services. The funding also has a social-democratic side, as the government jumps in with providing health care subsidies to cover part of the premiums for those with lower incomes. Key aspect of the model is choice, both for the customer as well as the health insurer. The health insurer is free to make contracts with health providers of whom it thinks the price/quality performance is sufficient.

The performances of hospitals are made public, the list Key Performance Indicators are set and evaluated by the Dutch Health Inspection (IGZ)[189]. It is possible patients who are covered by certain health insurer can only be treated at certain hospitals for specific treatments. This selective purchasing by the health insurer is still in a rather premature stage. Rationale is that hospitals will start to improve their price/quality by focusing, and excelling, in specific treatments. The Nza keeps control for the Dutch citizens that the market functions honest, efficient and transparent. The health insurers are free to act independent as long as they obey their legislative Health Care Obligation (HCO). The HCO states that the health insurers are responsible for delivering the care and/or reimbursement to which



[189] Ziekenhuizentransparant.nl (2013)

citizens have the right. The HCO demands the insurers to purchase the best possible care at the lowest price. The HCO leaves much room for interpretation, although some standards are anchored in the law. On the basis of the HCO the health insurer can decide not to contract (reimburse) certain health providers or certain services from health providers[190]. If the health insurer does not live up to the HCO the Minister of Health, or the Nza, are authorized to intervene in the health insurers practices (also see chapter 4.3.1).

Lastly, I would like to note that in 2010 an extraordinary event took place when health insurer DSW merged itself with the Vlietland hospital in Schiedam[191]. In first instance there was resistance from multiple actors, however the merge took place. The health insurer states that it does not intervene in any of the hospital's daily actions[192], however as the owner of the hospital the health insurer to some extent takes over the role of health provider, which could be attributed to the mechanism of drift causing a second order change.

5.1.3 History of the Preference Policy

But also on the level of the policy changes took place. The policy was introduced in 2006 and several (first and second order) changes have taken place. In June 2005 the health insurers started by implementing the ''common preference policy''. In this first stage all the health insurers worked together in negotiating and determining the lowest prices at which manufacturers were willing to offer. The medicine with the lowest price would be reimbursed by all the health insurers. Not short after the introduction of the pilot the resistance grew. In January 2008 collective summary proceedings were from the pharmaceutical manufacturers, to prohibit the preference policy, were denied by the court in Breda[193]. An appeal was made to the decision. Eventually, it was stated that the health insurers were no longer to proceed with the collective preference policy but solely on individual basis[194].

From then on the medicines that were purchased under the preference policy expanded rapidly. The individual approach of the health insurers did led to more incremental changes. These mainly were expressed by the development of alternatives by the major health insurers. What is interesting to note is that insurers are not obliged to use the preference policy.

[190] Nza (2013), Vermeulen (2013)
[191] Zorgvisie.nl (2013)
[192] DSW.nl (2013)
[193] Rechtbank Breda, (2008)
[194] Varkevisser, M. (2008) p.16

Alternatives

Achmea is one of the four large health insurers in the market. Whereas the others decided to continue with their individual preference policy, Achmea decided differently. Their main argument was that 'Achmea did not see effective solutions in policies that excluded the cooperation between all of the players in the pharmaceutical care provision chain'[195]. Instead Achmea developed the IDEA (Intergral cost-effective contract Excellent Pharmacies)-model. The name IDEA already gives away part of the idea. Instead of the health insurer purchasing the medicines it is the pharmacy that gets this task. In return however, the insurer and the pharmacist sign a ''lowest price declaration'' (IDEA-Contract). The model allows the pharmacist to become the buyer of the pharmaceutical. The Health Insurer only reimburses the lowest price, which is determined by the insurer's judgment. This judgment is set by a fixed Fee model, in which an average price for particular group op medicines is reimbursed to the pharmacy, for all the medicines individually in that group. In this case, if the pharmacy is able to negotiate lower prices themselves, they can profit from these margins. Alternatively, pharmacists can also agree on a Historical Price agreement, in which the pharmacist agrees to deliver a medicine for several years at a predetermined price in time. If the price of the medicine goes down in these years, the pharmacy can profit from this, if the price rises, the pharmacist has to compensate himself[196]. For the pharmacists who do not like to sign the declaration, Achmea uses the preference policy[197].

Health Insurer VGZ also developed an alternative model, which they call the ''covert-preference''. In the covert preference model the manufacturer gives the Health Insurer two prices. The first price is the price that stays secret and refers to the amount the health insurer has to pay to the manufacturer. The second price involves the, visible, price at which the medicine is to sell to the patients. Since the introduction of this policy, resistance against it has emerged. Patients and pharmacists point out the lack of transparency. What is relatively hard to understand for the patient is that the health insurer choses to prefer, what it looks to the patient, a more expensive medicine, due to the fact that he only sees the second price[198]. According to VGZ the secrecy leads to lower prices, as manufacturers are willing to pay (price drops) to keep prices secret so that other Health Insurers do not profit of the individual negation results between them and VGZ[199].

[195] Ibidem.
[196] Ter borg, Et all. (2009), p. 5
[197] Achmea, (2012)
[198] Radar, (2013)
[199] Ter borg, Et all. (2009), p. 5 | Altijd Wat (2013) | Radar (2013)

5.2.1 New Zealand's Health Care Sector

The first step towards a universal New Zealand Health care system we made in 1938 with the signing of the Social Security Act as a result of efforts made by the first Labor Government[200]. Subsidies were provided through the General Medical Service (GMS) which was founded in 1941[201]. The Act introduced free of charge health care provision to the whole nation financed through taxation. General practitioners preferred independency and ultimately negotiated a fee-for-service structure, rather than publicly financed salaries[202]. With funding coming from the central government, similarly did the centralization of power shape itself. The full decision making power came in the hands of the Minister and department of Health who was to be advised by the Board of Health and the Hospitals Advisory Council. The former functioned as monitoring agency of the Local Authorities who were responsible for environmental health and town planning. The latter was to monitor and represent the 29 hospital boards. The system ultimately led to a great rise in health care costs and long waiting lists for specific types of surgery. Rich patients had the choice of private clinics in this way avoiding the long public waiting lists[203].

In 1970 the department of health investigated the shortcomings of the system ultimately leading them to conclude the system had become too fragmented. In the review they wrote they recommended the establishment of local authorities, partly elected and partly appointed by the minister. The system decentralized, giving the newly established local area health boards (AHBs) as well as the greater autonomy for the hospital health boards[204]. With incremental reforms being put into place in the 70s and 80s the labor government in narrow collaboration with stakeholders implemented fully decentralized health care system. In total 14 AHBs were formed during the period of 1983 to 1989. The Hospital Health Boards were abolished in 1989 with the introduction of the Local Government Act. Minister and Department of health kept charge over the total budget and general policies. The AHBs were free to fill in the provision of health care, including the hospital care, within their allocated budget and these general policies. The General Practitioners remained operating on the fee-for-users system; however as their fees started rising government subsidy did not cover all of the primary health care provision of the GPs. As a result GPs demanded co-payments of their patients. This led to patients choosing to get primary health care at the hospital which was completely covered. To counter this development the Minister of Health first introduced user charges for hospital patients in 1992. These

[200] French, J. Et all (2001) p.24
[201] Parliament.nz, (2009) p.2
[202] French, J. Et all (2001) p.24
[203] Parliament.nz, (2009) p.2
[204] French, J. Et all (2001) p.25

charges were abolished the year after, ultimately leading the minister to higher the subsidies on General Practitioners services[205].

In 1993 another thorough reform was passed by the New Zealand government. As the waiting lists for specific medical treatments remained to exist and society perceived health care provision as unequal, fragmented and inaccessible the government was forced to act. In 91'The Area Health Boards were abolished after they were blamed for insufficiently transforming former health practices. The new idea was to split health care purchasing from health care provision. After a two year design stage the Health and Disability act was signed in 1993 splitting up the health care sector in three different responsibilities: ownership, provision and purchasing of health[206]. Several new institutions were established, most important of them: the Public Health Commission (PHC). The PHC was considered to be independent from the Ministry and Minister of health; a crown agency. The new agency was in charge of purchasing and monitoring the health services. The Area Health Boards were transformed into Crown Health Enterprises (CHEs), 23 in total, which were directly contracted by the PHC. The boards of the CHEs were appointed by the Minister of Health. The PHC however, did not survive long. In 1996 the government put through a new round of reforms abolishing the institution due to its complexity[207].

Besides the PHC and the CHE's a third institution was established in the form of regional health authorities (RHEs), of which four in total. These agencies which were directly accountable to the Minister of Health were in charge of monitoring the health needs of their populations, the role as a purchaser of health and disability services and the contracting and monitoring of health care providers. The budgets of the RHAs were set by the Minister of Health and their boards were appointed by that same Minister. In first instance also pharmaceutical expenditures were to be managed by the RHEs, however later they decided to centralize this responsibility into a national Agency named PHARMAC who was to manage the procurement and purchasing of pharmaceuticals on their behalf. Also worth noting is the establishment of community trusts which were allocated health services provision for smaller communities. The community trusts had a similar set up like the RHAs as they were independent providers with their own facilities and ability to contract to the RHAs[208].

Whereas the 1993 reforms were known for their steps towards more decentralization and introduction of crown agencies, the 2000 reforms brought back centralization into the system. The four Regional Health Areas were combined into a central institution named the Health Funding Authority (HFA)

[205] Parliament.nz, (2009) p.8
[206] French, J. Et all (2001) p.27
[207] Parliament.nz (2009) p. 10
[208] Parliament.nz (2009) p. 11

executing the same responsibilities (funding CHEs, Community Trusts and Private Health Providers) as the former RHAs only at the national level instead of the, considered too expensive, regional levels. The Minister of Crown Health Enterprises overlooking the former CHEs became part of the Ministry of Health and the CHEs themselves were transformed into 24 Hospital and Health Services. They relied on the Health Funding Authority for their finances, whereas they were monitored and owned by the Minister of Health. The Health Funding Authority received its general budget allocations from the Minister of Health[209].

The system did not last long. In 2001 the system was reformed again with the introduction of 21 district health boards (DHB's). The DHBs became in charge for the provision and purchasing of public health care services, whereas their funding was allocated by a restructured Ministry of health which was under direct control of the Minister of Health and the Parliament. Private health care providers remained to exist. The General Practitioners kept their service subsidy, for which make their agreements mainly with the District Health Boards and partly with the Ministry of Health. The Hospital Boards disappeared with their responsibilities taken over by the District Health Boards. The final structure got its form in 2008. PHARMAC remained unchanged since its introduction in 1993, still getting its advice from the District Health Board and internal committees. Its budget is set by by the Ministry of Health[210].

Change and reforms over the years

Overall we may state that over the last forty years the health care sector in New Zealand has been rather dynamic. The first steps towards a national health care system were made in 1941: the establishment of the General Medical Services (GMS). In this first reform, funding, budget allocation and provision came from the central government, purchasing was done by the GMS. In this early state we may thus state that funding was highly centralized and equal for everyone or social democratic. The execution of the policy was in the hands of their agent, the GMS, or else said: corporatist like.

By the 70's the experts concluded that the system had developed and drifted away. The operations had become too fragmented for the central government to coordinate. In 1983 with the introduction of the Local Area Health Boards (AHB's) the provision and purchasing became in the hands of these self-governing agencies, a more corporatist like approach. The budget-setting remained in the hands of the Minister of Health (social democratic).

[209] Ibidem, p.19
[210] Ibidem. P. 20.

In 93' also the funding side of the sector was corporatized, with the introduction of the independent Public Health Commission (PHC). The provision and purchase structure was revisited; the former AHB's were transformed into the 23 Central Health Authorities (CHE's), but remained to be a corporate approach. Between 93' and 96' the Area Health Boards were established, starting by sharing the function of purchasing care together with the PHC. In 96' the situation became too complex, ultimately leading the government to abolish the PHC and giving the responsibility for purchasing care completely in the hands of the AHB's.

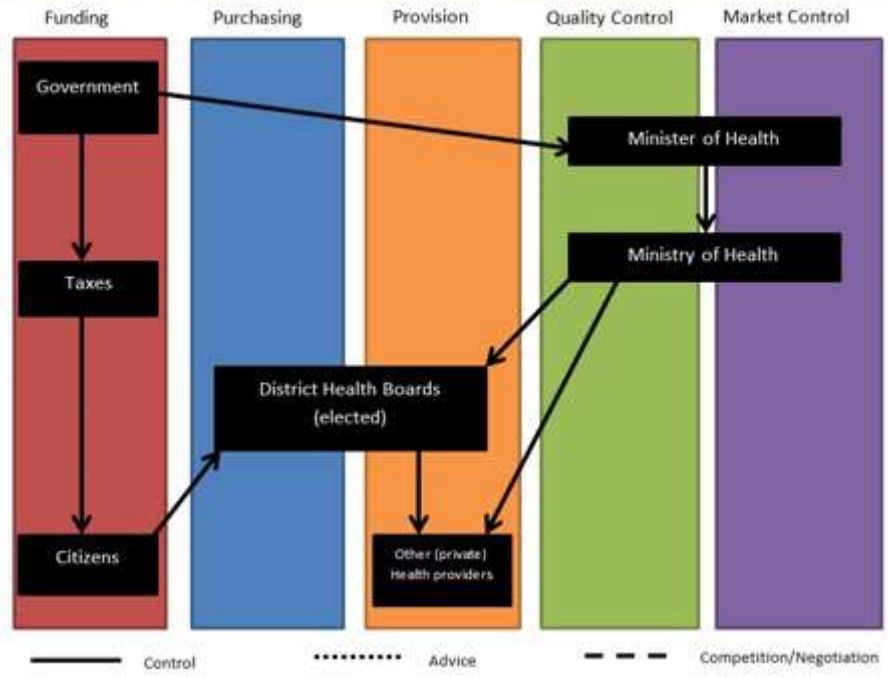
Table 5.2 Historical developments of New Zealand's Health Care Paradigm

Time-period	*Ruling Paradigm*	*Types of change*	*Agents*
- **1941**	Charity	None	
1941 - 1970	Social Democratic (Funding/Provision)	Displacement	Government
	Corporatist (Purchasing)	Displacement	GMS
1970 -1983	Corporatist	Drift	Fragmentation
1983 - 1989	Corporatist (Provision/Purchasing)	Displacement	AHB's (14)
	Social Democratic (Funding)	Conversion	Government
1991 - 1993	Corporatist (Purchasing)	Conversion	PHC/RHA's
	Corporatist (Provision)	Conversion	CHE's (23)
	Social Democratic (Funding)	None	Government
1993 - 1996	Corporatist (Purchasing)	Conversion	RHA's (4)
	Corporatist (Provision)	Conversion	CHE's (23)
	Social Democratic (Funding)	none	Government
2000 - 2001	Corporatist (Purchasing)	Conversion	HFA (1)
	Corporatist (Provision)	Conversion	HHS's (24)
	Social Democratic (Funding)	None	Government
2001 - 2009	Corporatist (Provision/purchasing)	Conversion	DHB's (21)
	Social Democratic (Funding)	none	Government

In 2000 the government centralized the purchasing function, by combining the four RHA's into a single national Health Funding Authority (HFA). Simultaneously, the Crown Health Agencies, responsible for the provision of care, were replaced by 24 Hospital Health Services. Already in 2001 the situation changes, as finally the HFA and the 24 HHSs were combined into 21 District Health Boards with the function of both purchasing as well as providing health care.

Overall the New Zealand system is marked by a social democratic funding structure, whereas the functions of provision and purchasing of care have always been somehow corporatized. The changes during history were not necessary reforms, as the paradigms remained in place. Moreover we can speak of second order reforms, as with every change the institutions performing the corporatist functions were replaced.

Figure 5.2: Organizational Chart New Zealand's Health Care Sector



5.2.2 The Current Situation in New Zealand

Figure 5.2 shows the system as it is today. In New Zealand the health care funding comes through general (progressive) taxations.

All New Zealanders are insured, with the option of additional private health insurance service coverage. The provision of the services is paid by the District Health Boards; these are also in charge for a large share of the provision of Health care as they are the owners of the public Hospitals[211]. Other health providers such as dentists, pharmacists and general practitioners are contracted annually on a fixed-fee-for-service basis. The Ministry of Health is mainly in charge for monitoring the health care system and the status of public health. The Minister has the authority to appoint up to four members, the chairman and the deputy chair. An additional seven members of the board are publicly elected every three years. The Ministry benchmarks the performances of the DHB's and publicly announces these on its website every quarter. The Minister has also the ability to appoint crown monitors into the DHB's[212].

[211] www. health. Govt.nz (2013)
[212] Ibidem.

5.2.3 History of the PHARMAC-model

PHARMAC has not changed significantly since it was introduced in 1993. The functions it has have expanded, as they started in 2001 by also involving themselves in the purchase of pharmaceuticals for Hospitals. Tordoff evaluated this shift in 2007 and judged it as moderately successful and stating that it might be useful for other countries to centralize their pharmaceutical expenditure as well[213]. Nowadays, PHARMAC is still expanding its function as purchaser for the hospitals, in September 2007 the minister decided to expand PHARMACS management to include medical devices[214].

As was already earlier stated over the years PHARMAC has developed a large number of strategies, besides blind bidding, in order to lower the prices of medicines. On the basis of their policy is the predetermined budget within which they will have to make choice, which they make on the basis of QALY's as earlier explained. Just recently however, they are asking the public whether they should change the criteria on which they determine the values of the treatments, by adding into their judgments the age of the patients. In other words: are medicines, or medical treatments, worth more if they are prescribed to young people? Or whether they are prescribed to rich people or poor? In other words, they are asking the public whether they should bring into account cultural determinants, instead of just considering every human life year of equal value. The discussion is interesting and one could argue whether this would also enhance a paradigm shift, for the preference policy was introduced as a mean to drive politics away from pharmaceutical spending. It might be interesting to follow in the near future as the discussion is still in an early stage[215].

5.3.1 The Hungarian Health Care Policies (Also see figures 3 from the Appendix)

The first step towards public health care in Hungary was made in 1876. Act XIV demanded that doctors and surgeons performed their services free of charge for people with low incomes. It was designed by the National Health council and signed in 1875 by Kalman Tisza, Prime Minister at the time. Not much later it was approved by the House of Commons and the Upper House[216]. Before the act, there were already forms of collective initiatives ensuring health care provided by the large mining companies. These enterprises were obliged by the Habsburg Ruler in 1854 to provide this early type of health insurance to its workers[217].

In the early years of the mining company funds, the workers were free to choose whether they took part in them. By 1885 over forty percent of the workers were covered by the initiatives. Mandatory

[213] Tordoff, J.M. (2007)
[214] PHARMAC, (2013)
[215] Dudding, A. (2013)
[216] Szekely, (1973) p. 79
[217] Gaal, (2011), p. 19

insurance started to develop in 1891 with the approval of Act XIV. The new regulation obliged all industrial workers to insure themselves. The law was similar to the insurance regulations which were introduced in Germany and Austria during the previous decade. A first nationwide Social Health Insurance was established in 1927 with the introduction of the National Social Insurance Institute (NSII). At the beginning it was to cover all Government Officials and Industrial Workers and their families. At the beginning of the 40s around thirty percent of the Hungarians were insured by the NSII[218].

After the Second World War the communist regime nationalized public health care completely. The provision of Health Care became a centralized responsibility of the national government. The National Council of Trade Unions was established to take over all the tasks of the former NSII and all private insurance initiatives were dismantled. All of the Hungarians were from then on covered for health care by the state. All physicians and medical personnel became government officials. All health care services were funded by the Ministry of Health. In the 50s the Hungarians' Health improved with the introduction of regulations and investments on sanitation and immunization of children[219].

From the 60s onward, the health care program started to show weaknesses. The provision of health care was not accessible to everyone. Equality was ensured by law, but in practice large parts of society had hardly access to services or the quality of service would significantly differ among providers. Corruption was rather high as informally payments were common practice. By the 80s the difference between Hungary and the Western World become so large that the government was forced to act. Reforms were introduced in by the end of the 80s, the last years of communism[220].

Private insurance initiatives were welcomed again in 1988 and a Social Insurance Fund was established to collect all the social insurance contributions into a fund separated from the government budget. The National Social Insurance Administration was established to maintain and monitor the new funds. The new agency was given the tasks of collecting the salary-related contributions as well as administering the cash benefits of the scheme. The early 90s were recognized by territorial decentralization of the responsibilities concerning health care provisions. Health care provision went local, giving local government control over the supply of health care[221].

After elaborate debates Hungary ended up choosing a single-insurance model. The Social Insurance Fund was split up into a Pension Insurance Fund and a National Health Insurance Fund in 1992.

[218] Ibidem.
[219] Gaal, (2011), Oeb.hu, 2013.
[220] Gaal, (2011).
[221] Ibidem.

Together with the funds, the administration was reformed. The National Health Insurance Fund Administration became in charge of monitoring and maintaining the former. The two funds and administrations were to be controlled by quasi-public institutions consisting out of elected officials. The Health Insurance Self-Government was established in 1993. Between 1994 and 1998 the Hungarian government continued with focusing on cost-containment of the health care. Budget cuts were put forward by the central government, open to the local governments to decide on how they would be achieved. Simultaneously the government focused on increasing the revenue side of the system increasing contributions as well as the adoption of a Lump-sum Tax[222].

In 1998 the Fidesz Party came into power. While the previous coalition was about to introduce a multi-insurance system, Fidesz decided differently. Cancelling the plans and instead abolishing the self-governing elected bodies which controlled the National Health Insurance Fund Administrations as well as the Pension Fund Administration. The control over the NHIFA was given to the Ministry of Finance, after it was shortly under direct control of the Prime Minister. The revenue side was increased by increasing the share coming from the Health Care Tax by adding a proportional component. Direct Health Insurance Fund contributions were lowered aiming at countering evasion of the obligatory payment. The tax office was made responsible for the collection of the contributions, where before this was the NHIFA's job[223].

From 2000 onwards, the government introduced more centralized legislation. General practitioners were no longer funded by local governments, but by a comprehensive national quota system. In 2001 the ownership over the NHIFA was given back to the Minister of Health. The rest of the health provision system was to be corporatized further, by expanding the authorities of the local governments[224].

In 2002 the Alliance of Free Democrats gained back majority in the parliament. The new coalition continued corporatization of health care by the establishments of regional health councils. In the next five years, the government tried to create a form of managed competition trough major reforms, however these attempt failed and not long after, the socialist Fidesz party gained a landslide victory. With absolute majority in the parliament they centralized seven ministries into one, including the Ministry of Health. The new Ministry of Human Resources was given ownership over the National Health Insurance Fund Administration and with it the authority over funding the health care system[225].

[222] Ibidem.
[223] Ibidem.
[224] Ibidem.
[225] Ibidem.

Change and reforms over the years

I start by recognizing that the situation before 1876 was a society in which health care was provided on a basis of charity. In 1875 with the signing of Act XIV a first step was made by the decision that doctors were obliged by national law to help the poor free of charge. This first step towards equality can be recognized as a reform towards a social democratic state. In the years until 1927 the government mainly expanded their social democratic principles by relying on demanding initiatives from the heavy industry.

In 1927 with the establishment of the National Social Insurance Institute further attempts were made to equalize the provision, but this time by means of a corporation who acted on behalf of the government. The initiative can be seen as a first reform in the corporatist direction. In the period afterwards, the share of population to profit from the NSII was expanded by incrementally adding new legislation.

The turning point can after WWII, when the communist centralized all health care provision. Service delivery, funding and ownership were in the hands of the Ministry of Health. The shift can be typified as a radical reform in the social democratic direction. It would take until 1988 before reforms were made. The first were those in the Liberal direction as private health insurers were allowed back in the market.

Table 5.3 Historical developments of the (Austrian-)Hungarian Health Care Paradigm

Time-period	*Ruling Paradigm*	*Types of change*
- **1876**	Charity	None
1876	Social Democratic/Liberal	Displacement
1876 - 1927	Corporatist (Social Democratic)	layering
1927 -1940	Corporatist (Social Democratic)	Displacement
1945 -1987	Social Democratic	Displacement
1988	Social Democratic (Liberal)	Layering
1993	Corporatist	Displacement
1993-1998	Corporatist	Conversion
1998 - 2010	Social Democratic (Funding/purchasing) Corporatist (Provision)	Displacement Conversion

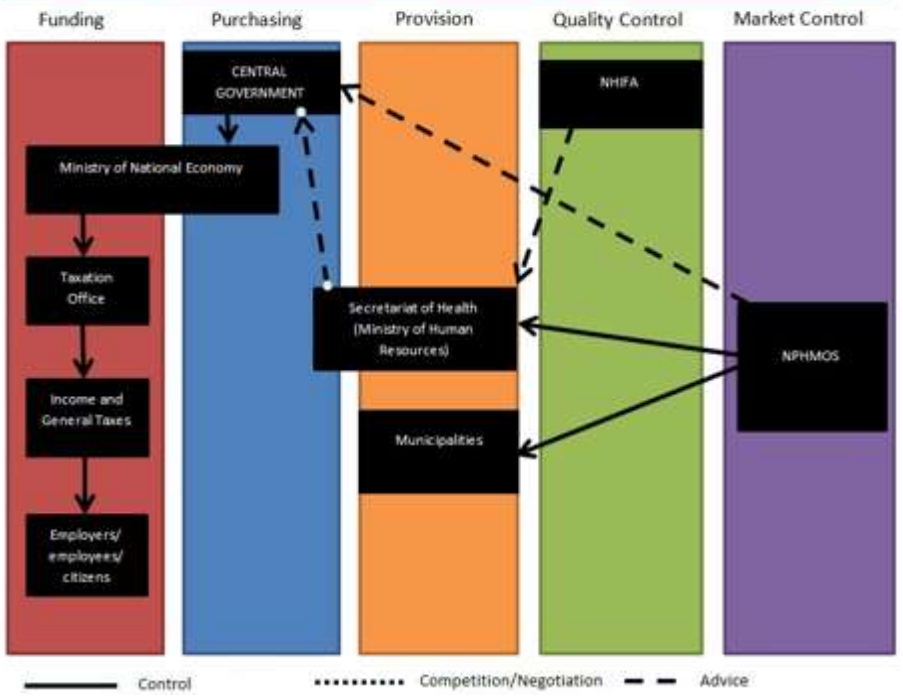
When the wall fell, the Hungarians quickly started to liberalize. For the health care sector it meant a more corporatist approach. Authority over the ownership and provision of health care was to be given to local governments, whereas the funding authority was given to the two quasi-public self-controlled NHIFA, led by elected officials. These times are marked by radical displacement of the social democratic system towards a corporatist system. Until 1998 the government increased their efforts for cost containment by converting the old social-democratic policies, open for the local governments to fill in how.

In 1998 the socialist Fidesz party reformed the corporatist funding side of the sector, by abolishing the self-controlled lead of the NHIFA. By putting direct ownership over the NHIFA first in the Prime Ministers hand and consequently in that of the Minister of Finance, we see the paradigm centralize towards a more social democratic approach. On the other side, the provision side of the health care sector was continued to be corporatized.

5.3.2 The Current Situation in Hungary

As for today, the division of authority in Hungary is somewhat difficult to determine. What is noticeable is that the Ministry of National Economy has strong influence on the funding of health care. 'The Ministry is responsible for fiscal policy and plays a central role in planning and approving budgets of the central governments, local governments and the Health Insurance Fund (HIF). The ministry is concerned primarily with the macroeconomic implications of health care financing and, in particular, with the impact of any deficit of the HIF, on fiscal balance, because the government is obliged to cover such deficit'[226]. Not only does the Ministry of National Economy determine the general budget it can also intervene in the NHIFA's actions by 'applying very strict cost-containment policies by imposing budget objectives for the NIF, but it has generally done so without taking into account the real needs of the HIF with regard to health care provision and financial balance'[227].

Figure 5.3: Organizational Chart of the Hungarian Health Care Sector



The impression I have is that the Ministry of National Economy acts primarily on their focus on budgetary efficiency. This view was also given by various stakeholders. They stated that the budget objectives that were set by the Szell Kalman Plan were made with consultation of neither the NHIF nor the Ministry of Health. On paper the Secretariat for Healthcare (part of the Ministry of Human

[226] Gaal (2011) p. 18
[227] Ibidem, p. 21

Resources) and the municipalities are responsible for helping to purchase and provision of health care. The secretariat is the owner of various agencies which are responsible for preparing the laws which are to guide the health care sector at the national level. The Ministry is owner of certain health providers. Most of the actual purchasing power is in the hands of the national assembly and the central government for they 'regulate the most important elements of the provider contract in acts and decrees, including reimbursement price, capacities, quantity of outputs, payment methods and financing of capital costs'[228]. I choose to put the Secretariat of Health as partly responsible for the purchasing decision, as they have the function to prepare the laws for the national assembly and therefor it is of significant influence on the purchasing decisions.

The municipalities are responsible under the principal of subsidiarity for legislation of health care provision on the municipal level. The municipalities are the owners of local health providers, such as hospitals, polyclinics and primary care surgeries. Funding comes from the Health Insurance Fund, who makes contractual agreements with the local providers and indirectly the municipalities. Between the municipalities and the national government there is also a layer of counties. These counties, or provinces, are just like the municipalities in charge for the purchase and provision of health care, as they are the owners of the county hospitals[229].

It is hard to exactly retrieve to which extent the Ministry of National Economy intervenes in the purchase of health care, as they are authorized to execute relatively strong authority over the actions of the NHIFA. The NHIFA is in charge of funding the agreements with the health purchasers/providers. 'It has no discretion over revenue collection or budget setting, however, and has only very limited discretion over purchasing decisions. The NHIFA is not allowed to engage in selective purchasing, and its contracting process is not based on systematic health needs assessment. It has to contract with all providers who have a territorial supply obligation'[230]. The national government regulates most of the purchaser-provider relationship and is therefore considered to be the provider itself. Although the NHIFA lacks the authority to make decisions themselves, they do play a significant role in the development of policies, as they help the secretariat of health in preparing their policy proposals. This support is based on what they learn from executing their function as purchaser of healthcare.

Lastly, I would like to not the existence of the NPHMOS. This organization provides some health care services, but is mainly in responsible for monitoring the health care quality. The NPHMOS is led by an appointed Chief Medical Officer. The NPHMOS is an organization which operates on the national,

[228] Ibidem, p.22
[229] Ibidem, p. 26
[230] Ibidem. P. 82

regional and sub-regional level. On the national level the organization consists out of nine departments, each focused on a specific functional health area. The NPHMOS is under the ownership of the Secretariat of Health. Besides the NPHMOS there are several other but smaller professional advisory agencies that help monitor and prepare government legislation[231]. One of the most important is the National Institute for Quality- and Organizational Development in Health Care and Medicines (GYEMSZI). The National Institute of Pharmacy who is in charge of the evaluation and authorization of pharmaceuticals is part of GYEMSZI. Furthermore, GYEMSZI is an important actor with monitoring, coordinating and consulting the health care sector.

Part of the tasks list of the GYEMSZI is to coordinate their efforts with those of the NPHMOS and other public health agencies[232]. The image which I was given was that of a fragmented and decentralized system of independent budgetary agencies lacking direct communication links with decision makers. In 2011 Peter Gaal also concluded that a transparent information management system within the Hungarian health care sector is lacking. Much of the data that is known by decision makers is inaccurate or outdated. Decision makers mainly base their choices on the financial data which is collected by the NHIFA[233].

For a more detailed schematic overview of the Hungarian health care system you may also see the appendix (Figure 3).

5.3.3 History of the Hungarian Pharmaceutical Policy

The Hungarian system for the provision of Pharmaceutical Care is primarily in the hands of the private sector. The chain that delivers the pharmaceuticals to patients consists out of manufacturers, distributors and retail pharmacists. The system is a result of two major liberalization efforts undertaken in the beginning of the 90s and in 2006. The public sector now owns just a fraction of the chain for provision (the public hospitals) giving it just a minor influence[234].

This used to be different under the situation of communism. Before the 90s the government owned all the organizations involved in the distribution and provision of pharmaceuticals. As result of the great economic transition the greater share of the wholesale and retail market had been liberalized. Ending 1997, no public pharmacy was owned by the state anymore[235].

[231] Ibidem, p. 33
[232] GYEMSZI, (2013)
[233] Gaál, P. Et all. (2011), p. 40-41
[234] Gaál, P. Et all. (2011), p. 145
[235] HSCO, (2001)

During and short after the communist era, the prices of pharmaceuticals were established by a comprehensive system of regulation and control. For innovative (patented) medicines the government used, and still uses, reference prices as a method to determine the prices of medicines. Prices used to be established as a result of direct negotiations between pharmaceutical manufacturers and representatives of the government, institutionalized in the so-called Insurance Price and Subsidy Committee. The method of external reference pricing is used, meaning that the NHIFA compares the price that is proposed with the price that is charged in other countries. It is the responsibility of the manufacturers themselves to include a list with external prices for their medicines that they want to apply. The proposed price may not be higher than the lowest reference price[236].

For generics, NHIFA used the tool of internal reference prices. The regulation was simple and clear. If a generic company wants to enter the market, it should be cheaper than the cheapest available. The race started off when a patent expires. The first generic company should be offering its medicine at a minimal discount of 30 percent of the original medicine with the same active substance. Consequently, if another generic company would like to enter the market, it should have offered its alternative for at least a 10 percent discount of the current cheapest version of the generic medicine. The third entry had to suffice for this 10% discount as well, whereas the fourth, and so on, just had to be cheaper than the ones before it[237]. Later, with the introduction of the Szell Kalman Plan, this procedure is replaced by the periodically rounds of blind bidding as described before.

5.2 Chapter Summary

In this paragraph I discussed the different historical backgrounds regarding the paradigms behind the pharmaceutical- and health care policies in New Zealand, The Netherlands and Hungary. What was discovered was that the Dutch health care sector has shifted from a Social-Democratic, via a more corporatist like state to a market dominated model. The pharmaceutical policies showed similar developments. New Zealand's health care system started as a Social Democratic Welfare state but gradually shifted towards a corporate ran model. Specialized and regional health boards have significant autonomy in purchasing and providing health care. The pharmaceutical policies are almost completely corporatist-like with purchasing and price-setting power in the hands of PHARMAC.

The Hungarian Policies have a Social Democratic history. After the collapse of the USSR attempts for implementing a market-type multi-insurance model in the health care sector have stranded twice. Nowadays we speak of a Social Democratic Health Care Sector with some heavily regulated agents executing the task of provision of health care. For the Pharmaceutical policies we may speak of a

[236] Ibidem.
[237] Ibidem.

corporatist-like system in which the NHIFA purchases medicines, however due to the heavy regulation the institution has almost no autonomy in its decision, making it in practice a Social-Democratic type system.

6. Qualitative Analysis Part II: Stakeholder Analysis

IN THIS STAKEHOLDER ANALYSIS I will try to retrieve the views that the different stakeholders have about the pharmaceutical policies in their countries. Aim is to find out whether and how they would like to see these policies change. I will start off with the Dutch stakeholders, followed by the ones in New Zealand and Hungary.

6.1 The Netherlands

The Government

The Dutch government is very much in favor of sustaining their preference policy. This is mainly due to the fact that the preference policy contributed significantly to their goals of cost containment. Over the last years, there have been multiple discussions in the parliament regarding the lack of uniformity and transparency of the policy; however this has not led to any significant top-down changes in the policy.

Most recently, in May 2013, a group of experts has been invited to come and give their opinion about the preference policy to the Dutch lower chamber. Their critics were mainly aimed at the two earlier stated shortcomings: a lack of uniformity and transparency. So far politics have not responded to the critics by implementing policy-changes.

This stresses the position of the minister and the leading coalition in The Netherlands, who last responded to parliamentary questions about the preference policy in November 2012. Schippers (Minister of Public Health) pointed out that, in the period of 2008 to 2010, the preference policy has saved the Dutch society 1,115 billion euros, while the total volume of purchased pharmaceuticals and care has risen. She also stated that she does not think the preference policy has so far led to a decrease in the quality of public health, nor that this is likely to happen in the future[238].

The Minister states further that she relies on the information she receives from the monitoring agencies such as the NZa and the Foundation for Complaints and Problems Health Insurance (SKGZ). Furthermore, patients can file complaints at the foundation Lareb if they experience problems due to side-effects of pharmaceuticals. The numbers they report do not give the Minister any incentives to assume that the preference policy has led to any increased health risks for society. Furthermore, Schippers points out that the Health Insurance law obliges health insurers to deliver the best quality of health care for the lowest price[239]. Schippesr stresses that she can think of ''no other alternative for

[238] Schippers, E.I. (2013)
[239] Ibidem.

the preference policy, which would be able to provide the same amount of savings, without decreasing the quality of health care provision''[240].

More recently (4 june 2013) the Minister seems to have changed her view. She started an investigation into the actual behavior of the Health Insurers in an attempt to find out whether they are providing their customer with the legislative obligatory best quality of care. She would like to see all involved parties think about adjustments which could improve the preference policy[241]. The results of this research and consultation have not yet been presented.

The Pharmacists

The Pharmacists are clearly against the Preference Policy in its current form. They name a rather long list of arguments why and how they think it should change.

Their main concern is the *lack of transparency* of the policy due to the fact that patients are not fully aware of the preference policy and because different health insurers have developed different alternatives (Also see Chapter 5.1.3) . Patients do not understand why they irregularly have to change their brands of medicines, nor do they understand why they have to pay a different price for a particular medicine compared to patients who joined other health insurers. The pharmacist is confronted with this inconvenience and there are even cases in which the pharmacist is confronted with aggression[242].

That in some case the prices of medicines differ significantly has a reason. As for today health insurers have managed to decrease the prices of generics drastically. The patients do realize this price drop, but they do not realize these price drops differ among insurers. The patient does not have the mean to compare prices of medicines from insurers with one another, making it not really a product to compete for. What patients do compare is the actual premiums they have to pay for health insurance[243].

Now, this causes the goal for health insurers is not to offer, but merely to acquire, the medicines for the cheapest price. as they are not really competing with one another by offering the lowest prices for medicines, but rather the lowest premiums for their health insurance. In first instance these two goals seem to be closely related, for if the prices of generics drop, so do the premiums. And to a certain extend this is true, however the health insurers have developed methods in which the price they have

[240] Ibidem.
[241] Optimafarma.nl (2013)
[242] Riesebosch, T. (2013), Baltesen, F. (2013)
[243] Riesebosch , T. (2013), Vermeulen, I. (2013)

to pay differs from the price that patients have to pay. There are practices that show that these price differences are rather significant (see example 6.1).

Example 6.1: The case of Rilutek

Rilutek is a medicine that is used in the treatment of Amyotrofe Laterale Sclerose (ALS). Just like for many generic medicines there are various alternative versions of this medicine available. In 2013, the Dutch consumers' association analyzed the prices of the medicine offered by five different health insurers. They found that the prices for Rilutek which were charged in the pharmacy differed significantly among insurers. The cheapest version was delivered by three out of five insurers charging 36 Euros for a medicine produced by manufacturer called Sun. Patients insured by VGZ and Achmea, two of the largest insurers, received a version manufactured by Actavis with a price charged of 547 Euros per package. The example shows that in some cases insurers seem to consciously choose to provide their customers with higher priced brands.

The question is why insurers would like to see themselves selling medicines at a higher price than they actually have to pay themselves. The reason for this could be the out-of-pocket contributions. In the Netherlands, all patients are obliged to pay a share of their health care themselves. Recently this amount has been raised to the first 350 euros of health expenditure per person per year, whereas it is possible to voluntarily higher this amount. These ''own-risk'' payments seem like a plausible reason for health insurers to wield the price discrepancies.

If a patient has to pay fifty euros for a medicine the health insurer actually pays only twelve euros for, the difference of thirty-eight euros (which the health insurer does not have to cover for the first 350 euros) is brought up by the patient himself. This profit can then be used to compete with the other health insurers by using it to lower the premiums. When the covert-alternative was introduced, this practice was soon identified by the government, which eventually led to health insurer to no longer charge any out-of-pocket-payments for preferred medicines. All out of pocket payments that had been done were paid back.

However, Riesebosch states that the health insurers do gain from the larger share the pharmacists have to pay as a result of the clawback. As we saw earlier, pharmacists have to pay 6.82% of the Pharmacy Purchasing Price (PPP). This percentage represents a larger amount if the PPP is higher. The PPP is derived from the price that the Health Insurer charges. In the case of Rilutek, the pharmacy has to pay 6.82% of 547 euros, which leads to the maximum of 6,80 Euros. If the real price the health insurer pays is only thirty six euros, the pharmacist is actually paying 19%, instead of 6,82%, of the medicine due to the clawback percentage[244] (also see example 6.2).

[244] Riesebosch, (2013)

Example 6.2: Possbile clawback exploitation				
Couvert Price	*Clawback amount*	*Reimbursed Price*	*Clawback amount*	*Real Clawback %*
36 euros	2,46	547,-	6.82% of 547 = 6,80 (maximum amount)	18.8%

However, this system in which the actual price the health insurer has to pay is kept secret could also be explained by the argument that the actual price at which the insurer buys, or the manufacturer sells, is considered to be competitive information. This can both be for the sake of the insurer who has to compete with other insurers, as for the generic manufacturer who also wants to sell his or her product to other insurers as well as in other countries. Giving away this information weakens the position of both the insurer as well as the manufacturer[245]. This argument is given by the Health Insurers themselves.

The manufacturers ensure the largest health insurers additional price cuts if they keep these prices secret. This way, other insurers cannot make use of the price information, making them less able to negotiate higher prices. Whether, the health insurers truly offer their patients lower prices is in no way retrievable, as only the insurers and the NZa know these prices. The health insurers ensure that this is the case, considering the fact that the NZa has not intervened in these practices, I personally believe that the secrecy contributes to lower prices. Personally I cannot judge whether these hidden savings are worth the lack of transparency; the insurers think they are, the pharmacists think they are not.

The pharmacies furthermore perceive that the preference policy has led to *shortages* of particular medicines. Especially in the period after a bid is won, manufacturers have difficulties in supplying the market with sufficient medicines. These situations are worrisome as they can represent practices of unfair competition. Pharmacists plead for taking into account the historic supplying performance of manufacturers instead of merely the lowest price[246].

Pharmacies are also worried about the dependency on single supplier, as for other manufacturers withdraw themselves out of the market if their medicines are not preferred and fully reimbursed. Furthermore, in case of scarcity the manufacturers rather choose to supply those markets in which they receive higher amounts for their medicines, leaving Netherlands positioned at the back of the line[247].

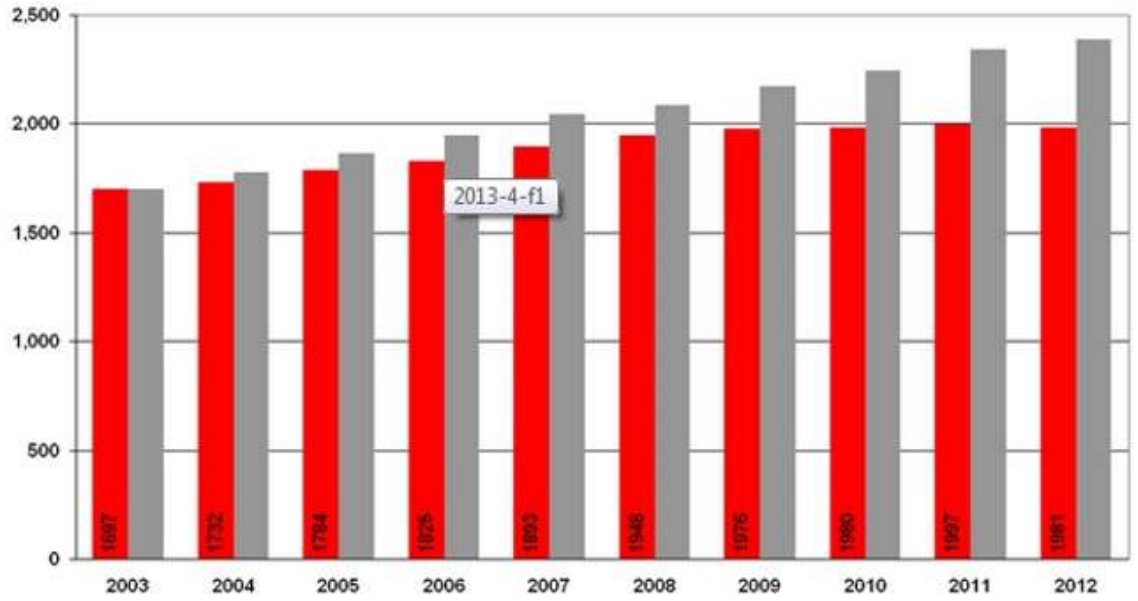
The pharmacists suggest the government, or health insurers, to put limits to the preference policy. The KNMP sees that the preference policy has led to significant price drops, which could not have realized

[245] Radar, (2012)
[246] SFK.nl (2013)
[247] Riesebosch, T. (2013)

by the pharmacies, but they also see that medicines at some point reach certain bottom prices. At these prices a bottom should be set: a price at which all generic suppliers are allowed to supply the market, instead of just one. This would attract more manufacturers to re-enter the market, making the Dutch pharmaceutical sector less dependent on the actions of a sole supplier[248].

The pharmacists understand that they have earned too much in the early days, however at the moment they feel that the government is squeezing their margins to their limits. Their *profits keep shrinking* with the introduction of the preference policy and the free-price model for pharmaceutical care, *while the amount of care and medicines they have to process is growing by the year*[249]. The pharmacists are backed by the most recent figures (see figure 6.1) that show that the demand for care and medicine has grown on yearly basis by 4%, while the amount of public pharmacies has only averagely grown by 1.7%. This shows that the pharmacies have to process more demand[250].

Figure 6.1: Pharmacies (red) vs. Pharmaceutical Demand (grey) [245]



The question remains how strong this argument is. I cannot judge how high the current work pressure on pharmacists is or which amount of work pressure would be reasonable. This may become clearer by more experience in the future. Zarroy believes this situation is not so critical, the pharmacists have been using the argument of shrinking margins and work pressure since 2008 but there have been no signs of pharmacist going bankrupt[251].

[248] Riesebosch, T. (2013)
[249] Riesebosch, T. (2013)
[250] Riesebosch, T. (2013), SFK, (2013)
[251] Zarroy, 2013

The Health Insurers (Agents)

The Health Insurers are satisfied with the Preference Policy as it is today. They respond to the main critic on the lack of transparency that this secrecy is needed in order to achieve higher results in their competition with other Health Insurers. *Lower expenditures* are the health insurers' primary target as it is their goal to attract as many customers as possible. Lower prices for pharmaceutical care and medicines gives the health insurer the ability to lower the premiums and attract more customers[252].

According to Zarroy it is important that pharmacists make their performances more visible. Zarroy argues that pharmacists consider their position weak in the negotiations with health insurers. The health insurer is responsible for purchasing pharmaceutical care, for this the insurer would like to see visible performances in return. If pharmacists want the health insurer to pay more, the health insurer wants to see that the pharmacists deliver more services or deliver a better quality of their services[253].

Zarroy and Visser do not see shortages of medicines as a result of the preference policy. The purchasers of pharmaceuticals state that shortages are the results of global trends, which are not influenced by national policies. In the contracts between manufacturers and health insurer the two parties agree on a supply obligation. If the supplier is not able to deliver, it should notify the health insurer of this in advance. The health insurers have the ability to fine the suppliers if the contractual supply obligation is not met without solid reason. The Health insurers do not take into account the historical supply-performances of manufacturers in their choice for a new preferred medicine. This is solely based on financial arguments[254].

The Manufacturers

It is not hard to imagine that the interests of the pharmaceutical manufacturers are being hampered by the preference policy. As the manufacturers are forced to offer their pharmaceuticals at lower prices due to the competition their *profit margins shrink*. Some arguments are given that simultaneously the manufacturers save significant amounts on promotion of medicines, which is no longer needed. Zarroy (2013) states that: not all manufacturers are, or have been, taken position against the preference policy. He notes that without the generic manufacturers the preference policy would have not been suitable for implementation. He further states that these generic companies are largely profiting from the preference policy as their promotion budgets are not as high as those of

[252] Zarroy, S. (2013) Visser, F. (2013)
[253] Ibidem.
[254] Ibidem.

premium brands; in the preference policy promotion is mostly done by reducing the price[255]. However, this advantage disappears over time when medicines hit bottom price levels.

However, due to the new alternatives of the preference model (covert-preference policy, IDEA-model, etc.) the position of these small specialized generic manufacturers is changing. 'The initiatives taken by Achmea and VGZ call for a more portfolio based approach, for which the larger generics companies may be better positioned to profit'[256]. As a result we see resistance of specialized generic manufacturers towards these alternative preference policies grow.

The Wholesaler

Since the introduction, the wholesalers have tried to hamper the development of the preference policy. In 2005 they started by pressing charges trying to prohibit further expansion by court ruling, the attempt did not succeed. However, the manufacturers did not give up their resistance. Halfway 2012, one of the biggest wholesalers, Brocaref, announced that it was to cause a crisis by putting the delivery of a thousand pharmaceuticals on hold, by the start of November 2012, due to shrinking margins. They received support from pharmacies and other competitors, however their resistance was discontinued when they got notice that their competitor Mosadex came to an agreement with the health insurers on a fixed remuneration of at least 22 cents per package for the wholesalers' practices[257].

The Dutch Health Authorithy (NZa)

The NZa performs its function as market regulator. On a yearly basis they perform market scans, in which they give a detailed overview on the state of the market. The NZa functions on behalf of the Dutch population; as a result they judge the market by three different interests: Affordability, Accessibility and Quality. But in fact, these interests are not judged on equal bases. The NZa is mainly interested in the *costs of the medicines and* care and this is rather easy to measure. The accessibility is only taken into account by counting the total amount of pharmacies. For their idea on quality they rely on the judgment of the Inspection for Health Care (IGZ)[258].

The NZa did notice a decrease in the total amount of pharmacies, but did not notice a decrease in quality or accessibility due to this. What the NZa did notice was that health insurers buy insufficient levels of pharmaceutical care. The NZa would like to see that health insurers compose more detailed

[255] Zarroy, S. (2013), Visser, F. (2013)
[256] Ter borg, J., Warmerdam, J. Et all. 2009: 7
[257] Pharmaceutisch Weekblad (2012)
[258] Vermeulen, I. (2013), Marktscan (2013), p. 9

contracts with the pharmacies on the delivery of pharmaceutical care. Important is that health insurers get a better indication about the quality of pharmaceutical care that individual pharmacies deliver. The better the quality, the higher the remuneration the pharmacy should get. Pharmacies should be remunerated by the fact that they obey to certain requirements such as: patients satisfaction surveys, the use of mystery-shoppers and the actual performances of additional care[259].

What the NZa would like to see is the development of more choice for the customers, especially in the area of pharmaceutical care. Patients have to be informed about the contracts that the health insurers have with the pharmacies on the quality of care. Insurers have to make more detailed contracts, with lower remuneration for lower quality care, which also costs the pharmacy less. This way the patient can choose whether he or she wants an insurance that only covers contracts for basic pharmaceutical care and for which he might have to travel a little bit further, or whether he wants a more expensive insurance by which also the level of pharmaceutical care is higher and thus he can go to the pharmacy around the corner. However, as for today, this differentiation is not yet achieved with the free-prices model for pharmaceutical care and all pharmacies are considered and remunerated equally[260].

The Patients

The patients do not directly express their opinion to the public. In this case I rely on the association(s) that represents the patients, the NPCF. Together with the association for General Practitioners (LHV) and the Union for Elderly (Unie KBO) the NPCF shares in the arguments of the pharmacists that there is a lack of *uniformity and a lack of transparency*. Out of the latest results of the NPCF's patient survey can be deduced that the majority of the patients (56%) has experienced problems with the preference policy in the last two years[261].

What worries them most is the fact that patients have to irregularly change the brand of their medication. The associations prefer the government to act to improve the correct use of medicines. The associations believe fair amounts of money can be saved by preventing patients from using their medicines incorrectly[262]. Although, they are not completely clear on how to achieve this. What is of primary importance is that health insurers take more responsibility in their task to inform patients about the procedures and effects related to the preference policy. At the moment this information function is too much in the hands of the specialists[263].

[259] Marktscan, (2013), p.10
[260] Vermeulen, I. (2013).
[261] Pharmaceutische Weekblad (2013)
[262] Optimafarma.nl (2013)
[263] Pharmaceutische weekblad (2013)

Although the latest research results show that the majority of the patients experience problems with the preference policy, two thirds of the patients think the economic advantages outweigh these problems. 67% of the patients state that the government should not abandon the policy[264]. The association started a national hotline for patients to report when they experience problems due to the preference policy[265].

The Experts

The pharmaceutical industry seems to have responded to the preference model in an innovative way. While physicians are not allowed anymore to determine particular brands, they are still the ones who are in charge for prescribing which medicine the patient should be treated with. In the case of the brands, we talk about the active ingredients in a medicine. Generics are alternatives for medicines with similar active ingredients. The preference policy gives the health insurers the freedom to prefer one medicine among those that have similar ingredients. The pharmaceutical industry has responded to this, by developing new medicines, with sometimes similar ingredients in different proportions, to treat the exact same ailments, arguably, more effectively[266]. These type of ''not-so-innovative alternatives are called me-too drugs[267].

In this case, if the specialist prescribes these new patented medicines, the health insurer is not allowed to prescribe the cheaper generic. This because of the fact that the preference policy does not categorizes drugs by their effects, but merely by their active ingredients of the drugs[268]. Experts have calculated that changing this categorization could save the Dutch government up to a hundred million euros a year[269]. However, these categorizations are controversial as there are discussions to which extent the health insurer will sit on the seat of the specialist.

In the beginning of 2013 an independent committee was tasked with analyzing the effects of the introduction of free-prices for pharmaceutical care. The overall results was that the new mechanism, in which insurers negotiate with pharmacies over the prices charged for providing pharmaceutical care, was not causing significant dissatisfaction among consumers[270]. On the other side the committee did agree with the NZa and the Pharmacists, that the health insurers do not purchase sufficient

[264] Ibidem.
[265] Nierniews.nl, (2013)
[266] Altijd wat, 2013
[267] Garattini, S.
[268] Schellekens, 2013
[269] Altijd wat, 2013
[270] Reibestein, R., Rinnooy Kan, A. (2013)

pharmaceutical care since the introduction of the free-prices, nor do they negotiate with the pharmacies on equal level playing field.

Summary

As to expect from a political context, everyone has his own opinion. The preference policy is unlikely to reform, as only the manufacturers are the ones pursuing this. More likely to happen are some additional incremental changes. In tables 6.1 and 6.2 I have tried to give an overview of the arguments that the different stakeholders have given and to which extent this would require reform to change, according to them.

Table 6.1: Stakeholder arguments

Party	*Arguments*	*Preference Policy*
Government	Cost Containment	+++
	Quality of Health Care	-
Health Insurers	Cost Containment/Competitiveness	+++
Pharmacists	Lack of Uniformity/transparency	-
	Shortages	-
	Workflow	-
	Loss of profits	-
Manufacturers	Loss of profits	---
Wholesalers	Loss of profits	-
NZa	Lower costs	+++
	Lack of competition health care providers	-
Patients	Lack of Uniformity/transparency	-
Experts	Leeway for Patent Abuse	-

Table 6.2 :Stakeholder Position

Radical Change	*Incremental Change*	*Sustain/ Expand*
Manufacturers	Pharmacists / Patients/ Experts Wholesalers / Government	Health Insurers / NZa/ Government

Main concern for successful continuation of the preference policy is the transparency issue. The government, distributors, pharmacies and patients demand more transparency of health insurers considering their purchasing decisions. On the other side, the NZa, the government and the health insurers demand more transparency of the pharmacies considering the care they give. More transparency will help the environment to become more competitive which is needed to get the fullest out of the policy.

6.2 New Zealand

The results PHARMAC has achieved in the last twenty years show that resistance towards the policy has been limited. As is to expect, not all parties agree with the policy, however over the years their opinions have shifted. Nowadays, there is still discussion on the topic and recent changes in the environment have played a significant role influencing the discussion and the actors who take part in it. In the upcoming paragraphs I will try to make clear the positions of the most involved actors.

The Government

The PHARMAC model has broad support among New Zealand's parliament[271]. This is stressed by a parliamentary session of 2010 in which the parliament representatives of the two largest parties (making up for over 75% of the parliament seats) in New Zealand entitled PHARMAC as being ''brilliant''[272]. The trust and support of the government is expressed by their minimal interventions. Since the introduction in 1993, the government has only intervened twice in a PHARMAC decision[273].

However, in the last three to four years also the government reacted to some signals coming from the environment. One is the negotiation on a Transpacific Trade agreement, on which I will come back later. Another is that of limited accessibility. The capped budget of PHARMAC has caused certain the accessibility to certain medicines to be lower than that in neighboring countries. Since 2010 the government has therefor started again to increase the pharmaceutical budget, rather than to aim at constant decrease of the budget on a yearly basis.

PHARMAC (Agent)

In theory, we may conclude that PHARMAC, as a bureau, pursues to safe keep their existence. According to Niskanen, we would even have to assume that they would try as hard as they can to to expand their budgets and their functions. However, in practice this is hard to determine. PHARMAC states that it is completely indifferent when it comes to the policy-making process on the highest level[274]. Their own decision-making power reaches to the levels of first order change, as they are almost completely free to decide how they realize the lowest prices for medicines. This has led to the successful development of new strategies (also see 4.3.2.). Their performance has strengthened their position as a vital mean to reach the government's objective, making it very unlikely that the policy will be abandoned due to their actions.

[271] Ashton, (2013), Tegenlicht, (2013)
[272] Damian O'Connor (2010), Maurice Williams (2013)
[273] Cummings, (2010)
[274] Williams, L. (2013)

The Pharmacists

What is likely to expect from the pharmacies is that they rather see the PHARMAC go. The contrary is true, over the years pharmacies have become used to the PHARMAC model. Pharmacies have become dependent on the CPSOG for their income (also see 4.3.2.). This council, in which the community pharmacists themselves have five seats, determines the height of the dispensing and service fees the pharmacists are allowed to charge. In this way, the pharmacists are no longer depending on the actual prices of the medicines. Margin profits have been replaced by the remuneration profits, like dispensing fees, funded by the regional DHB's.

Privett(2013) states that pharmacists are required to be careful with managing the stocks of their medicines. Pharmacists have to make sure themselves that they keep their stocks low, especially when price changes are announced. From the date of announcement pharmacists are bound to sell their medicines at the, by PHARMAC, determined prices. This means selling the stock which they already bought at the old prices have to be sold with lower profits, or even losses. Previtt (2013) does state that in the recent five years PHARMAC has improved its consultation with pharmacies on informing them about approaching price changes[275]. The thorough institutionalized consultations have caused the resistance of the pharmacies to decrease to merely demanding incremental corrections now and then.

The Wholesalers

Just like in the Dutch system, the wholesalers are among the serious losers of the policy. As they are dependent on margins of the factory prices, their profits shrink significant. Especially, after a so- called 'patent-cliff', the moment at which innovative medicines lose their patent, these manufacturing prices decrease rapidly[276]. Since the introduction of PHARMAC the total amount of pharmaceutical wholesalers has shrunk from sixteen to just five. Most of the wholesalers are cooperatives, who receive a net margin of around 10 percent on the manufacturing price for the distribution of pharmaceutical to the retailers[277]. This way, wholesalers remain to depend on the negotiated manufacturers prices for their profits, a reason for them to resist against the PHARMAC model.

[275] Privett, A. (2013).
[276] Taylor, C. (2012)
[277] Davis, W.

The Manufacturers

The pharmaceutical industry in New Zealand is very small. They are not pleased at all by the PHARMAC model, but their influence can be considered to be very small[278]. Medicines New Zealand (MNZ) is the industry association that represents the pharmaceutical manufacturers and developers. Recently, they stated that they are disappointed that PHARMAC's funding decisions lack transparency. They would like to see the savings that are the result of PHARMAC's efforts and patent expiry, to flow back into the industry by means of an increased share of the budget that goes to funding innovative medicines[279].

This argument on the lack of transparency also comes from foreign pharmaceutical manufacturers who have achieved to make PHARMACs pricing policy part of the Transpacific Trade Agreement negotiations. Moynihan states in the British Medical Journal that the pharmaceutical policies in New Zealand have been a major topic of discussion in the negotiations of a Free Trans-Pacific Trade Partnership with the United States. In total nine countries are candidates to get involved in a free trade agreement targeting the exchange of multiple commodities, including pharmaceuticals. The United States diplomats have been urged by almost thirty senators to protect US companies, especially those manufacturing pharmaceuticals. The author states that the American pharmaceutical industry demands the negotiation process of PHARMAC to become more transparent.

The critics of the Free-Trade proposal note that the demand of the United States could entail the procedure of negotiations to become legally bounded and even including a possibility for manufacturers to take legal actions to PHARMACS decisions[280]. The prime minister of New Zealand has responded to the free trade demands by saying repeatedly that 'New Zealand will not sign up to a free trade agreement that is not in the country's best interests.'[281]

The Patients

Accessibility is one of the major objections coming from the patients. The influence of these patients however, is not of impressive size. PHARMAC serves the interests of a large majority of the patients as they get cheap access to medicines. However, patients with rare disorders suffer from the system. The New Zealand Organization for Rare Disorders (NZORD) accused PHARMAC for not taking sufficient care of ensuring access to innovative expensive medicines. According to NZORD PHARMAC is unable to

[278] Ashton, (2013), Tegenlicht, (2013)
[279] Taylor, C. (2013)
[280] Moynihan, (2011), p. 1.
[281] The New Zealand Herald (2013)

ensure this access due to the framework within they operate[282]. The NZORD refers with this to the capped budget that PHARMAC is bound to stay within. 'Patients are being abandoned by the health system'. The NZORD called upon PHARMAC and the government to develop special programs to provide also these small groups of patients fully reimbursed treatments[283].

The Experts

Within New Zealand the experts do not directly get themselves involved directly in the debates on PHARMAC. As for PHARMAC itself it employs committees of experts who perform the clinical assessments which form the bases for their funding decisions. Recently, scholars at the University of Auckland have investigated the effects of PHARMAC's policies on the accessibility of medicines to New Zealanders. The discussion has been a heated one for PHARMAC did not agree on the results.

To start, I should note that the scholars base their conclusion on the comparisons between New Zealand and Australia. But their conclusions were clear: PHARMAC makes 'access to medicines in New Zealand slower and poorer compared to Australia'[284]. Their data was straightforward, in the last decade New Zealanders had only been given access to nearly half of the medicines the Australians had gained access to[285]. The authors related these results to the fact that PBS (the Australian equivalent of PHARMAC) is not legislated to stay within a fixed budget. The Australians have given the authority to PBS to allow the expansion of their budget '' in order to accommodate as many new medicines that can demonstrate clinical importance, clear evidence of effectiveness, affordability, cost-effectiveness and other qualities''. Simultaneously, the authors state that Australia saw its pharmaceutical expenditures raise steadily, whereas New Zealand was able to contain its costs[286].

PHARMAC responded to the article by stating the conclusions were somewhat superficial. PHARMAC refers to the fact that the government had just recently, since 2010, decided to allocate higher budgets for pharmaceuticals for rare diseases (the research investigated the time period 2000 – 2009)[287]. This argument is backed by the pharmacists' guild who also stated that, in the last five years, the government has provided PHARMAC more funds to provide access to more expensive and innovative medicines for uncommon treatments[288]. However, Wonder's most recent research has shown that also

[282] Ibidem.
[283] Rarediseaseday (2013) | Grocott
[284] Wonder, R. (2011). (December), The New Zealand Herald (2012)
[285] Wonder, R. (2011). (November)
[286] Ibidem
[287] Moodie, P. (2011)
[288] Privett, (2013)

in 2012, access to drugs in New Zealand is still significantly behind that of Australia. 'New Zealand continues to play catch up with Australia'[289].

PHARMAC did admit that the registration time in New Zealand is significantly longer compared to that in Australia, however they blamed this mainly to the industry, who simply registers the pharmaceuticals in late stage, due to the market of New Zealand is smaller and less profitable. Wonder (et all) states that this is true, but besides the time between registration and reimbursement takes up to two years longer compared to Australia. The authors state this is harmful to the New Zealanders as they do not get the benefits of medicines during the assessment phase. The delay seems to be inherent to the fact that PHARMAC is strictly bound to their budget and thus needs to assess the opportunity costs of new medicines ''more careful''[290].

To total amount of time it averagely took in New Zealand to register and reimbursed is 32.7 months[291]. I also looked up this average in the Netherlands and here it was 328 days, about 11 months (in 2011)[292]. In 2009 European Union Commissioner for competition Kroes researched and concluded that the delay in access to generics in Europe caused the costs for patients to raise by over 20% in the first seven months after the patent of the innovative medicine expired. The commission urged the European government to adjust their regulations in order to increase the speed of the process allowing generics to enter the markets[293].

Varol states that there is a close correlation between registration time and the extent of market regulation. It shows that if governments choose for regulating the market it is almost inevitable that manufacturers will register their products later. The same goes for the argument of shortages, as already said, in case of scarcity of drugs, manufacturers tend to sell their products in non-regulated markets in which they are more likely to sell their products at higher prices[294].

Summary

Also for New Zealand I will try to capture all the opinions of the different stakeholders into orderly structure tables (Table 6.3 and 6.4). The main question is what influence the negotiations of the Transpacific Trade Agreement will have on the opinion of the government. The missing out on such significant economic advantages may be a reason for certain politicians to overthink their policies.

[289] Wonder, R. (2013)
[290] Wonder, R. (2011). (December), The New Zealand Herald (2012)
[291] Wonder, R. (2011). (November)
[292] Nefarma.nl, (2013)
[293] Skipr, (2009)
[294] Varol, et al (2011)

Table 6.3: Stakeholder arguments		
Party	*Arguments*	*Preference Policy*
Government/DHB's	Cost Containment	+++
	Accessibility	-
	Economic advantage of Free Trade	?
PHARMAC	Cost Containment	+++
Pharmacists	Lack of Information	-
	Shortages	-
Manufacturers	Loss of profits	---
Wholesalers	Loss of profits	---
Patients	Accessibility	-
Experts	Accessibility	-
	Duration of registration process	-

Table 6.4: Stakeholder Position		
Radical Change	*Incremental Change*	*Sustain/ Expand*
Manufacturers/ Wholesalers/ Trans-pacific Trade Agreement	Patients/ Experts	PHARMAC/ Government / Pharmacists

Main concerns for New Zealand are the delay in market registration of generic products and the negotiation proposals of the Transpacific Free Trade agreement.

The costs of pharmaceuticals are among the lowest in the world, as a result manufacturers are hesitative concerning the entrance to New Zealand's market. Often manufacturers choose to first register their product in those markets in which prices of pharmaceuticals are high, before entering New Zealand's market. Additionally the process of PHARMACS decision-making (the cost-utility analysis) requires more time compared to that in other countries. These factors cause pharmaceuticals to access New Zealand's market with a significant delay. The delay causes kiwis to miss out on the economic advantages of generic entrance, meaning that they depend longer on more expensive innovative medicines.

6.3 Hungary

The stakeholder analysis for Hungary is rather short compared to the previous two. The fact that the blind biding system, and as a result the strong decrease of prices of pharmaceuticals, have only been in effect for a relatively short period, makes stakeholders less aware of the policy, giving them a rather premature opinion. Likely that over time, when the results become more noticeable, stakeholders will become more prominently engaged in opposing, or supporting, the policy. I will again start by discussing the position of the government.

The Government

As earlier stated, the national government of Hungary is the most prominent actor when it comes to decision-making in the Hungarian health care sector, including the pharmaceutical sector. Purchasing authority is largely exercised by the national assembly (read 2/3 majority Fidesz coalition). The governments' main concern seems to be that of budgetary efficiency. Therefore, in the recent years the government has implemented harsh measures and blunt taxations to the pharmaceutical sector. The taxes on promoting, producing and researching pharmaceuticals have risen. The measures have helped Hungary to gain fast financial gains in their pharmaceutical sector, but might have caused a decrease in the quality. So far this decrease is not yet visible[295]. Accessibility has improved as profit margins of pharmacists, manufacturers and wholesalers have been cut.

Some effects of the decreased margins have not gone unnoticed by the government. In 2012 the government intervened by increasing NHIFA's budget. The IHS predicted that if the government would have not intervened, a crash of the pharmaceutical chain would have been inevitable[296]. According to the market analysts of seenews.com the government also intervened in the emergence of shortages in the Hungarian pharmaceutical sector, by no longer taking into account bids of companies who have shown to be unable to supply the Hungarian market sufficiently after winning a previous bidding round[297]. This is comparable to what pharmacists suggested the Dutch health insurers to do[298]

The National Health Insurance Fund Administration (Agent)

The National Health Insurance Fund is under direct control of the government. The agency has almost no influence on decision making as it is merely an executive agency. After multiple requests the NHIFA was not prepared to take part in this research.

The Pharmacists

The pharmacists in Hungary are rather worried about their position within the Hungarian pharmaceutical market. The major budget and price cuts on medicines have directly led to a significant decrease in the profits of the pharmacists. This is inherent to the remuneration system in which pharmacists are funded according to a percentage of the manufacturers' price. While these percentages have been raised moderately by the government, they do not compare to the amounts of losses that are the result of the lower prices[299]. According to IMS and Healthaware, the revenues of

[295] Horvath, (2013)
[296] IHS.com (2013)
[297] Seenews.com (2013) | Weborvos.hu (2013)
[298] Riesebosch, (2013)
[299] Zlinszky, J. (2013)

pharmacists have decreased by almost 10 percent in 2012[300], whereas in the first period of 2013 this trend has continued[301].

Simultaneously the pharmacists are confronted with the government requirements for ownership. In the last two years the government has started to push through legislation which requires those who operate the pharmacies to also own (a majority share of) the pharmacies (See Table 7.5) . This has put pressure on the pharmacists; with profits decreasing they cannot afford to purchase their own pharmacy. The government has offered these pharmacists government loans with favorable conditions. The legislation affects over 487 of the 2330 pharmacies in Hungary. The law obliges these pharmacists to purchase their shares before the end of 2017, those who do not risk being nationalized[302].

Table 6.5: Pharmacy Ownership

The ownership requirements of community pharmacies in Hungary tend to change rather frequently. Before the 90's all pharmacies were in public hands. After the fall of the iron curtain, Hungary started liberalizing its market, including these pharmacies. In 1994 the policy started of by requiring pharmacists to own at least 25% of the pharmacy in which they operate. The other 75% share could be in the hands of unlimited liability partners. During the time wholesalers and manufacturers gained shares in the pharmacies and pharmacy chains started to emerge. Between 1998 and 2002 the government tightened the legislation promoting more pharmacists owned pharmacies by requiring at least 50% of a community pharmacy to be in the hands of the operating pharmacists. The policy failed which led the government in 2006 to liberalize the market completely; No more limitations regarding the ownership shares. Integration started once again, horizontally as pharmacy chains started to expand once again (by 2010 nearly 15-20% of the market was working under a chain), as well as vertically, as wholesalers and manufacturers started to regain their shares[303].

The liberalization led to a rapid increase in the amount of pharmacies growing by a total of 20%. In 2010 the liberalization came to a radical standstill. The new government turned back to their old principals by implementing strict legislation promoting pharmacist owned pharmacies. Their targets are set: 25% pharmacists share by the end of 2013 and 50% by 2017. Foreign companies are not allowed any longer to maintain pharmacy shares at all[304].

[300] IHS.com (2013)
[301] Healthaware.hu (2013)
[302] MTI, (2013), Molnár, Z. (2013)
[303] Gaál, P. (2011)
[304] Gaal, P. (2011), MTI, (2013)

This legislation has a negative effect on the sustainability of the strongly decentralized Hungarian market of pharmacists. Whereas the decreasing margins for pharmacists require them to become more centralized and efficient, the government is aiming at stronger decentralization of the market. It seems like two policies which are in conflict with one another. The question is why a government would like pharmacists to own their pharmacy. According to experts this is to prevent the vertical integration of decisions. Pharmacists should take into account the needs of the patients, whereas wholesalers primarily focus on selling as many pharmaceuticals as possible. Pharmaceutical decisions should be made by pharmaceutical experts, rather than commercial parties[305].

The Wholesalers

Just like the pharmacists, the margins for wholesalers are determined by the government. Their margin is paid as a percentage of the manufacturers' price, making them to be directly affected by price drops. IMS reports that the wholesalers have serious troubles in coping with the results of the intensified blind bidding procedure. By the end of 2012 some leading pharmaceutical wholesaler in Hungary announced programs for downsizing their organizations as a result of the lower profits, or even losses, they made[306].

The Manufacturers

Just like the pharmacists and the wholesalers, the manufacturers experience negative consequences of the Szell Kalman Plan. Hungary has an extensive pharmaceutical industry with multinationals like Egis and Gideon Richter. Along with the drop in prices went the profits of these, and foreign, manufacturers. The largest companies are affected in multiple ways. Not only their margins on medicines dropped, besides the taxes on medicines, the promotion of medicines and their investments in research & development, increased significantly. Egis, one of Hungary's largest manufacturers of generics, stated that the consequences of the Szell Kalman plan, including the blind bidding, procedure have become visible since the first quarter of 2012. The company stated that each round of blind bidding had led to a decrease of revenue around half a billion Hungarian forints and with it the termination of the sale of various generic medicines in Hungary[307].

In an interview Tamás Dávid, board member of the Association of Innovative Pharmaceutical Manufactures, states that the opinions of various manufacturers within the country differs, especially coming up with an answer to their decreasing margins. Dávid states that the generic manufacturers,

[305] Antares Consulting, (2008)
[306] IHS.com (2013)
[307] Chemrar.hu (2012)

mainly consisting out of national companies, prefer the government to increase their measures taxing the development of innovative medicines. Dávid, representing the innovative pharmaceutical manufacturers, would like to see the prices of generics drop. He thinks a more competitive environment for health insurances could also contribute to achieving significant savings. The chances getting such reforms implemented in Hungary Dávid entitles to be small, as the ruling conservative majority of the Fidesz party has contested such solutions for long[308].

The division might be an advantage for the government; due to the diffuse opinions of manufacturers how to solve their troubles related to the effects of the price drops, resistance towards the policy seems weaker compared to if this was not the case.

The Patients

For the patients, the cheaper prices of medicines have improved their accessibility. Currently, no direct quality losses have been noticed, leading the patients not (yet) to complain. Hungary seems to have an advantage compared to the Netherlands and New Zealand as the government measures were implemented in a relatively low quality health care sector. From this starting point, improvements are easier to be (noticeably) made, whereas further deprivation of quality could be less noticeable for the patients, or more broadly speaking: society.

A more concrete indicator which might predict the future reactions of the patients towards the policy is the amount and extent they have to co-finance the pharmaceuticals. The NHIFA keeps track of the levels of co-payments. In the last year, the levels co-payment levels have in most cases decreased, however, in 41 percent of the cases of price changes, these co-payments have increased (also see table 6.6). What is interesting to see is that not all reimbursements gains, are translated into lower co-payments for the patients. In fact, we might assume that some reimbursement levels have decreased as a result of increasing the levels of co-payments. This is remarkable as the government has stated that 'co-payments cannot increase'[309]. Acting different compared to what was politically promised could be a decisive incentive for the public to start roaring themselves in the debate.

[308] http://www.pharmaboardroom.com/article/interview-with-tam-s-d-vid-deputy-director-market-access-specialist-association-of-innovative-pharma
[309] Ibidem.

Table 6.6: Development of Pharmaceutical Prices and Co-payments

Changes in the public drug list							
	2013 January	2013 February	2013 March	2013 April	2013 May	2013 June	2013 Total
Reimbursement							
Decrease	71	7	16	1346	6	1	1447
Increase	4	0	3	224	0	0	231
Co-payment							
Decrease	63	18	27	942	12	9	1071
Increase	22	0	1	729	2	0	754

Source: Healthware analysis based on OEP-PUPHA

The Experts

The experts at the IHS somewhat agree with the arguments of the wholesalers and the pharmacists. Following the current trends they expect their profit margins to reach critical levels within the next year, or two. The government has responded by raising the tariffs the two parties receive, however the IHS does not see this as a sustainable answer to this problem. Not reacting determinatively, could lead the market to reach these critical levels, causing the pharmaceutical chain to crash and develop into a serious crisis. The IHS confirms that serious cost savings have been realized so far[310]. Especially, the innovative medicines are among the cheapest in Europe.

Very recently, PriceWaterhouseCoopers was also involved in analyzing the challenges for the pharmaceutical market in Hungary between now and 2020. PWC expects new information technologies to be of crucial importance in the upcoming years. Consumers will become more aware of the quality of their health care, which will demand the actors in the pharmaceutical chain to become more consumer oriented. The Hungarian society is expected to become more critical and better informed about pharmaceuticals and the process of provision[311].

The actors within the pharmaceutical market will be faced with more challenging markets, demanding them to adapt more flexible organizational structures and innovative strategies. The government should aim to play a guiding role in this process, allowing more competition to enter the system. In the past years, the government has confronted the pharmaceutical industry with regulations and taxes which directly targeted the profitability of these companies; PWC hopes that in the future the

[310] Melck, (2013), IHS.com (2013)
[311] Márton, (2013)

government will create a regulated environment in which there is room for a demand of efficiency coming from the market[312].

Summary

As said at the beginning of this part on Hungary, the effects of the blind bidding policies have yet to impact society. In this early stage however, we can already detect some resistance, as well can we predict where further growth of resistance might arise. The main incentive could be the dependency of the full pharmaceutical chain on the negotiated prices. As long as these prices drop, all of the involved actors will see their profits shrink. The government should come up with regulations which will prevent critical limits of these profits to be reached. An example could be to look at the Netherlands or New Zealand, in which these profit margins have become independent from the manufacturers prices. Tables 6.7 and 6.8 give clear view on all the actors positions, the brackets show how these positions might develop, if the current policies are sustained.

Table 6.7: Stakeholder arguments

Party	*Arguments*	*Preference Policy*
Government	Cost Containment	+++
	Pharmacy ownership	-
Pharmacists	Loss of profits	--(-)
Manufacturers	Loss of profits	--(-)
Wholesalers	Loss of profits	--(-)
Patients	Co-payments	?
	Accessibility/Lower Prices	++
Experts	Margin Squeeze Limits	--
	Not Future Proof/Inflexible	--

Table 6.8 :Stakeholder Position

Radical Change	*Incremental Change*	*Sustain/ Expand*
Manufacturers/ Wholesalers/ Pharmacies	Experts	Government / Patients

[312] Ibidem.

6.2 Chapter Summary

The stakeholder analysis has shown that in the different countries the stakeholders experience different effects. They base their opinions on how the pharmaceutical policies help, or hamper, them in achieving their goals. Some of the problems that were described only occur in particular countries, such as the lack of uniformity in the Netherlands. Other problems are experience in all of the countries. What is most interesting to learn is that some of the problems that occur in certain countries, have already been tackled by the experience of others.

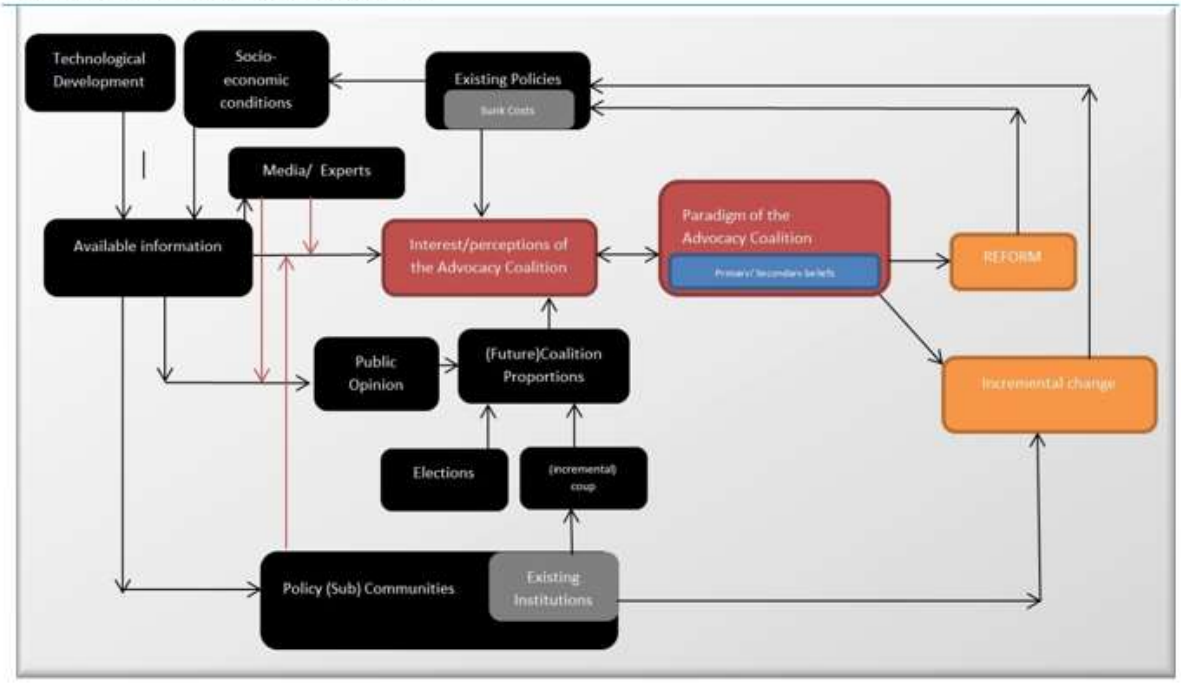
Examples of these problems are the loss of profits of wholesalers and pharmacists in Hungary which are inherent to the lower manufacturers' prices that are negotiated by the government. In the Netherlands and New Zealand they managed to limit this relation causing the resistance from these two parties to descend to lower levels. Simultaneously, the Dutch experience the resistance of pharmacists due to the occurrence of pharmaceutical shortages, Hungary solved this effect by excluding suppliers, from whom they experienced earlier shortages, from the blind bidding process.

Overall this chapter has learned us a great deal on how the actors can learn from one another. It is now time to present my conclusions; it is the thing I will do in the following chapter seven.

7. Conclusions & Recommendations

AS I AM REACHING THE END of my Master Thesis I would like to present to my readers my most important findings and recommendations. I started by stating my research objective, which was *to comprehensively map the different pharmaceutical policies in order to find out whether the Hungarian pharmaceutical policies could be improved with the help of best practices of New Zealand and the Netherlands.* I explained to my readers that I was to structure my research into two parts, a quantitative part to investigate the economic performances of the different policies, and a qualitative part in which I would research the social impacts and the institutional/political contexts of the different alternatives. A comprehensive theoretical framework gave me guidance in the collection and analysis of the data. I ended up with developing a constructivist model, in which policy change, and the size of this change, was determined by multiple variables which were to be measured. The framework has led me to develop eight different research questions. I will re-introduce and answer them with the help of, the familiar, figure 7.1.

Figure 7.1: The Variables to Reform.



Question 1: What existing policies and what institutions are in place?

My first question was to ask what the different policies entail. I started by described the processes for, funding, purchasing, providing and monitoring pharmaceuticals and pharmaceutical care in the three countries. I also identified the institutions that play a vital role in executing the policy. I came to the conclusion that the process and institutional structures in New Zealand and Hungary were quiet alike, whereas that of the Dutch preference policy was significantly different. With it came the fact that the

venues of authority were different in each of the countries. I will refer to this elaborately in a later stage of this chapter.

The answer to this first question lays the foundations for later research. Both the description of the policy and the identification of the agents are of importance to examine the performance and the impacts of the policy, but also for the analysis of the institutional and political context surrounding the it.

Question 2: What are the results of the existing policies

I continued by investigating the performance of the different policies. For this I established four key indicators: expenditures, costs of the policy, accessibility and future predictions. The variable of accessibility I researched partly in my qualitative part, whereas the other three were mainly investigated in the quantitative part.

Table 7.1: The IMPACT-assessment

	Hungary	Netherlands	New Zealand
Pharmaceutical Exp. Until 2010	-	+	++++
Pharmaceuticals Expenditure	-	+	++++
Prices of medicines (Micro) (2013 June)	+	++++	+++
Costs of the Policy	++++	+	+++
Future Predictions for Hungary	+++(+)	++++	++++
Accessibility	++	++++	+
Margins Pharmacies	---	+/-	+/-
Margins Wholesalers	---	+/-	+/-
Control over agent	++++	+	+++
Pharmacists Market	-	++++	-
Patients Choice for Medicine	-	--	---
Overall Performance	++	+++	+++

What we could conclude from the performances was that the Dutch and The New Zealand policy had achieved significantly better results before 2011. After 2011, the Hungarian government has started with implementing a rather radical reform program: the Szell Kalman Plan. The program has rather bluntly intervened in the pharmaceutical budget by increasing the taxes on the sales, promotion and development of medicines by almost a quarter. Besides the government had expanded its 'blind bidding' procedure like is also commonly used by the Dutch health insurers and PHARMAC.

The fact that the Hungarian government has only implemented these measures so recently makes it harder to compare the policy with those of The Netherlands and New Zealand. In first instance, the price decreases of medicines that have been realized since 2011 look promising. However

simultaneously, it makes it hard to compare the effects of the policy on the pharmaceutical chain and the quality and accessibility of the pharmaceutical sector. Additionally, the question can be asked to which extent the decision-makers have yet perceived these consequences as they are situated rather far from the 'action' and monitoring institutions are fragmented.

Question 3: What paradigm is in place? (Also see figures 4a, 4b & 4c from the Appendix)

The question that we can ask is to which extent the Hungarians can learn from the two alternative policies. For this, I explained, it is of importance to study the institutional and political context surrounding the policies. Only then one can judge whether (parts of) the alternative policies are likely to be feasible for implementation and whether they will have similar effects. My analysis involved creating a current overview of active paradigms, and institutional settings, considering the health care systems as a whole and the pharmaceutical policies specifically.

Table 7.2: Paradigms & Instruments

Paradigms in:	*Hungary*	*New Zealand*	*The Netherlands*
National Health Insurance			
- ***Funding***	Social Democratic	Social Democratic	Liberal (Social Democratic)
- ***Purchasing***	Social Democratic	Corporatist	Liberal
- ***Provision***	Corporatist	Corporatist	Liberal
- ***Control***	Soc. Democrat./Corporatist	Corporatist/Soc. Democrat	Corporatist
Pharmaceutical policies			
- ***Funding***	Social Democratic	Social Democratic	Liberal (Social Democratic)
- ***Purchasing***	Social Democratic	Corporatist	Liberal
- ***Price-setting***	Liberal (corporatist)	Corporatist (Liberal)	Liberal
- ***Provision***	Corporatist	Corporatist	Liberal
Authority of Agents	Price-setting	Purchasing, Price Setting, Provision	Funding, Purchasing, Price-setting
Instruments for Price Setting pharmaceuticals	Blind Bidding	Blind Bidding,	Bind Bidding, Covert Blind Bidding, Pharmacy-Performance contracts
Pharmaceutical Care Policies			
- ***Funding***	Social democratic	Corporatist	Liberal
- ***Purchasing***	Social democratic	Corporatist	Liberal
- ***Price-setting***	Social democratic	Corporatist	Liberal
- ***Provision***	Liberal/Corporatist	Liberal/Corporatist	Liberal
- ***Control***	Social Democratic	Liberal	Corporatist/Liberal
Instruments determining Pharmaceutical Care remunerations	Government	Consultation	Negotiation / market
Remuneration method			
- ***Pharmacies***	Margins	Fixed Fee For Services	Fixed Fee For Services
- ***Wholesalers***	Margins	Margins	Fixed Fee For Services

What could be concluded was that most of the pharmaceutical policies in a certain country were well in line with the paradigm of the health care system in that same country. The main variable determining the paradigm is the institution that has the authority over a certain function and is considered the main venue of power.

In the Netherlands both the health care, as well as pharmaceutical, is in largely put the hands of a private market ran by non-profit health insurers. Key for the health insurers is to gain customers by offering the highest quality for the lowest prices. The health insurers are not meant to make profit; instead they are cooperatives of whom the customers are its members. Profits have to flow back towards these members, mainly through lowering the premiums. The health insurers are authorized to selectively purchase care, it may deny to reimburse (services of) health providers if they think their quality is not sufficient. The customer can make his choice which health insurer he wants to join and pay premiums to. This decision can be made on the basis of the level of the premiums and by the quality of service that is delivered. Example could be: rather to a higher premium and be reimbursed for the health provider around the corner, or pay less and having to travel distances to get reimbursed care. What is further of importance to note, is that customers do not base their decisions on the actual prices of medicines. Health insurers seem to make use of this fact by making the surrounding procedures around their price-setting for pharmaceuticals rather vague.

In Hungary the general budget for health care and pharmaceuticals is set by the government. Besides also the purchaser-provider relationships are legislated by the central government. In this case we may say that the central government is both the funder as well as the purchaser of health care. The provision of health care and pharmaceuticals (what treatment/medicine to use and when) is determined corporatist agents such as municipalities, counties and the secretariat of health who own most of the health providers. The price-setting for pharmaceuticals is performed by the market in a blind bidding process that is facilitated by the National Health Insurance Fund Administration. The NHIFA has only the authority to appoint the cheapest bidder as preferred supplier. The remunerations for pharmaceutical care delivery from wholesalers and pharmacists is determined by margins that related to the medicine prices. The height of these margins is determined by the central government through legislation.

Lastly, in New Zealand the health- and pharmaceutical care sector is a predominantly corporatist one. For the general budget-setting authority is in the hands of the Ministry of Health. All reimbursed care and medicines are funded through general taxation. For medical care, the purchasing and provision function is in the hands of the regional District Health Boards (DHB's). The DHB's are partly public elected and partly appointed by the Minister of Health. The DHB's are the providers of health care for they are the owners of most of the health providers. For pharmaceuticals purchasing power and provision is determined by a corporatist agency named PHARMAC. PHARMAC determines which medicines are reimbursed and also for what treatments they are reimbursed. The remunerations for pharmacists are determined by a council consisting of representatives of the DHB's and the pharmacies

themselves (CPSOG). Wholesalers receive a margin, related to the price of the medicine, which is determined by the DHB's.

Question 4: How was the paradigm established?

To retrieve the influence of path dependency I analyzed the development of the paradigms over the years. What is most important to conclude is that the Hungarian system has never successfully implemented liberal changes in their health care sector. Most of the funding and purchasing has always remained a function of the state, or an elected specialized Health Insurance Fund. In the last years, under the Fidesz party, most authority has been centralized. The introduction and expansion of the blind bidding process, in which the prices of medicines are determined by the market, rather than pre-set legislation of the government is one of the first and the results are extraordinary positive. This first small liberalization (2nd order reform), could be a trigger for developing more liberal policies in the health care sector. It could be a trigger for reform by means of the mechanism that was described as policy learning and/or policy deviation.

Question 5: Who are the stakeholders in the existing policy? What is their view on the policy? What is their influence? How do they execute the policy?

The Stakeholders are crucial in sustaining or changing a policy. As I stated in the theory the principal is dependent on his stake holders, for without he would not be able to execute his policy. A government can have negotiated the lowest prices in the world, if pharmacists and wholesalers do not distribute, the lowest prices are worthless. A decision maker has to try and keep his stake holders satisfied by involving them in his decision. If stake holders are not involved, they might start acting on their own. The later the decision-maker realizes that the stake-holders are acting differently, the larger the changes he will have to make to get them back involved in his ideas.

This principal is closely related to the advocacy coalitions that I discussed. A policy is sustained as long as the coalition is strong enough. The coalition must involve as many involved stakeholders as possible. However, sometimes a government cannot please all the stakeholders and in this case he might be better of excluding them from the policy. The stakeholders involved in the pharmaceutical policies are identified as followed:

Table 7.3: Stakeholder Analysis (Pharmaceutical Policies)			
Stakeholders	**Hungary**	**The Netherlands**	**New Zealand**
The Government	Positive	Positive	Positive
The Agent	Neutral	Positive	Neutral
The Manufacturer	Negative	Negative	Negative
The Wholesaler	Negative	Neutral	Negative
The Pharmacist	Negative	Neutral	Neutral
The Patient	Neutral	Neutral	Neutral
The Expert	Negative	Neutral	Neutral

What is identified is that the Hungarian policies receive more resistance from its stakeholders. This is mainly due to the fact that the pharmaceutical policies directly influence the whole pharmaceutical chain. This is caused by the fact that all remunerations, the Pharmacies, Wholesalers and Manufacturers, are all dependent on the manufacturers' price. In the Netherlands and New Zealand they adjusted this situation by offering the pharmacies, and in the case of the Netherlands the wholesalers as well, fixed fees for their services. In this way the pharmacists and the wholesalers do not longer care whether the manufacturing prices are decreasing. As we saw in the examples of the Netherlands and New Zealand these fixed fees can still be topic of periodically planned negotiations in an effort to gain efficiency gains of the chain.

The advice for the Hungarian government is to monitor and consult with their stakeholders more closely. As a result of the excessive decrease in profit margins and a blunt introduction of heavy taxes, the government might be confronted with a sudden and large decrease in the quality of pharmaceutical care, which could eventually demand reform and the end of their current pharmaceutical policies. Another remark was made that the Hungarian pharmaceutical market as it is today, is rather inefficient considering their numbers and average size. As the pharmacists depend on their remunerations they get from the government, savings could be made if the pharmacists would be gradually pushed towards becoming more centralized, achieving more advantages of scale.

Question 6: What is the relationship between the Government and the Actors who execute the policies?

This question refers to the discussion on the principal-agent dilemma. With the discussion of the dilemma I identified several solutions for principals (governments) to keep control over the actions of their agents (agencies and health insures) in an effort to make sure that they achieve the goals the principal wants.

Table 7.4: Principal-Agent relations		
Country	**Agents**	**Mechanism**
Hungary	NHIFA	Hierarchical Control
New Zealand	PHARMAC	Involvement, discretionary budget
Netherlands	Non-profit health insurers	Competition, Involvement

The relation that is chosen by the different governments has largely to do with the given discretion to the agents. In Hungary, the NHIFA has relatively little authority, they are merely an executing agency that has to receive the offers from the 'blind bidding' and select the cheapest. For the health care they are allowed to make contractual agreements with the providers, but also here they have no authority of selective buying and most of the tariffs and services have been determined by the central government. In this case it is obvious that hierarchical control is an efficient tool for supervision, simply due to the fact that there is not that much to supervise.

Much different that is in the case of PHARMAC and for the Health Insurers in the Netherlands. PHARMAC is not bound to selecting the cheapest medicines, or forced to even organize blind biddings, they are simply obliged to gain the best quality for the optimal price. The organization is free in deciding its strategies on how to achieve this optimal balance. In some cases this means buying more expensive medicines in a package deal. Their budget is capped and determined by intensive consultations between the Ministry of Health, the DHB's and the Agency itself. There is a clear distinction between the budget that is destined to purchase medicines and treatments and that for running the organization itself.

The Dutch Health Insurers are the most free of all. The law states that they have a health care obligation to deliver the best quality of service at the lowest price and to assure that all the patients get the reimbursements and medical care to which they have the legislative right. In the daily operations there is no involvement of the Minister. The market is monitored by the Dutch Health Authority (Nza), a government agency, whereas the quality is monitored by the Dutch Health Inspection (IGZ). This last agency is also responsible for defining the standards of quality of care. The competition among the health insurers is to make sure that these private agents always pursue that what the patient wants: low costs and high quality. The Patient is free to choose, if a health insurer does not invest sufficiently in its customers, the customers are free to choose another insurers. The health insurers are not meant to make profits, they are cooperatives and their customers are their members. All profits should flow directly to its members, either by better quality of service or by lower premiums. It is up to the Dutch citizens to determine which insurer offers the price/quality that suits him best.

Question 7: Is reform needed?

This last question gives answer to the central question of this research; can the Hungarians learn from the others? The answer to this question is: 'definitely'. The second question that can be asked is whether these lessons require the Hungarians to reform their policies. The answer to this question is what I judge to be: 'no'. The performances of the Hungarian policies seem to be rather well in terms of the price decreases that have been realized already in the recent three years. However, there are lessons which can be learned and implemented within the current institutional settings of the Hungarian pharmaceutical policies. These lessons are learned from the experiences that the Dutch and New Zealand had since the introduction of their cost-containment policies in 2006 and 1993.

Table 7.5: Disadvantages of the Different Pharmaceutical Policies	
The Dutch Preference Policy	
Profits cannot be spend by the Government	++++
Lack of Coherency	+++
Lack of transparency	+++
More labor intensive	+++
Room for patent abuse	++
Shortages	+
Higher Costs (Siloism)	+
New Zealand	
Limited accessibility to expensive treatments	++++
Longer reimbursement procedure	+++
Later medicine registration	+++
Wholesaler margins	++
Lack of choice	++
Shortages	+
Lack of transparency	+
Hungary	
Pharmacist margins	+++
Wholesaler margins	++
Fragmented policies	++
Lack of choice	++
Fragmented supervision	++

The reason why I would not suggest the Hungarians to reform is the disadvantages that are experienced by both the Dutch and the New Zealand. Although, some of these negative experiences will probably also be an effect of the Hungarian policies in a later stage, I do not see the significant value of reforming the current policies towards radical different models such as the two alternatives discussed. I would like to discuss the shortages which I think are inherent to the policy alternatives of The Netherlands and New Zealand.

To start with the Netherlands, I think the fact that all premiums that are paid by the Dutch citizens go into the hands of a private insurer is not directly to be considered positive. Within the insurance companies large sums of money are paid to certain individuals, on which the government has little influence. If health insurers are making profits they are authorized to do whatever they want with this. What is seen in the last two years is that these 'companies' primarily use this money to increase their reserves. I personally think this is undesirable. For what I have noticed before with housing cooperatives, money is used to speculate on financial markets and is invested generously in offices. I think that it is more desirable that the health care delivery is ran break-even and that profits and reserves flow to the authority of the publicly elected state, especially in those states coping with significant levels of corruption.

Furthermore there is a lack of coherency and more administrative work in the Dutch model. Each health insurer seems to develop its own strategy to achieve the lowest prices. The pharmacists and the patients are the ones that have to deal with this variety. It makes understanding the differences, and the actual, prices incredibly hard. The pharmacists have seen their profits decrease by the introduction of the policy; their policies are shrinking further due to the free-pricing policy, while their amount of work expands due to the fact that the demand for pharmaceutical still grows and the extra amount of work they have to put into understanding and explaining the health insurers' pricing policies.

For New Zealand there are also negative sides. The biggest is that of accessibility. Due to the capped budget and the use of QALY's, rare and expensive medicines and treatments are often not reimbursed. I think this is undesirable. The minorities are suffering under the joy of the majority, for they alone are not strong enough to influence decision-making. The many small profits for the majority overrule the large misery that is experienced by that of the minority with rare diseases. Is this inherent to the policy? I think not, the maximum budget should just be raised. However, if this is done, the question remains how much more effective New Zealand's policy is compared to that of the Hungarian ones in the future. Lowering total expenditures on pharmaceuticals is easy by just reimbursing less pharmaceutical. What we already saw was that the actual prices of the basket of thirty-four medicines that were analyzed, was already 6% higher than those in the Netherlands.

Another problem, which is inherent to PHARMAC is the amount of time it takes to make a reimbursement decision. The use of QALY's and calculation of opportunity costs in comparison with all the ever changing prices of all those other medicines, takes up a serious amount of time. The experts calculated that due to this procedure, the Kiwis get, averagely, two years later access to medicines

compared to Australia, due to the time PHARMAC takes to make a reimbursement decision. I think that this extra time can be shortened, but remains to exist due to the structure of PHARMAC.

Question 8: How can Hungary ensure the continuation of their current policy?

At the end of chapter four I concluded by adding an additional research question. As the most recent data showed that Hungary has successfully decreased its prices for pharmaceuticals in the last three years by rapidly expanding their blind bidding strategy for determining the prices of medicines, the following question was put forward:

Instead of reforming its current working policies, how can Hungary make sure that it can continue its current policy in order to continue achieving the results of decreasing prices?

In these final paragraphs I would like to make clear what challenges and threats I see for the sustainability of the policy. For this I refer back to the theoretical framework and the policy perception framework. In chapter 2.6 I explained that in order to achieve reform the perception of the decision-maker has to be challenged. This could be achieved through influencing three key perceptions: the perception of a real socio-economic crisis, the perception of policy deviation and the perception of a changing mandate. I also discussed which variables influence these perceptions:

- The social-economic conditions
- The existing paradigm
- The historic trend in policy making
- The existing institutions and investments
- The mandate behind the policies
- The technical developments

In the following paragraphs I will discuss these variables, describing how they are currently influencing the policy, how they are likely to influence the policy in future and how Hungary might limit the influence of these variables if they are of threat to the stability.

The Socio-Economic conditions

For determining the effect of social-economic environment I looked at the two main goals the government pursues to achieve with their pharmaceutical policy: efficiency and quality. The first is easy to measure by giving an answer to the question: by implementing the new policies (blind bidding) to which extent did prices of medicines decrease? Answering this question gives us the answer that prices have decreased significantly in the last three years. As the economic conditions are positively

affected by the policy, we may state that this side of the environment has a positive effect on sustaining the policy.

Looking at the social goal, we may best speak of quality. In this thesis I measured this quality in terms of accessibility. The blind bidding process has no influence on the quality if the access to medicines has remained as high, or even higher, compared to the situation before the implementation of the policy. So far, the policy is stated to have low influence on the decrease of quality in the pharmaceutical sector. There are some developments however that could cause the quality of the pharmaceutical sector to go down. The first is a trend, which has not been thoroughly researched in this thesis, that co-payment levels are rising (also 6.6). Asking higher contributions from patients may eventually lead to a decrease in affordability and directly to a decrease in accessibility. At a certain point this will be experienced by society and expressed by public dissatisfaction.

Another second threat is that of shrinking margins for wholesalers, pharmacists on manufacturers. These actors already describe their situation as worrisome, however so far this remains towards a crisis which is framed and not (yet) experienced by the government as worrisome. A serious crisis could develop if one of these parties decides to stop performing their task within the pharmaceutical chain. This would lead to a situation in which patients will not be able to get their medicines. In the Netherlands the government has already been confronted with such situation regarding wholesalers. In the later discussion on the mandate variable I will elaborate on this.

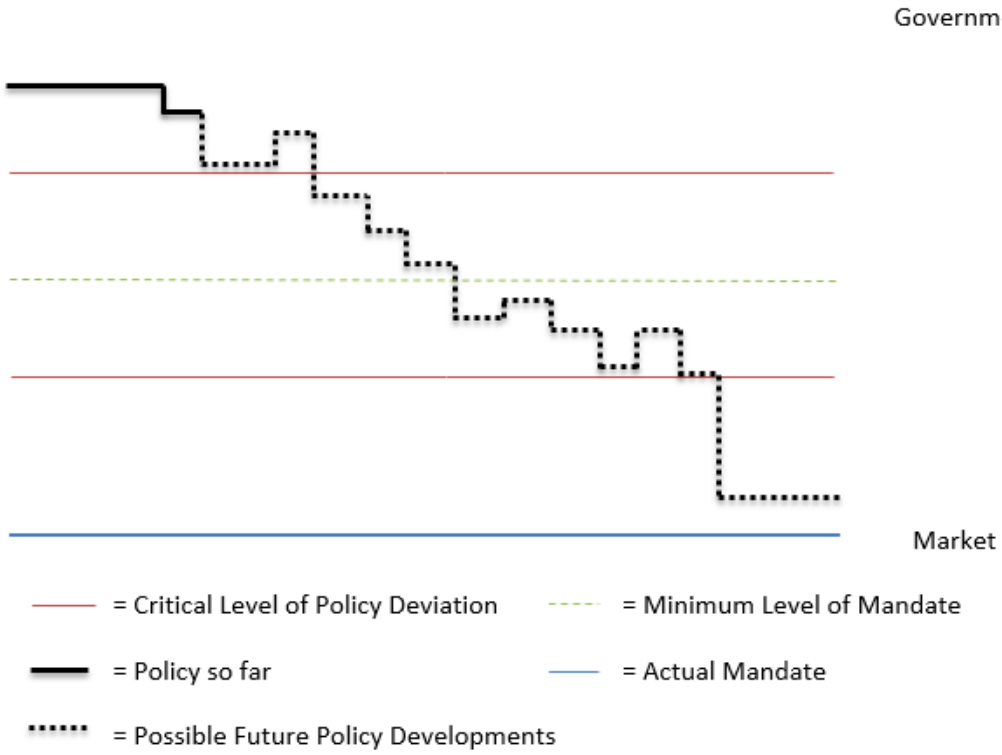
The last negative effect of the decreasing prices for pharmaceuticals trough policies is that of later registration and shortages. As a result of the lower margins, manufacturers often choose to register their products first to those markets in which their potential gains are higher. Result is that people who live in the countries with low priced pharmaceuticals will be able to profit later from generic alternatives, compared to those patients in other countries. Similar effects are seen in the case of scarcity of medicines. Also in time in which there is high demand, manufacturers choose to supply those markets first who pay the most. In certain urgent cases, such as the swine flu pandemic in 2009, this might lead to a serious crisis in which governments are forced to implement drastic changes.

The existing paradigm

Considering the existing paradigm, the current policy is an exception. As I described, the Hungarian health care sector is dominated by state. Much of the funding, purchasing and even provision is in the hands of the central authority. The price determination of pharmaceuticals is one of the only parts in the sector which is realized by competition. The ruling paradigm is thus a threat for the actual policy. However, we may also turn this rationale around. Towards the health care sector as a whole, the liberal

pharmaceutical policies for the price-setting of medicines might be one of the first policy deviations. As this deviation has led to a success considering the decrease of health care cost, this deviation might be picked up by other policy sub-communities. The most likely community is that of medical devices and hospital pharmaceuticals. This trend was already shown to have taken place in New Zealand where PHARMAC received the authority to purchase and negotiate the prices of these products.

Figure 7.2: The Hungarian Pharmaceutical Policies a first step towards a more liberal Health Care Sector?



This trend for deregulation was also suggested by several experts. In the future health care market , in which patients will have more information on the performance and quality of health care, the experts hope to see the government in the role of facilitator, instead of the role of regulator and owner it has now.

The historic trend in policy making

However, whether competition will ever be fully implemented is very unlikely given the history of Hungarian policy making. Since the fall of communism, governments have unsuccessfully tried two times to implement a multi-insurers system. Not only did they just fail, they primarily failed due to the pressure of the currently ruling conservative Fidesz government. Considering the historic trend of pharmaceutical policies, before the blind bidding process prices were determined by fixed requirements and margins for generic manufacturers to enter the market. As the authority of funding,

purchasing and provision remains to be in the hands of the government, the current pharmaceutical policies remain to fit rather stable within the existing trend of decision making.

The existing institutions and investments

And here I already come to the matter of institutions and investment. With the introduction of the blind bidding procedure no new institutions or investments were required. The NHIFA who is to execute the blind bidding process already existed and the authority is still in the hands of the national government. The NHIFA is merely executive agency with no interpretative discretion, only to select the medicine on the pre-set requirement of cheapest price. Later the government has added an additional requirement that of historic reliability of the bidding parties concerning the ability to actually supply the market with their medicine.

Mandate

A policy stands or falls with the support of its community. For opposing coalitions who would like to see change there are two options to expand its support: convince (parts of) the advocacy coalition or add more stakeholders from their own opposing paradigm into the community. For those that would like a stable policy we can say the opposite. The advocacy coalitions should try to make sure to increase their support by either convincing the opposing coalition or by excluding them from the policy community. This last is done by the Dutch and New Zealand.

Instead of making pharmacists and wholesalers' dependent on the pharmaceuticals price, they added additional and separate polices (layering) to determine their remunerations. In the Netherlands their remunerations are not presented by margins of the manufacturers' price, by fixed fees that are negotiated separately between health insurers and them. Result is that the pharmacists and wholesalers do no longer involve themselves in the policies which are targeted to lower the prices of medicines. They relocated to separate policy communities, making the preference policy more sustainable.

Hungary could learn from this. Recently, the government increased the margins for remunerations that pharmacists and wholesalers get. These adjustments are the result of static changes in a response to a dynamic environment. The pharmacists already reacted that the changes in margins do not reflect the decreases in the medicine prices. I would suggest following the Dutch example by giving pharmacists and wholesalers fixed remunerations and make them independent from the manufacturer's price. In this case Hungary would decrease the support for the opposing coalition, making the share of the advocacy coalition relatively bigger and the policy more sustainable.

The technical developments

Technical developments can cause a natural crisis. Due to the fact that the policy did not adjust itself to the expanding possibilities of the environment, its quality becomes worse. The internet was one of the key incentives for the Dutch to implement their liberal system based on the patient's choice. It made the government realize that the performance of health providers could be easily captured and presented. The internet made the health provision more transparent abolishing the market failure of asymmetric information between market and patient. Less market failures needed less government intervention. The market took over and will probably expand in the future with new policies such as the 'free-pricing' for pharmaceutical care which was introduced in 2012.

The technical developments can serve as a stabilizing factor for expanding the liberal policies within the health care sector in Hungary. Compared to New Zealand and the Netherlands the Hungarian health care sector does little with the options that technological advancements have opened. As earlier stated, experts from renowned consultancy firms expect efficiency to be gained from the decreasing gap of asymmetric information between health providers and the government, the health providers and the patients and the government and the society due to the new technical possibilities. These advancements might eventually cause the Hungarian government to find itself forced to implement new (liberal) alternatives.

Additional Recommendation: Incremental changes to the existing policies

For my recommendations I would suggest some adjustments in the existing Hungarian policies. These are incremental changes which could be fit into the existing system and policies. They are derived from the practices and results of the pharmaceutical policies in the Netherlands and New Zealand.

The strategies from PHARMAC

Learning from New Zealand it might be useful to look at the tactics that PHARMAC has developed to improve their results of price negotiations with manufacturers. PHARMAC started off by using the blind bidding procedure, but over the last 20 years they have developed more methods to improve their results. The NHIFA might be able to learn from these strategies. The strategies involve:

Treatment relation

PHARMAC not only determines whether a medicine will be reimbursed, but also for which treatments they will be reimbursed. In this case PHARMAC splits up the pie, instead of just being able to offer the supply to the complete market, they can sell the market share by share. In this case a manufacturer will have to lower his price even more to supply all patients that could benefit from his medicines. The

fact that PHARMAC relates the medicines to the treatments also gives manufacturers less ability to abuse their patent-abilities as what is happening in the Netherlands. Therefor the Dutch could also learn from this strategy.

Multi-product-deals

PHARMAC does not only look at negotiating the lowest prices for specific medicines, instead they give manufacturers the make offers for the delivery of multiple medicines. In this case PHARMAC compares the costs of a whole package of medicines. A medicine can be reimbursed even while it is not the cheapest, the prices the manufacturer offers on other medicines overall leads to more financial gains.

Blind Bidding prevention

PHARMAC offers sole-suppliers who won the previous bet, to make them an offer of a price-reduction. With this offer, suppliers have the ability to prevent blind bidding procedures from taking place, giving them the ability to remain sole-supplier for the price they determined themselves.

Consultation

Already before, I discussed the importance of stakeholders in order to achieve political stability. Unquestionable it is almost impossible to gain the support of all stakeholders; however it is of importance that the decision maker knows the stakeholders and recognizes their actions. Consultation is a good method to identify these actions and to, visibly, respond to these actions. Trough consultation the decision maker may identify early forms of policy deviations and decrease of stakeholder support. In these early stages the decision maker can counter these threats by incremental changes realized with the support of the stakeholder in order to regain their support or to answer/counter paradigm deviations.

The advice I would like to give the Hungarian government is to further institutionalize consultations between stakeholders (especially those that are part of the pharmaceutical supply chain) and the decision maker (mainly the government itself). This could help to prevent future crises and improve the alignment between the policy and the impacted environment. Parties enjoy the advantages of improved relations between decision maker and stakeholders by lowering the gap of asymmetric information.

Selective purchasing

The selective purchasing process could make health providers more responsible. If the NHIFA would be able to deny certain health providers remunerations, or bring some form of relation between the

price and the quality of the care, the providers would have more incentives to improve their care. The selective purchasing makes the market for health care provision more efficient as providers are better specializing in certain fields. The selective purchasing tactic could work for Hungary, however I must admit that this is only the case in geographical areas with health provision is abundant. For the rural areas this method will not be feasible, as the Hungarians struggle with finding personnel at all. I am not aware whether this is the case, but the government could give higher financial remunerations to health personnel who is willing to operate in the rural areas, this could also be some form of selective purchasing.

Performance setting and bench-marking

The idea in the Netherlands and New Zealand is that competition enhances the quality of care. As a result the government and the health insurers implement all sorts of benchmarks. Not only for themselves but also open for the public. In New Zealand the central government monitors and benchmarks the different health boards on several health targets. Hungary could choose to publish such lists for its local and regional health providers such as municipalities and counties. The performances do not directly have to relate to budgetary consequences, rather to the public scrutiny. New technologies have made these forms of transparency easy to implement for governments and data easy to access for citizens.

7.2 For further research

With these last paragraphs, my work is done. It is up to others to expand on my work. I hope there will be interest in further applying and developing my framework for the theories I discussed are complex and detailed, further integration of the more detailed aspects of the theories involved, or possible additions of one or two more. I would welcome all suggestions or feedback on what might need change.

For the case-study itself, I think research on this topic never end. The pharmaceutical policies develop and I have only discussed until recent. Especially in a country such as Hungary, in which the political landscape is very dynamic with coalitions divided to the extreme, policies are changing rather unpredictable.

8. References

1) Garattini, L. and S. Ghislandi (2006). "Off-patent drugs in Italy." *The European Journal of Health Economics* 7(1): 79-83.

2) Rodda, C. (2013) *'Economics for AQA Students',* Chrisrodda.com, via: http://www.chrisrodda.com/ASMicroeconomics/meritgoods.html
3) WHO, (2013), *'The pharmaceutical industry'*, via: http://www.who.int/trade/glossary/story073/en/index.html
4) Fisher, W.W., Rigamonti, C.P. (2005) *'The South Africa AIDS Controversy. A Case Study in Patent Law and Policy'.* Harvard Law School, Feb. 2010. Via: http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf
5) Moon, S. *'Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health.'* Global Health Governance, Vol. 2, No. 2. Found via: http://www.ghgj.org/moon2.2medecinespublicgood.htm
6) OECD (2013) *'Achieving better Health Care for Money'*, 9 November, via: http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/achieving-better-value-for-money-in-health-care_9789264074231-en
7) PHARMAC (2013) *'Annual Report 2012',* via: http://www.pharmacy.govt.nz
8) Kanavos, P., Ferrario, A., Nicod, E. (2012) *'Tender systems for outpatient pharmaceuticals in the European Union: Evidence from The netherlands and Germany'*, LSE Health, London School of Economics. London.
9) Horvath, B. (2013) *Interview.*
10) EMA (2013) *'About us',* via: http://ema.europa.eu
11) Medsafe (2013) *'About us',* via: http://www.medsafe.govt.nz
12) Maxwell, J.A. (2004), '*Conceptual Framework: what do you think is going on'',* SAGE Publications, London. Via: http://www.scribd.com/doc/49507350/Maxwell-Conceptual-Framework-What-do-you-think-is-going-on
13) Miles, M.B. & Huberman, A.M. (1994) *'Qualitative Data Analysis: An Expanded Sourcebook'*, SAGE Publications, London.
14) Keeler, J.T.S. (1993) 'Opening the Window for ReformL Mandates, Crises, and Extraordinary Policy-making' *Comparative Political Studies*, Vol. 25, 433-486.
15) Bannink, D., and Resodihardjo, S. (2006) 'The Myths of Reform', in: Heyse, L., Resodihardjo, S., Lantink, T. and Lettinga, B. (eds), Reform in Europe: Breaking the Barriers in Government., Aldershot: Ashgate, pp. 1-20.
16) Streeck, W. Thelen, K. (2005) *'Beyond Continuity: Institutional Change in Advanced Political Economies'* Oxford University Press.
17) Ibidem.
18) Dolota, U. (2011) 'Radical Change as Gradual Transformation: Characteristics and Variants of Socio-technical Transitions'. Institute for Social Science, University of Stuttgart, Germany. Via: http://www.uni-stuttgart.de/soz/oi/publikationen/soi3_dolata_radical_change.pdf
19) Streeck, W. Thelen, K. (2005) *'Beyond Continuity: Institutional Change in Advanced Political Economies'* Oxford University Press.
20) Dolota, U. (2011) 'Radical Change as Gradual Transformation: Characteristics and Variants of Socio-technical Transitions'. Institute for Social Science, University of Stuttgart, Germany. Via: http://www.uni-stuttgart.de/soz/oi/publikationen/soi3_dolata_radical_change.pdf
21) Ibidem.
22) Bannink, D., and Resodihardjo, S. (2006) 'The Myths of Reform', in: Heyse, L., Resodihardjo, S., Lantink, T. and Lettinga, B. (eds), Reform in Europe: Breaking the Barriers in Government., Aldershot: Ashgate, pp. 1-20.
23) Ibidem.
24) Hill, M. J. (2009) *'The Public Policy Process'*, Longman, fifth edition, United Kingdom.
25) Jones, B.D. (2002) '*Bounded rationality and public policy: Herbert A. Simon and the decisional foundation of collective choice'* Policy Sciences, Vol. 35, Nr. 3.
26) Ibidem.
27) Jones, B.D. (2003) *'Bounded Rationality and Political Science: Lessons from Public Administration and Public Policy'*, University of Washington. Via: http://www.esf.edu/es/felleman/696am%20bounded%20rationality.pdf
28) Ibidem.
29) Heclo, H. (1974) '*Modern Social Policies in Britain and Sweden: From Relief to Income Maintenance*' New Haven, CT: Yale University Press | Hall, P. (1993) 'Policy Paradigms, Social Learning, and the State: The Case of Economic Policymaking in Britain' , *Comparative Politics,* Vol. 25, Nr. 3, 275-296. | Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
30) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
31) Bannink, D., and Resodihardjo, S. (2006) 'The Myths of Reform', in: Heyse, L., Resodihardjo, S., Lantink, T. and Lettinga, B. (eds), Reform in Europe: Breaking the Barriers in Government., Aldershot: Ashgate, pp. 1-20.
32) Schwitzgebel, E. (2006), "Belief", *The Stanford Encyclopedia of Philosophy*, Stanford, CA: The Metaphysics Research Lab.
33) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
34) Ibidem.
35) Lindblom, C.E. (1969) 'The Science of ''Muddling Through''' *Public Administration Review*, Vol. 19, Nr. 2, pp. 79-88.
36) Sapru, R.K. (1994) *'Public Policy: Formulation, Implementation and Evaluation'*, Sterling Publishers, New Dehli.
37) Bannink, D., and Resodihardjo, S. (2006) 'The Myths of Reform', in: Heyse, L., Resodihardjo, S., Lantink, T. and Lettinga, B. (eds), Reform in Europe: Breaking the Barriers in Government., Aldershot: Ashgate, pp. 1-20.
38) Ibidem.
39) Ibidem.
40) Ibidem.
41) *Esping-Andersen, G. (1994) 'Welfare States and the Economy', in N. J. Smelser and R. Swedberg(eds) The Handbook of Economic Sociology, pp.711–32. Princeton/New York: Princeton*
42) Ira C. Colby, Catherine N. Dulmus, Karen M. Sowers. Connecting Social Welfare Policy to Fields of Practice. John Wiley & Sons, 2012. P. 29.

43) Thomas Meyer, Lewis P. Hinchman. *The theory of social democracy*. Cambridge, England, UK; Malden, Massachusetts, USA: Polity Press, 2007. Pp. 137.
44) R. J. Barry Jones. *Routledge Encyclopedia of International Political Economy: Entries A-F*. Taylor & Frances, 2001. Pp. 243.
45) ibidem
46) Wildeboer-Schut, J.M., Vrooman, J.C., de Beer, P.T. (2000) ''De maat van de Verzorgingsstaat: Inrichting en werking van het sociaal-economisch bestel in elf westerse landen'' Sociaal Plan Bureau, Den Haag. Found via: www.scp.nl/dsresource?objectid=21325&type=pdf
47) Arts, W.A., Gelissen, J. (2002) ''Three Worlds of Welfare Capiratlism or more? A state-of-the-art report'', *Journal of European Social Policy*, 12, 137. Found via: http://media.library.ku.edu.tr/reserve/resspring08/cshs511_JDixon/Three%20worlds%20of%20welfare%20capitalism%20or%20more.pdf
48) *Esping-Andersen, G. (1994) 'Welfare States and the Economy', in N. J. Smelser and R. Swedberg(eds) The Handbook of Economic Sociology, pp.711–32. Princeton/New York: Princeton*
49) Levi-Faur, D. (2013) *'The welfare state: a regulatory perspective'*, Department of Political Science & School of Public Policy, Hebrew University Jerusalem, June 2013.
50) Ibidem.
51) Sabatier, P.A. & Jenkings-Smith, H.J. (1999) *"The Advocacy Coalition Framework: An Assessment."* In Theories of the Policy Process, ed.
52) Blythe, E.L. (1983) *'The Maximization of Discretionary Budget: an Explanation for the Pattern of Computer Investments in the Federal Governmen'*, Master of Urban Affairs, in: Urban Affairs, Blacksburg, Virginia.
53) Niskanen, W.A. (1975) *'Bureaucracy and Representive Government',* Chicago: Aldine-Atherton.
54) Niskanen, W.A. (1971) *'Bureaucracy: Servant or Master?'*, Great Britain: The Institute of Economic Affairs.
55) Lane, J.E. (2008) *'Public Administration and Public Management'.* Routledge, Abingdon.
56) Miller, G. (2005) *'Solutions to Principal-Agent Problems in Firms'*, Handbook of New Institutional Economics, 349-370, 2005, Springer, The Netherlands.
57) Ibidem. | Strausz, R. (1997) '*Delegation of Monitoring in a Principal-Agent Ralationship'*. Review of Econic Studies, 64, pp. 337 – 357
58) Gailrmard, S. (2010) 'Politics, Principal-Agent Problems, And Public Service Motivation' *International Public Management Journal,* 13(1), p. 35-45
59) Ibidem.
60) Migue, J. L., Balanger, G. (1974) *'Toward a General Theory of Managerial Discretion',* Public Choice, Spring, p.27
61) Prado, M., Trebilcock, M. (2009) *Path Dependence, Development, and The Dynamics of Institutional Reform'* University of Toronto Law Journal, Canada, via: http://www.law.utoronto.ca/utfl_file/count/documents/trebilcock/Prado-Trebilcock%20-%20Path%20-%20UTLJ.pdf
62) Kay, A. (2005) *'A Critique of the Use of Path Depency in Policy Studies'*, Public Administration, 15 Augus, Vol. 83, Iss. 3, 553-571.
63) Pierson, P. (2000) 'Increasing Returns, Path Dependence, and the Study of Politics', *The American Poltical Science Review,* Vol. 94, No.2.
64) Ibidem
65) Politt, C., Buckeart, G. (1999) *'Public Management Reform : A Comparative Analysis'*, Xoford University Press, Oxford.
66) Layzer, J. (2012), *'Open for Business: Conservatives' Opposition to Environmental Regulation', Massachusetts Institute of Technology,* MIT Press, Cambridge.
67) Ibidem.
68) Comodromos, G., Ferrer, J. (2011) *Incremental Institutional Change and Australian Universities',* International Review of Business Research Papers, Vol. 7 No. 1. Jan 2011. Pp. 33 – 339.
69) Ibidem.
70) Ibidem.
71) Ibidem.
72) Kingdon, J. (1984), *'Agendas, alternatives, and public policies.',* Boston: Little, Brown and Company.
73) Keeler, J.T.S. (1993) 'Opening the Window for ReformL Mandates, Crises, and Extraordinary Policy-making' *Comparative Political Studies*, Vol. 25, 433-486.
74) Ibidem.
75) Public Broadcasting Service (PBS), (2013) ''The Cuban Missile Criss; Three Men go to War'' March 2013, found via: http://www.youtube.com/watch?v=MhFByQpYvp4
76) Ibidem.
77) Ibidem.
78) Ibidem.
79) Ibidem.
80) Dows, A. (1957) 'An Economic Theory of Political Action in a Democracy', *The Journal of Political Economy,* Vol. 65, Iss. 2, p. 135-150
81) Ibidem.
82) Ibidem.
83) Hill, M. J. (2005) *'The Public Policy Process',* Pearson Education. New York.
84) *P. Sabatier, (1991) 'Towards Better Theories of the Public Policy Process'. Boulder, CO: Westview Press. p. 117–166*
85) Sabatier, P.A. & Jenkings-Smith, H.J. (1999) *"The Advocacy Coalition Framework: An Assessment."* In Theories of the Policy Process, ed.
86) Weible. C. M., Sabatier, P.A. (2005) 'Comparing Policy Networks: Marine Protected Areas in California', *The Policy Studies Journal,* Vol. 33, No. 2.
87) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
88) Ibidem.
89) Ibidem.

90) Salisbury, R. H., J. P. Heinz, E. O. Laumann, and R. L. Nelson. 1987. "Who Works with Whom? Interest Group Alliances and Opposition." *American Political Science Review,* 81 (4): 1217–34.
91) Weible. C. M., Sabatier, P.A. (2005) 'Comparing Policy Networks: Marine Protected Areas in California', *The Policy Studies Journal,* Vol. 33, No. 2.
92) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
93) Walker, Jack L., Jr. 1977. "Setting the Agenda in the U.S. Senate: A Theory of Problem Selection." British Journal of Political Science 7: 423–445.
94) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
95) Goldstein, J., Keohane, O. (1993) *'Ideas and foreign policy: Beleifs, Institutions and Poltical change',* Cornell Universiy Press, New York.
96) Ibidem, p.12
97) Katznelson, I. Weingast, B.R. (2005) *'Preferences and Situations: Points of Intersection Between Historical and Rational Choice Institutionalism'*, Russel Sage Foundation. New York.
98) Epstein, (1997) 'Do political preferences change?', *The Journal of Politics, Vol. 60, No. 3.* p. 816.
99) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
100) Hall, P. (1993) *'Policy Paradigms, Social Learning, and the State: The Case of Economic Policymaking in Britain' Comparativa Politics,* Vol. 25, No. 3, pp. 275-296.
101) Baumgartner, F. R. (2012) 'Ideas and Policy Change', *Governance: An International Journal of Policy, Administration, and Institutions,* University of North Carolina, Chapel Hill.
102) Helderman, J., Schut, F.T., van der Grinten, E. D., van de Vent, W. P. M. M. (2005) 'Market-oriented Health Care Reforms and Policy Learning in the Netherlands', Department of Health Policy and Management, Erasmus University, Rotterdam.

103) M.S. de Vries, (2010) *'Performance measurement and the search for best practices'*, Review of Administrative Sciences, Vol 76(2), Sagepub, Nijmegen, The Netherlands
104) Ibidem. | Löffler, E (1999) 'The Value of Public Management Evaluations from an International Perspective', paper presented at the International Public Management Network workshop, Siena.
105) Ibidem.
106) Löffler, E (1999) *'The Value of Public Management Evaluations from an International Perspective',* paper presented at the International Public Management Network workshop, Siena.
107) M.S. de Vries, (2010) *'Performance measurement and the search for best practices'*, Review of Administrative Sciences, Vol 76(2), Sagepub, Nijmegen, The Netherlands
108) Ibidem.
109) Golafshani, N. (2003) *'Understanding Reliability and Validity in Qualitative Research',* The Quality Report, Vol 8, Nr. 4, University of Toronto, Canada, pp. 597 – 607.
110) Joppe, M. (2000). '*The Research Process.'* Basingstoke and New York: Palgrave Macmillan. Via: http://www.ryerson.ca/~mjoppe/rp.htm
111) 't Hart, H., Boeije, H., Hox, J. (2009) *'Methode van Onderzoek'*, Boom Lemma Uitgevers. 8th print.
112) Patton, M. Q. (2002). *'Qualitative evaluation and research methods'* (3rd ed.). Thousand Oaks, CA: Sage Publications, Inc
113) 't Hart, H., Boeije, H., Hox, J. (2009) *'Methode van Onderzoek'*, Boom Lemma Uitgevers. 8th print.
114) OECD, (2009)
115) European Commission, (2008), via: http://ec.europa.eu/governance/better_regulation/impact_en.htm
116) OECD, (2012) Country Statiscs Data
117) Ibidem.
118) Statista.com, (2012) *'Average wages around the world, adjusted by purchasing power'*
119) OECD, (2012) Country Statiscs Data
120) Ibidem.
121) Ibidem.
122) Schmeer, K (2000) *'Stakeholder Analysis Guidelines'*, Section 2, Germany. Via: http://www.eestum.eu/voorbeelden/Stakeholders_analysis_guidelines.pdf
123) Ibidem.
124) Ibidem.
125) Reulink, N., Lindeman, L. (2005) *'Kwalitatief Onderzoek',* Radboud University, Nijmegen, The Netherlands. Via: http://www.cs.ru.nl/~tomh/onderwijs/om2%20(2005)/om2_files/syllabus/kwalitatief.pdf
126) Gaál, P., Szigeti, S., Csere, M., Gaskins, M., Panteli, D. (2011) 'Hungary: Health system review', *Health Systems in Tranistion,* Vol. 13, Nr. 5, p: XX
127) Ibidem, p XXI
128) Ibidem, p XVIII
129) Ball, P. (2011) 'The pharmaceutical chain'
130) Maarse, H. (2009) ''Health Policy Monitor: Drug preference policy'', University of Maastricht, Maastricht, found via: http://hpm.org/nl/a14/1.pdf
131) Z-Index.nl, (2013), via: http://www.z-index.nl/taxe
132) Riesebosch, T. (2013) Interview
133) Zarroy, S. (2013) Interview, Visser, F. (2013) Interview, Vermeulen, I. (2013) Interview
134) http://www.nza.nl/over
135) Ibidem.
136) http://www.lgz.nl/organization
137) PHARMAC (2013) *'Our place in the medicine system',* via: http://www.pharmac.govt.nz/about

138) Grocott, R. (2009) *'Applying Programme Budgeting Marginal Analysis in the health sector: 12 years of experience''*, Expert Reviews, Wellington, found via: http://www.expert-reviews.com/doi/pdf/10.1586/erp.09.2

139) Cummings, J. (2010) 'How New Zealand has contained expenditure on drugs', *British Medical Journal,* Vol. 340

140) Grocott, R. (2009) *'Applying Programme Budgeting Marginal Analysis in the health sector: 12 years of experience''*, Expert Reviews, Wellington, found via: http://www.expert-reviews.com/doi/pdf/10.1586/erp.09.2

141) Detsky, A.S., Laupacis A. (2007 "Relevance of cost-effectiveness analysis to clinicians and policy makers.' JAMA, 298(2), 221-224.

142) Grocott, R. (2009) *'Applying Programme Budgeting Marginal Analysis in the health sector: 12 years of experience''*, Expert Reviews, Wellington, found via: http://www.expert-reviews.com/doi/pdf/10.1586/erp.09.2

143) Ibidem.

144) O'Connor, D. & Williams, M. (2010) 'Parliamentary debate on: New Zealand Public Health and Disability Amendment Bill', 12 october 2010, via: http://theyworkforyou.co.nz/bills/nz_public_health_disability_amendment_2010/2010/oct/12/second_reading_2

145) Centraltas*, 'Community Pharmacy Services Implementations Update No.1'*, 26 July 2012, via: http://www.centraltas.co.nz/LinkClick.aspx?fileticket=v5E9zjvehdU%3D&tabid=253&mid=926

146) Kormany, (2011) ''Hungary's Structural Reform Programme 2011 – 2014'' , found via: http://www.kormany.hu/download/b/23/20000/Hungary's%20Structural%20Reform.pdf

147) Government of the Republic of Hungary, (2011), '*National Reform Programme of Hungary: Based on the Széll Kálmán Plan'*, April 2011, via: http://ec.europa.eu/europe2020/pdf/nrp/nrp_hungary_en.pdf

148) Cotarcea, R. (2011), *'Extra Pharma Sector Taxes is Hungary: A European Overview and Interpretation Issues',* GC Grapevine, 24 October. Via: http://gcgrapevine.com/index.php?option=com_k2&view=item&id=35:extra-pharma-sector-taxes-in-hungary-an-european-overview-and-interpretation-issues&Itemid=160

149) Torok, E. (2011) Interview on Szell Kalman plan – GC-Grapevind.com, found via: http://gcgrapevine.com/index.php?option=com_k2&view=item&id=5:interview-with-dr-eszter-torok&Itemid=159

150) http://www.oep.hu

151) GYEMSZI, (2013) 'Hungarian Health System Scan 2013), Vol 7, Nr. 1, May, via: http://www.eski.hu/new3/hirlevel_en/2013/HHSC-2013-1.pdf

152) Http://www.gyemszi.hu/aboutus | Http://www.antsz.hu/organization

153) OECD, (2008) *'OECD Health Policy Studies'*

154) http://www.vgz.nl/overvgz

155) Redactie Trouw, (2013) *'Zorgverzkeraars maakten 1,4 miljard euro winst'*, 11 april, via: http://www.trouw.nl/tr/nl/4516/Gezondheid/article/detail/3424118/2013/04/11/Zorgverzekeraars-maakten-1-4-miljard-euro-winst.dhtml | nu.nl, (2013) *'Zorgverzkeraars maakten 1,4 miljard winst'*, 11 april, via: http://www.nu.nl/economie/3395280/zorgverzekeraars-maakten-14-miljard-winst.html | Riesebosch, T. (2013) Interview.

156) Zarroy, S. (2013) Interview | Visser, F. (2013) Interview | nu.nl, (2013) *'Zorgverzkeraars maakten 1,4 miljard winst'*, 11 april, via: http://www.nu.nl/economie/3395280/zorgverzekeraars-maakten-14-miljard-winst.html

157) Redactie Trouw, (2013) *'Zorgverzkeraars maakten 1,4 miljard euro winst'*, 11 april, via: http://www.trouw.nl/tr/nl/4516/Gezondheid/article/detail/3424118/2013/04/11/Zorgverzekeraars-maakten-1-4-miljard-euro-winst.dhtml

158) ONVZ, (2013) *'Free Choice of Medicines'*, via: http://www.onvz.nl/zorg.htm?ch=def&id=free-choice-medicines

159) Visser, (2013) Interview | Riesebosch, (2013) Interview

160) PHARMAC, (2013) | Privett (2013)

161) GYEMSZI, (2013) '*Hungarian Health System Scan 2013)*, Vol 7, Nr. 1, May, via: http://www.eski.hu/new3/hirlevel_en/2013/HHSC-2013-1.pdf

162) Baji, P., Péntek, M., Boncz, I., Brodszky, V., Loblova, O., Brodszky, N., Gulászi, L. (2013) *'The impact of the recession on health care in Central and Eastern European Countries',* Not yet Published, Corvinus University, Budapest.

163) Ibidem.

164) MTI, (2013) '*Gyógyszerárcsökkenést hozott a legutóbbi vaklicit',* 13 march, via: http://nol.hu/belfold/gyogyszerarcsokkenest_hozott_a_legutobbi_vaklicit?ref=sso

165) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) The Netherlands Health system review In: Health Systems in Transistion Vol. 12 No. 1 2010.

166) Nos.nl (2005) *'Ziekenfonds: instituut met rijke historie'* 23 december, via: http://nos.nl/artikel/120918/

167) Ibidem.

168) http://www.kenniscentrumhistoriezorgverzekeraars.nl , (2013) .

169) Nos.nl (2005) *'Ziekenfonds: instituut met rijke historie'* 23 december, via: http://nos.nl/artikel/120918/

170) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) *The Netherlands Health system review In: Health Systems in Transistion* Vol. 12 No. 1 2010

171) Van der Grinten, T.E.D, Kasdorp, J.P. (1999) 'Choices in Dutch health care: mixing strategies and responsibilities', *Health Policy,* vol. 50, 105-122.

172) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) *The Netherlands Health system review In: Health Systems in Transistion* Vol. 12 No. 1 2010

173) Van der Grinten, T.E.D, Kasdorp, J.P. (1999) 'Choices in Dutch health care: mixing strategies and responsibilities', *Health Policy,* vol. 50, 105-122.

174) http://www.kennsilink.nl (2013)

175) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) *The Netherlands Health system review In: Health Systems in Transistion* Vol. 12 No. 1 2010

176) Dunning, A.J. (2001) *'De basisverzekering: voor elk wat wils?'* 25 januari, via: http://retro.nrc.nl/W2/Lab/Profiel/Zorgstelsel/basisverzekering.html

177) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) *The Netherlands Health system review In: Health Systems in Transistion* Vol. 12 No. 1 2010

178) Kirkman-Liff BL, Van de Ven WPMM. Improving Efficiency in the Dutch health Care System: Current innovations and future options. Health Policy 1989;13:35–53.

179) Rutten, F. (2004) 'The impact of healthcare reform in the Netherlands'. Erasmus University, Rotterdam. Found via: http://www.ncbi.nlm.nih.gov/pubmed/15660478
180) Helderman, J., Schut, F.T., van der Grinten, E. D., van de Vent, W. P. M. M. (2005) 'Market-oriented Health Care Reforms and Policy Learning in the Netherlands', Department of Health Policy and Management, Erasmus University, Rotterdam.
181) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) *The Netherlands Health system review In: Health Systems in Transistion* Vol. 12 No. 1 2010
182) Helderman, J., Schut, F.T., van der Grinten, E. D., van de Vent, W. P. M. M. (2005) 'Market-oriented Health Care Reforms and Policy Learning in the Netherlands', Department of Health Policy and Management, Erasmus University, Rotterdam.
183) Van der Grinten, T.E.D, Kasdorp, J.P. (1999) 'Choices in Dutch health care: mixing strategies and responsibilities', *Health Policy,* vol. 50, 105-122.
184) Ibidem.
185) Helderman, J., Schut, F.T., van der Grinten, E. D., van de Vent, W. P. M. M. (2005) 'Market-oriented Health Care Reforms and Policy Learning in the Netherlands', Department of Health Policy and Management, Erasmus University, Rotterdam.
186) Schäfer, W., Kroneman, M., Boerma, W., Van den Berg, M., Westert, G., Devillé, W. Van Ginneken, E. (2010) *The Netherlands Health system review In: Health Systems in Transistion* Vol. 12 No. 1 2010
187) A.P. den Exter, 'Purchasers as the public's agent: Consumers participation and accountability' in: *Effective purchasing for health gain*. R. Robinson, E. Jakubowski and J. Figueras (eds) Open University Press, Buckingham (2005), pp. 122-139
188) Lieverdink, H. 2001. 'The Marginal Success of Regulated Competition Policy in the Netherlands.' *Social Science and Medicine* 52: 1183–1194.
189) http://www.ziekenhuizentransparant.nl/
190) http://www.nza.nl/zorgonderwerpen/dossiers/zorgverzekering/veelgestelde-vragen/zorgplicht/ | Vermeulen, I. (2013) Interview.
191) Genakker, H. (2013) *'Fusie Vlietland Ziekenhuis en verzekeraar DSW gaat door',* via: http://www.zorgvisie.nl/Home/Nieuws/2010/10/Fusie-Vlietland-Ziekenhuis-en-verzekeraar-DSW-gaat-door-ZVS009706W/
192) http://www.dsw.nl
193) Rechtbank Breda, (2008), uitspraak: 183442/KG,
194) Schut, F.T. en M. Varkevisser (2008), Wenselijkheid zorgfusies staat wel degelijk ter discussie, VGE Bulletin, 25(3): 18-19
195) Ibidem.
196) Ter Borg, J. Warmerdam, J. Nieuwhof, M. (2009) ''Players' Impact on Medicines Purchasing in the Netherlands', IMS Health Incorporated, Cappelle a/d Ijssel.
197) http://www.achmea.nl/preferentiebeleid
198) Tros Radar Consumer Television Program, (2013) Episode on the Preference Policy, part 2/2.
199) Ibidem. | Ter Borg, J. Warmerdam, J. Nieuwhof, M. (2009) ''Players' Impact on Medicines Purchasing in the Netherlands', IMS Health Incorporated, Cappelle a/d Ijssel.
200) French, S., Old, A., Healy, J. (2001) *'Health Care Systems in Transition: New Zealand',* European observatory on Health Care Systems, New York.
201) Parliament New Zealand, (2009) *'New Zealand Health System Reforms',* April 26, via: http://www.parliament.nz/en-nz/parl-support/research-papers/00PLSocRP09031/new-zealand-health-system-reforms
202) French, S., Old, A., Healy, J. (2001) *'Health Care Systems in Transition: New Zealand',* European observatory on Health Care Systems, New York.
203) Ibidem | Parliament New Zealand, (2009) *'New Zealand Health System Reforms',* April 26, via: http://www.parliament.nz/en-nz/parl-support/research-papers/00PLSocRP09031/new-zealand-health-system-reforms
204) Ibidem | French, S., Old, A., Healy, J. (2001) *'Health Care Systems in Transition: New Zealand',* European observatory on Health Care Systems, New York.
205) Parliament New Zealand, (2009) *'New Zealand Health System Reforms',* April 26, via: http://www.parliament.nz/en-nz/parl-support/research-papers/00PLSocRP09031/new-zealand-health-system-reforms
206) French, S., Old, A., Healy, J. (2001) *'Health Care Systems in Transition: New Zealand',* European observatory on Health Care Systems, New York.
207) Ibidem | Parliament New Zealand, (2009) *'New Zealand Health System Reforms',* April 26, via: http://www.parliament.nz/en-nz/parl-support/research-papers/00PLSocRP09031/new-zealand-health-system-reforms
208) Parliament New Zealand, (2009) *'New Zealand Health System Reforms',* April 26, via: http://www.parliament.nz/en-nz/parl-support/research-papers/00PLSocRP09031/new-zealand-health-system-reforms
209) Ibidem
210) Ibidem
211) Ministry of Health New Zealand (2013), *'District Health Board Performances',* June, http://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/district-health-boards
212) Ibidem.
213) Tordoff, M., Norris, P.T., Reith, D. M. (2005) 'Managing Prices for Hospital Pharmacueticals: A Succesful Strategy for New Zealand?', *Value in Health,* Vol 8, Iss. 3, p 201-208.
214) Pharmacy.govt.nz, '*The Role of PHARMAC*', via: http://pharmac.govt.nz
215) Dudding, A. (2013) *'The pills bills: It's life or death'*, The Dominion Post, 23 June, via: http://www.stuff.co.nz/dominion-post/news/8830990/The-pills-bills-Its-life-or-death
216) Székely, S. (1973), ''on the Preparation of the Hungarian Health Act of 1876'', Comm. Hist. Artis. Med. 66-68. Found via: http://www.orvostortenet.hu/tankonyvek/tk-05/pdf/4.20.6/1973_066_068_szekely_sandor_preparation_hungarian.pdf
217) Gaál, P., Szigeti, S., Csere, M., Gaskins, M., Panteli, D. (2011) 'Hungary: Health system review', Health Systems in Tranistion, Vol. 13, Nr. 5,
218) Ibidem.
219) Ibidem. | http://www.oep.hu
220) Ibidem
221) Ibidem
222) Ibidem

223) Ibidem
224) Ibidem
225) Ibidem
226) Ibidem
227) Ibidem
228) Ibidem
229) Ibidem
230) Ibidem
231) Ibidem
232) GYEMSZI (2013) *'Deed of Foundation of the National Institute for Quality- and Organizational Development in Healthcare and Medicines', via:* http://www2.gyemszi.hu/site/index.php?page=en/General_information/Deed_of_Foundation
233) Gaál, P., Szigeti, S., Csere, M., Gaskins, M., Panteli, D. (2011) 'Hungary: Health system review', Health Systems in Tranistion, Vol. 13, Nr. 5
234) Ibidem
235) HSCO, (2001) *Yearbook of health statistics 2002*
236) Gaál, P., Szigeti, S., Csere, M., Gaskins, M., Panteli, D. (2011) 'Hungary: Health system review', Health Systems in Tranistion, Vol. 13, Nr. 5
237) Ibidem
238) Schippers, E.I. (2012) *'Beantwoording Kamervragen over de gevolgen van het preferentiebeleid medicatie',*15 November, Tweede Kamer, Den Haag, via: http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2012/11/15/beantwoording-kamervragen-over-de-gevolgen-van-het-preferentiebeleid-medicatie.html
239) Ibidem
240) Ibidem
241) Optimafarma.nl (2013) *'VWS wil onderzoek naar zorgplicht verzekeraars'*, 4 June, via: http://www.optimafarma.nl/nieuws/vws-wil-onderzoek-naar-zorgplicht-verzekeraars/
242) Riesebosch, T. (2013) Interview | Baltesen, F. (2013) *'Meer agressie in de apotheek door preferentiebeleid'*, 16 May, via: http://www.pw.nl/nieuws/cartoon-1/meer-agressie-in-de-apotheek-door-preferentiebeleid
243) Riesebosch, T. (2013) Interview | Vermeulen, I. (2013) Interview
244) Riesebosch, T. (2013) Interview
245) Tros Radar Consumer Television Program, (2013) Episode on the Preference Policy, part 1/2.
246) Riesebosch, T. (2013) Interview
247) Ibidem
248) Ibidem
249) Ibidem | Stichting Farmaceutische Kengetalen, (2013) *'Feiten en cijfers'*, via: http://www.sfk.nl
250) Stichting Farmaceutische Kengetalen, (2013) *'Feiten en cijfers'*, via: http://www.sfk.nl
251) Zarroy, S. (2013) Interview
252) Zarroy, S. (2013) Interview | Visser, F. (2013) Interview
253) Zarroy, S. (2013) Interview | Visser, F. (2013) Interview
254) Ibidem.
255) Zarroy, S. (2013), Visser, F. (2013)
256) Ter Borg, J. Warmerdam, J. Nieuwhof, M. (2009) ''Players' Impact on Medicines Purchasing in the Netherlands', IMS Health Incorporated, Cappelle a/d Ijssel.
257) Pharmaceutisch Weekblad (2013) *'Groothandel krijgt 22 cent per doosje: Brocaref zet levering preferente middelen door'*, 7 December, via: http://www.pw.nl/nieuws/nieuwsberichten/2012/groothandel-krijgt-22-cent-per-doosje
258) Vermeulen, I. (2013) Interview | NZA (2013) *'Marktscan 2009 – 2013: Zorgverzekeringsmarkt'*, via: http://www.nza.nl/104107/105773/742312/Marktscan_en_beleidsbrief_Zorgverzekeringsmarkt_2013.pdf
259) Ibidem.
260) Vermeulen, I. (2013) Interview
261) Pharmaceutisch Weekblad (2013) *'Medlactie NPCF: Veel problemen door preferentiebleid'*, 30 July, via: http://www.pw.nl/nieuws/nieuwsberichten/npcf-veel-problemen-door-preferentiebeleid
262) Optimafarma.nl (2012) *'Experts in Tweede Kamer: preferntiebeleid kraakt'*, 23 may, via: http://www.optimafarma.nl/nieuws/experts-tweede-kamer-preferentiebeleid-kraakt/
263) Pharmaceutisch Weekblad (2013) *'Medlactie NPCF: Veel problemen door preferentiebleid'*, 30 July, via: http://www.pw.nl/nieuws/nieuwsberichten/npcf-veel-problemen-door-preferentiebeleid
264) Ibidem.
265) Niernieuws.nl (2013) *'Medicijngebruiker van het kastje naar de muur door preferentiebeleid'*, 18 June, via: http://www.niernieuws.nl/?cat=In&artid=6410
266) Altijd Wat Television program (2013) *'De macht van de farmaceuten',* 1 Juli, via: http://altijdwat.ncrv.nl/nieuwsblogs/deze-week-macht-van-farmaceuten
267) Garattini, L. and S. Ghislandi (2006). "Off-patent drugs in Italy." *The European Journal of Health Economics* 7(1): 79-83.
268) Altijd Wat Television program (2013) *'De macht van de farmaceuten',* 1 Juli, via: http://altijdwat.ncrv.nl/nieuwsblogs/deze-week-macht-van-farmaceuten
269) Altijd Wat Television program (2013) *'De macht van de farmaceuten',* 1 Juli, via: http://altijdwat.ncrv.nl/nieuwsblogs/deze-week-macht-van-farmaceuten
270) Riebestein, R., Rinnoy Kan, A. (2013) *'Letter to the Minister: Verkenners extramurale farmaceutische zorg'*, 28 februari, The Hague, via: https://zoek.officielebekendmakingen.nl/blg-211178.html
271) Ashton, T. (2013) Interview
272) O'Connor, D. & Williams, M. (2010) 'Parliamentary debate on: New Zealand Public Health and Deisability Amendment Bill', 12 october 2010, via: http://theyworkforyou.co.nz/bills/nz_public_health_disability_amendment_2010/2010/oct/12/second_reading_2

273) Cummings, J. (2010) 'How New Zealand has contained expenditure on drugs', British Medical Journal, Vol. 340
274) Williams, L. (2013) Interview
275) Privett. A. (2013) Interview
276) Taylor, C. (2012) *'Wholesalers take a $56m hit from lipitor'*, Pharmacy Today, 12 October, via: http://www.pharmacytoday.co.nz/in-print/2012/october-2012/october-2012/wholesalers-take-a-$56m-hit-from-lipitor.aspx
277) Davis, W. (2008) *'Co-op pharmacists under pressure',* Cooperatives News, June-July 2008, via: http://nz.coop/assets/Uploads/Cooperatives-News/PWL-Central-guest-editorial.pdf
278) Ashton, T. (2013) Interview | Tegenlicht Dutch Research Television (2012) *'Expeditie Beter Nederland',* 12 November, via: http://tvblik.nl/tegenlicht/expeditie-beter-nederland
279) Taylor, C. (2012) *'CPSOG looking for 'easy wins' to increase efficiency'*, 12 May, via: http://www.pharmacytoday.co.nz/login.aspx?ReturnUrl=/news/2013/may-2013/15/cpsog-looking-for-%E2%80%98easy-wins%E2%80%99-to-increase-efficiency.aspx&returnid=18378
280) Moynihan, R (2011) ''New Zealand agency comes under pressure to pay more for drugs'', British Medical Journal, 342:d3933, Byron Bar, Australia.
281) The New Zealand Herald, (2013) *'Kevin Sheehy: Medicines debate need not threaten PHARMAC'*, 27 September, via: http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10836857
282) Ibidem.
283) New Zealand Rare Disease day (2013) '*Calls for an orphan drugs access policy to overcome Pharmac's systems failure with specialized mdecisines',* 28 February, via: http://www.rarediseaseday.org.nz/media/2013/new_zealand_rare_disease_day_press_release_28_february_2013 | Grocott R, Metcalfe S. 'Going against the flow: the impact of PHARMAC not funding COX-2 inhibitors for chronic arthritis.', *New Zealand Medical Journal* ,2005;118 (1223):U1690.
284) Wonder M, Milne R. 'Access to new medicines in New Zealand and Australia.' *New Zealand Medical Journal*. , 2011, Vol. 124, No. 1346, via: http://journal.nzma.org.nz/journal/124-1346/4966 | The New Zealand Herald, (2013) 'Kevin Sheehy: Medicines debate need not threaten PHARMAC', 27 September, via: http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10836857
285) Ibidem.
286) Ibidem.
287) Moodie, P., Metcalfe, S., Pynton, M. (2011) *'Do Pharmaceutical score cards give us the answers we seek?',* 2011, Vol 124, No 1346, via: http://journal.nzma.org.nz/journal/124-1346/4976/content.pdf
288) Privett, A. (2013) Interview
289) Wonder, R. (2013) *'Reimbursement of new medicines in Australia and New Zealand in 2012'*, January, via: http://reimbursement-newmedicines-ausnz2012.blogspot.nl/
290) Wonder M, Milne R. 'Access to new medicines in New Zealand and Australia.' *New Zealand Medical Journal*. , 2011, Vol. 124, No. 1346, via: http://journal.nzma.org.nz/journal/124-1346/4966 | The New Zealand Herald, (2013) *'Kevin Sheehy: Medicines debate need not threaten PHARMAC'*, 27 September, via: http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10836857
291) Ibidem.
292) Nefarma.nl (2013) *'Ontwikkeling van een medicijn',* via: http://www.nefarma.nl/feiten-en-cijfers/ontwikkeling-van-een-medicijn
293) Skipr Redactie (2009) *'Kroes: Marktgang merkloze medicijnente traag'*, Skipr, 8 July, via: http://www.skipr.nl/actueel/id1539-kroes-marktgang-merkloze-medicijnen-te-traag.html
294) Varol, N., Costa-Font, J., McGuire, A. (2011) *'Does Pharmaceutical Price Regulation Affect the Adoption of Generic Competition? Evidence from the OECD, 1999-2008'* , CESifo Working Paper, May 2011, via: http://www.cesifo-group.de/portal/pls/portal/docs/1/1200488.PDF
295) Horvath, B. (2013) Interview | European Commission (2013) *'Convergence Programme of Hungary 2013 – 2016'*, European Commission, via: http://ec.europa.eu/europe2020/pdf/nd/cp2013_hungary_en.pdf
296) HIS Health (2013) *'Hospital sector flourishes in Hungary but pharma market value edges down in 2012'*, 4 may, Same-Day Analysis. Via: http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065977782
297) Seenews.com (2013) *'Equilor Daily Newsletter Richter Liquidity in the Focus'*, 13 may, via: http://reports.seenews.com/reports/equilor-daily-newsletter-richter-liquidity-in-the-focus-may-13-2012-352479 | Weborvos.hu (2013) *'El akarják kerülni az esetleges gyógyszerhiányt'* , via: http://www.weborvos.hu/egeszsegpolitika/el_akarjak_kerulni_esetleges/204636/
298) Riesebosch, T. (2013) Interview
299) Zylinski, J. (2013) *'Hungarian Pharmacies see their Margins shrink'*
300) IHS Health (2013) *'Hospital sector flourishes in Hungary but pharma market value edges down in 2012'*, 4 may, Same-Day Analysis. Via: http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065977782
301) Healthaware.hu (2013) *'Newsletter June'*, via: http://www.healhtaware.hu/newsletter
302) MTI (2013) *'Gov't approves subsidized credit for pharmacy buyouts',* Politics.hu, 13 June, via: http://www.politics.hu/20130613/govt-approves-subsidized-credit-for-pharmacy-buyouts/
303) Gaál, P., Szigeti, S., Csere, M., Gaskins, M., Panteli, D. (2011) 'Hungary: Health system review', Health Systems in Tranistion, Vol. 13, Nr. 5
304) MTI (2013) *'Opposition charges new law would lead to nationalization of pharmacies', Politics.hu,* June 27, via: http://www.politics.hu/20130627/opposition-charges-new-law-would-lead-to-nationalization-of-pharmacies/ | MTI (2013) *'Bill allows state to buy stakes in pharmacies'*, Politics.hu, 21 June, via: http://www.politics.hu/20130621/bill-allows-state-to-buy-stakes-in-pharmacies/
305) Antares Consulting S.A., (2008) *'the Sanish model of the community pharmacy'*, Presentation Slides, via: http://ec.europa.eu/internal_market/services/docs/pharmacy/20081015_antares_en.pdf
306) IHS Health (2013) *'Hospital sector flourishes in Hungary but pharma market value edges down in 2012'*, 4 may, Same-Day Analysis. Via: http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065977782
307) Chemrar (2012) *'What does Hungary's Egis expect in 2012?'*, 18 May, via: http://www.chemrar.ru/eng/i-news/index.php?ELEMENT_ID=13875

308) Tamas, D. (2012) *'Interview with Tamas David, Deputy Director & Market Access Specialist, Association of Innovative Pharmaceutical Manufacturers (AIPM) Hungary',* 28 July, PharmaBoardroom.com, via: http://www.pharmaboardroom.com/article/interview-with-tam-s-d-vid-deputy-director-market-access-specialist-association-of-innovative-pharma
309) Ibidem.
310) Melck, B. (2013) Interview | IHS Health (2013) 'Hospital sector flourishes in Hungary but pharma market value edges down in 2012', 4 may, Same-Day Analysis. Via: http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065977782
311) Márton, V. (2013) 'Fogyasztói forradalom a gyógyszer- és egészségiparban is', *Világgazdaság Online*, 4 June, via: http://www.vg.hu/vallalatok/egeszsegugy/fogyasztoi-forradalom-a-gyogyszer-es-egeszsegiparban-is-405011
312) Ibidem.

9. Appendix

Figure 1: The Cost Utility Analysis used by PHARMAC (source: PHARMAC 2012)

Input / Output	Recommendation
Type of analysis	Cost-utility analysis (or cost-minimisation analysis if appropriate).
Perspective	PHARMAC's decision criteria.
Target population	New Zealand population most likely to receive treatment.
Comparator	Treatment that most prescribers would replace in New Zealand clinical practice, and the treatment prescribed to the largest number of patients (if this differs from the treatment most prescribers would replace).
Clinical outcomes	Well conducted randomised controlled trials (RCTs) and meta-analyses are the preferred data sources when estimating relative treatment effects. In the absence of valid RCTs, evidence from the highest available level of study design should be considered. All trials should be critically appraised and analysed using data from the intention-to-treat (ITT) population.
Economic modelling	Economic models should avoid unnecessary complexity; be transparent; and include all statistically significant clinical events. The methodology, limitations, and any possible bias associated with extrapolating data should be clearly described in the report and explored through sensitivity analysis. This includes extrapolating data from clinical trials to the longer term (or to final outcomes); generalising results from clinical trials to the New Zealand clinical setting by taking into account non-compliance; and undertaking indirect comparisons of trials.
HR-QOL	Health-related quality of life (HR-QoL) should be measured using quality-adjusted life years (QALYs) based on NZ EQ-5D Tariff 2. The Global Burden of Disease (GBD) disability weights and published utility values should be used to check for consistency.
Pharmaceutical Costs	Pharmaceutical costs should take into account any proposed rebate, and should be based on the dose used in the key clinical trials (unless there is evidence of efficacy for different doses in clinical practice). Dispensing fees and pharmacy mark-up should be included. The analysis should also include the lower cost of a future generic pharmaceutical.
Other Costs	Hospital, outpatient and direct patient costs should be included. Direct patient costs should be restricted to healthcare costs that the government partially subsidises, and should be based on the cost to government plus the additional cost to the patient. These costs include General Practitioner visits, pharmaceutical co-payments and continuing care. Costs to non-healthcare government departments and indirect patient costs should not be included in CUAs for PHARMAC.
Discount rate	Discount all costs and benefits in CUAs at a 3.5% discount rate. Include rates of 0% and 5% in the sensitivity analyses.
Results	The results of cost-utility analyses should be reported as incremental utility cost ratios (IUCRs), i.e. incremental QALY gains per unit net costs. IUCRs are expressed as incremental QALYs per $1 million of the total budget invested. The overall incremental QALYs per $1 million result should be reported as a point estimate as well as the range over which the cost per QALY is likely to vary. The cost per QALY result should be reported alongside the IUCR.
Sensitivity Analysis	Sensitivity analysis should include univariate (simple) analysis and multivariate analysis.

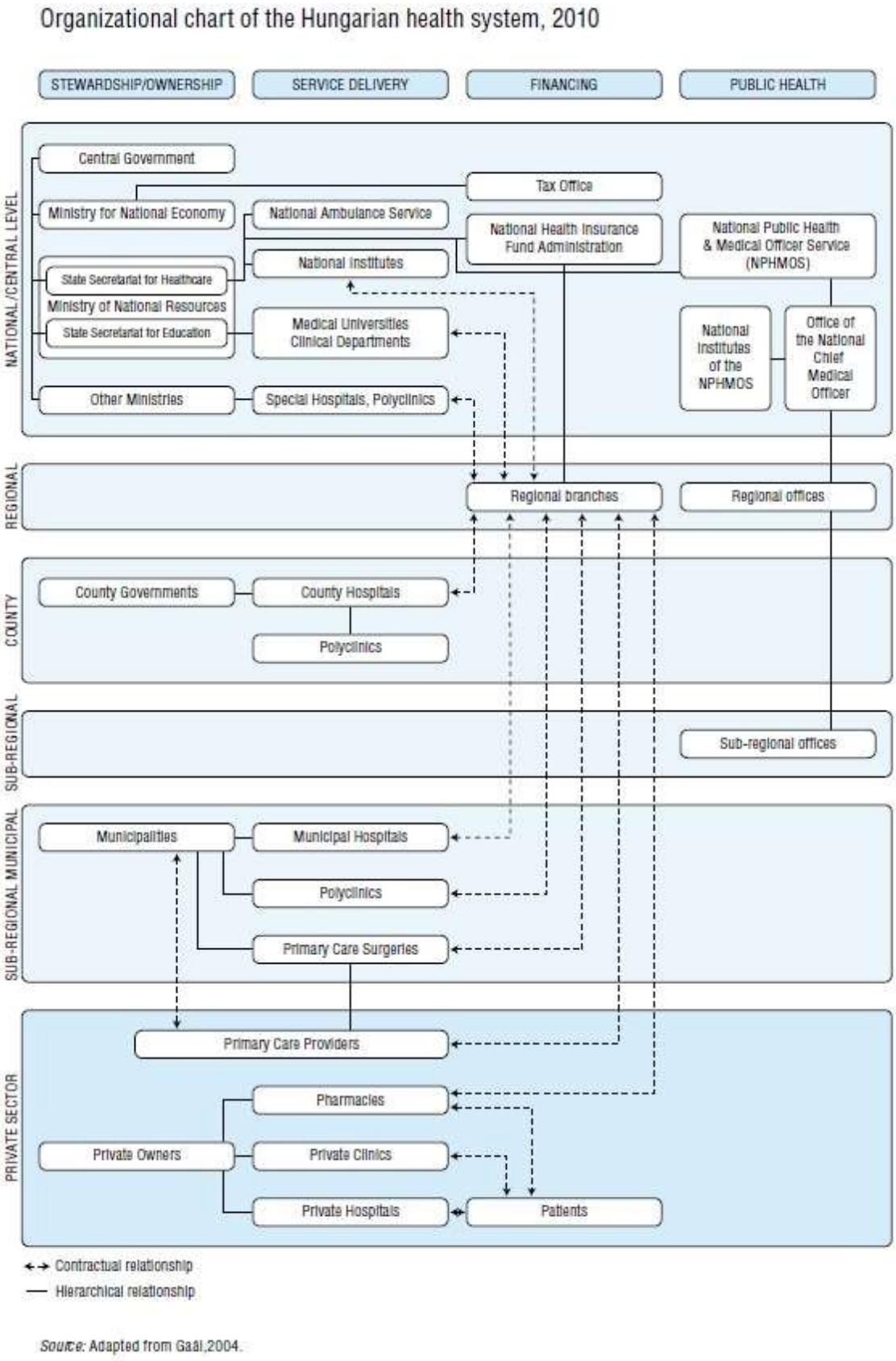
Figure 2a: The top 50 ATC5 groups with the highest reduction in daily therapeutical cost in 2012 compared to 2011. *(Source: Ministry of National Resources 2013)*

Ssz	ATC	Megnevezés	TB tám 2012	NTK 2011	NTK 2012	Változás Ft	Változás %
1	L02BB	Antiandrogenek	284 079 540	513.2	152.6	- 360.54	-70.3%
2	D10BA	Retinoidok az acne kezeléséhez	106 315 760	183.1	94.0	- 89.09	-48.7%
3	A02BC	Protonpumpa inhibitorok	4 246 757 347	47.9	27.4	- 20.49	-42.8%
4	R03DC	Leukotriene receptor antagonisták	1 948 789 779	384.4	231.1	- 153.27	-39.9%
5	C10AA	HMG CoA reductase inhibitorok	15 235 155 918	73.9	47.3	- 26.54	-35.9%
6	N05AH	Diazepinek, oxazepinek, thiazepinek és oxepinek	6 086 273 344	711.4	461.2	- 250.16	-35.2%
7	C07AG	Alfa- és beta-adrenerg receptorblockolók	1 104 161 256	50.6	33.2	- 17.41	-34.4%
8	L02BG	Aromatase inhibitorok	2 486 127 119	563.1	382.8	- 180.30	-32.0%
9	M05BB	Bisphosphonatok, kombinációk	778 925 697	105.2	74.5	- 30.67	-29.2%
10	C09BB	Angiotensin-konvertáló enzim (ACE) gátlók és Ca-csa.block.	3 436 348 632	23.2	16.8	- 6.40	-27.5%
11	B01AC	Thrombocyta-aggregatio gátlók, kivéve heparin	3 308 421 828	21.1	15.4	- 5.73	-27.1%
12	C09CA	Angiotensin II antagonisták önmagukban	2 746 099 674	27.6	20.7	- 6.94	-25.1%
13	C09AA	ACE-inhibitorok, önmagukban	5 580 173 711	18.1	13.6	- 4.50	-24.8%
14	C09DA	Angiotensin II antagonisták és diureticumok	2 742 206 496	25.8	19.5	- 6.31	-24.5%
15	B03XA	Egyéb vérszegénység elleni készítmények	1 740 363 519	2 480.9	1 897.3	- 583.60	-23.5%
16	C08CA	Dihydropiridin-származékok	3 066 418 475	15.8	12.1	- 3.70	-23.4%
17	S01EE	Prostaglandin-analógok	1 002 599 180	116.8	90.3	- 26.52	-22.7%
18	A04AA	Serotonin (5-HT3) antagonisták	689 520 694	1 313.2	1 021.8	- 291.44	-22.2%
19	D01BA	Gombásodás elleni systemás készítmények	79 011 874	56.7	44.2	- 12.50	-22.1%
20	N04BC	Dopamine agonisták	1 627 809 990	574.4	450.9	- 123.49	-21.5%
21	M01AC	Oxicamok	178 645 396	11.3	9.0	- 2.23	-19.8%
22	N07CA	Szédülés elleni készítmények	264 073 322	9.0	7.3	- 1.73	-19.2%
23	N05AE	Indole-származékok	342 790 303	612.9	498.6	- 114.36	-18.7%
24	C07AB	Szelektív beta-receptor blockolók önmagukban	4 356 242 256	29.7	24.2	- 5.53	-18.6%
25	C02AC	Imidazoline receptor agonisták	1 386 048 777	40.4	33.0	- 7.38	-18.3%
26	C01BC	Antiarrhythmiás szerek Ic csoport	793 394 641	59.1	48.3	- 10.75	-18.2%
27	G04CA	Alfa-adrenoreceptor antagonisták	578 470 215	23.1	19.0	- 4.14	-17.9%
28	R06AX	Egyéb systemás antihistaminok	324 181 477	17.8	14.6	- 3.18	-17.9%
29	N06DA	Anticholinesterase-ok	274 060 393	211.1	174.1	- 37.00	-17.5%
30	R06AE	Piperazine-származékok	194 144 278	9.3	7.6	- 1.62	-17.5%
31	J01MA	Fluoroquinolonok	537 921 240	96.0	79.7	- 16.31	-17.0%
32	C09BA	ACE-inhibitorok és diureticumok	5 390 068 202	20.2	17.0	- 3.12	-15.5%
33	B03AD	Vas és folsav kombinációi	158 187 573	19.3	16.4	- 2.86	-14.8%
34	N06AX	Egyéb antidepressansok	5 025 211 490	178.9	152.8	- 26.06	-14.6%
35	N05AL	Benzamidok	1 183 418 518	214.7	187.1	- 27.66	-12.9%
36	C03BA	Sulfonamidok önmagukban	752 190 883	21.6	18.9	- 2.68	-12.4%
37	M05BA	Bisphosphonatok	5 588 587 660	414.4	364.7	- 49.77	-12.0%
38	N02AX	Egyéb opioidok	455 644 292	47.0	42.1	- 4.94	-10.5%
39	A10BF	Alfa glucosidase inhibitorok	146 560 672	62.3	56.0	- 6.32	-10.1%
40	N06AG	MAO-A inhibitorok	144 983 065	100.7	90.6	- 10.05	-10.0%
41	S01AX	Egyéb fertőzésellenes szerek	68 598 377	16.3	14.7	- 1.62	-9.9%
42	S01ED	Beta-receptor blockoló szerek	2 378 201 001	95.1	86.3	- 8.87	-9.3%
43	N03AX	Egyéb antiepilepticumok	5 915 484 652	574.3	520.8	- 53.50	-9.3%
44	N06AB	Szelektív serotonin reuptake-gátlók	3 480 245 868	63.1	57.5	- 5.58	-8.8%
45	N02AB	Phenylpiperidine-származékok	1 289 414 963	575.1	524.3	- 50.80	-8.8%
46	J01FF	Lincosamidok	128 776 152	76.9	70.2	- 6.68	-8.7%
47	C01EB	Egyéb szívgyógyszerek	1 431 160 191	18.8	17.2	- 1.61	-8.6%
48	M03BX	Egyéb központi hatású szerek	473 879 580	14.4	13.2	- 1.17	-8.1%
49	C02CA	Alfa-adrenerg receptorblockolók	1 866 723 714	40.9	37.7	- 3.26	-8.0%
50	A02BA	H2-receptor antagonisták	1 505 131 227	21.1	19.4	- 1.62	-7.7%

Figure 2b: **The top 40 products or active ingredient with the highest reimbursement in 2012 and the changes compared to 2011.** *(Source: Ministry of National Resources 2013)*

Ssz	ATC	Megnevezés	2012 TB	MS	Változás (Ft)	Változás (%)
1	C10AA05	(atorvastatin piac)	7 713 207 214	2.7%	- 6 142 796 954	-44.3%
2	L01XE01	GLIVEC	6 618 063 427	2.3%	- 12 884 212	-0.2%
3	R03AK07	(formoterol kombi piac)	6 275 512 072	2.2%	96 561 693	1.6%
4	B01AB05	CLEXANE	6 101 330 057	2.1%	841 070 806	16.0%
5	N05AX08	(risperidon piac)	5 794 416 827	2.0%	- 478 450 599	-7.6%
6	R03BB04	SPIRIVA	5 582 145 450	2.0%	- 169 294 445	-2.9%
7	C10AA07	(rosuvastatin piac)	5 453 280 849	1.9%	- 296 913 574	-5.2%
8	R03AK06	(salmeterol kombi piac)	4 470 547 759	1.6%	- 494 368 345	-10.0%
9	A10AE04	LANTUS	3 967 562 598	1.4%	- 217 658 948	-5.2%
10	A10AB01	(human insulin piac)	3 808 561 807	1.3%	250 712 130	7.0%
11	C09BA04	(perindopril kombi piac)	3 641 450 936	1.3%	- 465 153 057	-11.3%
12	L03AB07	(interferon beta-1a piac)	3 626 169 795	1.3%	382 341 858	11.8%
13	L03AA13	NEULASTA	3 225 726 288	1.1%	- 2 281 085 488	-41.4%
14	L01XE04	SUTENT	3 159 904 945	1.1%	132 328 143	4.4%
15	N05AH03	(olanzapin piac)	3 103 091 563	1.1%	- 2 186 488 665	-41.3%
16	A10AE05	LEVEMIR	3 016 621 097	1.1%	154 316 470	5.4%
17	L02AE02	(leuprorelin piac)	2 930 108 017	1.0%	- 240 317 064	-7.6%
18	M05BA08	(zoledronsav piac)	2 698 372 374	0.9%	- 327 328 118	-10.8%
19	C08CA01	(amlodipin piac)	2 697 915 880	0.9%	- 1 049 088 876	-28.0%
20	N05AH04	(quetiapin piac)	2 566 172 146	0.9%	- 687 130 266	-21.1%
21	C01DA02	(gliceril-trinitrát piac)	2 520 771 812	0.9%	- 431 764 862	-14.6%
22	A10AB05	NOVORAPID	2 480 387 086	0.9%	305 234 381	14.0%
23	L03AA02	(filgrastim piac)	2 447 516 283	0.9%	222 775 422	10.0%
24	H01AC01	(szomatropin piac)	2 416 686 357	0.8%	50 238 813	2.1%
25	C09BB04	(perindopril+amlodipine piac)	2 310 239 885	0.8%	- 279 335 576	-10.8%
26	A10AC01	(human insulin piac)	2 195 957 555	0.8%	169 687 012	8.4%
27	S01ED51	(timolol kombi piac)	2 195 525 135	0.8%	- 316 154 158	-12.6%
28	N05AX12	ABILIFY	2 139 696 697	0.8%	114 848 859	5.7%
29	N03AX16	LYRICA	2 116 204 338	0.7%	272 698 444	14.8%
30	A07EC02	(mesalazin piac)	2 107 699 339	0.7%	94 330 778	4.7%
31	C09AA05	(ramipril piac)	2 094 173 915	0.7%	- 1 076 408 718	-33.9%
32	C09AA04	(perindopril piac)	2 087 256 566	0.7%	- 1 145 011 277	-35.4%
33	C10BA02	INEGY	1 925 866 349	0.7%	- 333 710 901	-14.8%
34	R03DC03	(montelukast piac)	1 904 993 357	0.7%	- 945 625 606	-33.2%
35	B01AB06	(nadroparin piac)	1 900 539 070	0.7%	163 979 013	9.4%
36	N05BA12	(alprazolam piac)	1 826 069 839	0.6%	- 58 574 334	-3.1%
37	N06AX21	CYMBALTA	1 821 297 873	0.6%	76 435 482	4.4%
38	C07AB12	(nebivolol piac)	1 784 049 476	0.6%	- 480 766 323	-21.2%
39	L04AA06	(mycophenolsav piac)	1 736 377 614	0.6%	203 324 304	13.3%
40	A02BC02	(pantoprazol piac)	1 726 053 357	0.6%	- 1 875 833 748	-52.1%
		Összes többi ATC 7 csoport	156 845 026 697	55.0%	- 18 203 142 449	-10.4%

Figure 3: Organizational Chart of the Hungarian Health Care System (Source: Gaal, P. 2011)



Source: Adapted from Gaál,2004.

Figure 4a: Dutch Paradigm (pile up sheets)

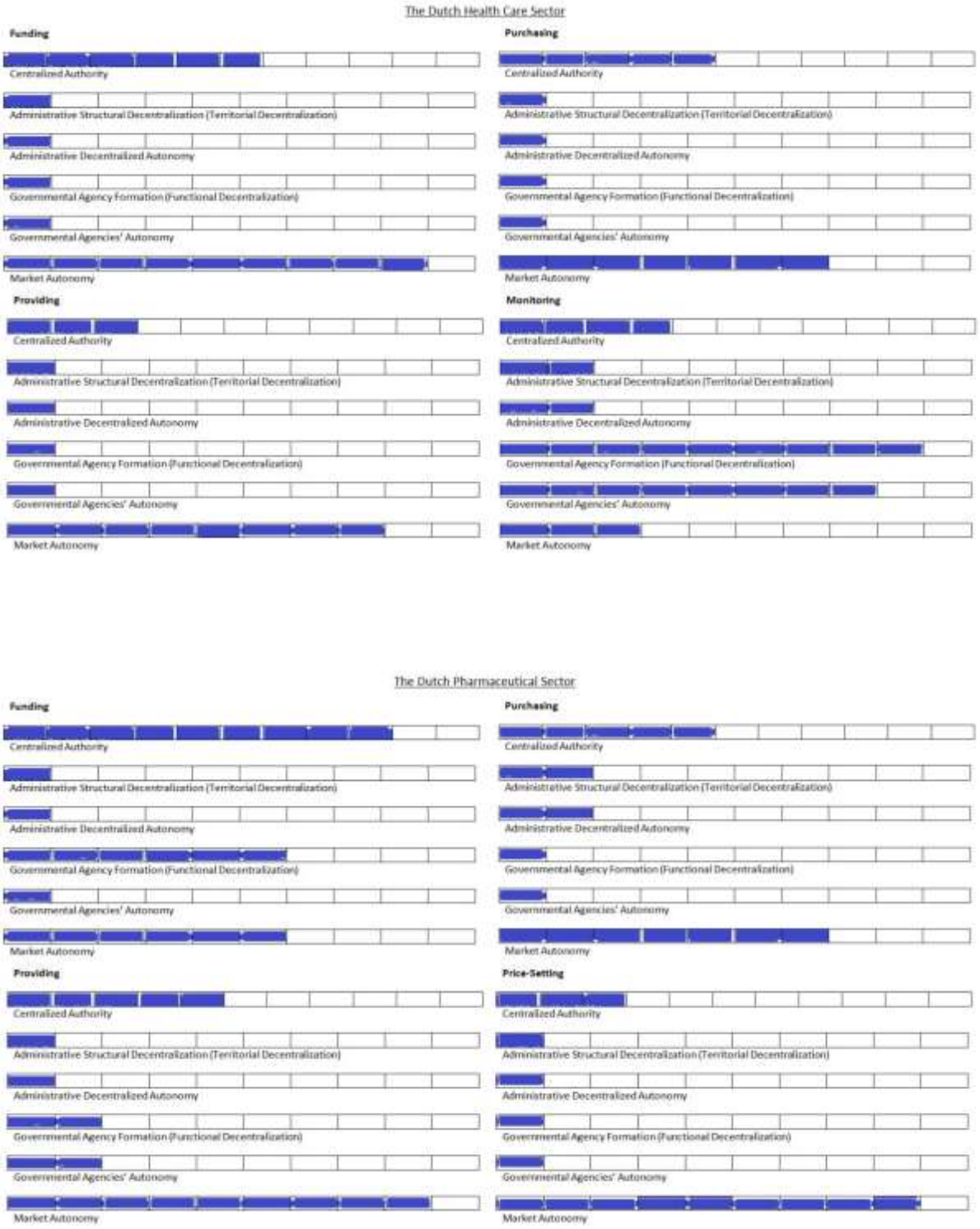


Figure 4b: Hungarian Paradigm (pile up sheets)

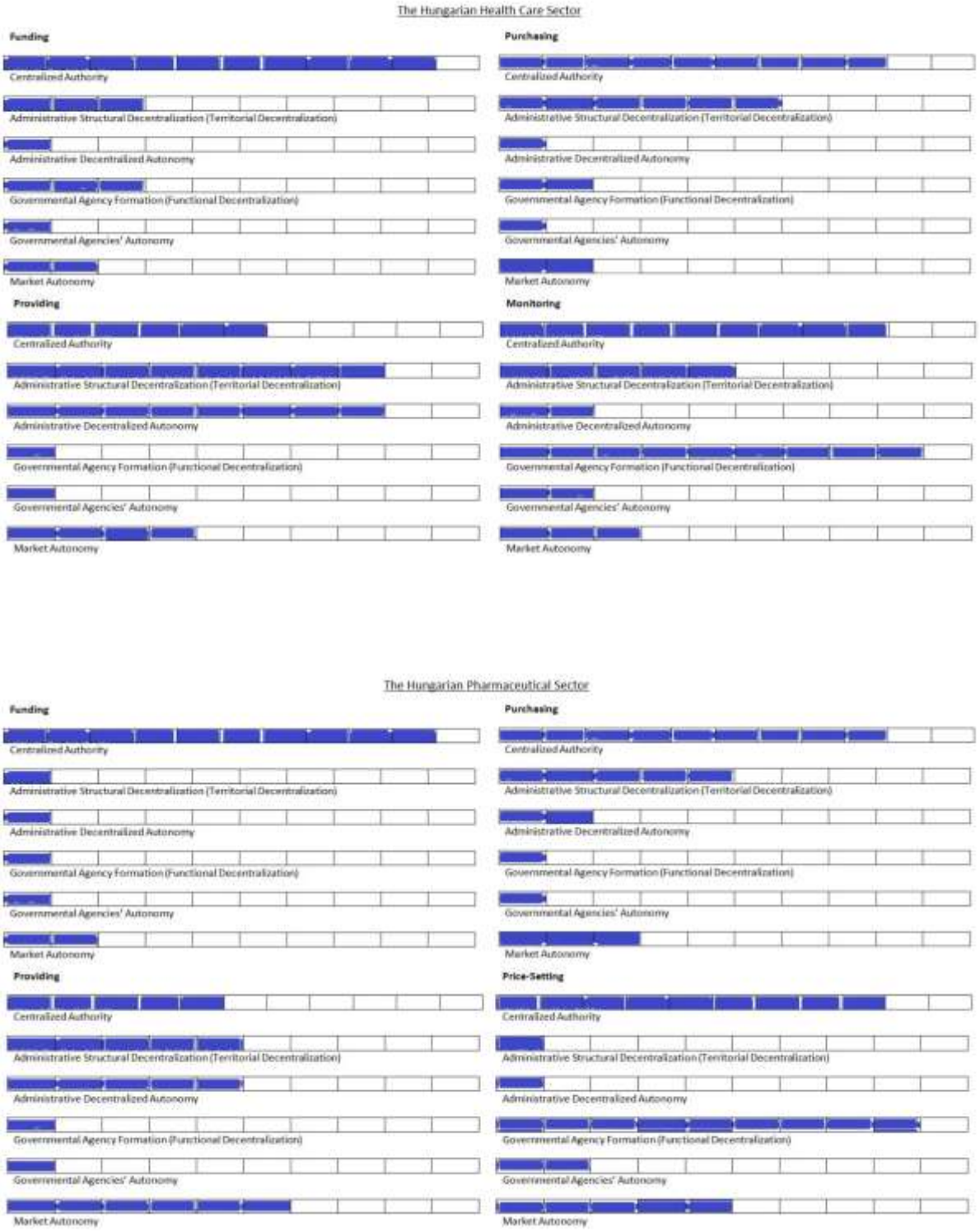


Figure 4c: New Zealand Paradigm (pile up sheets)

New Zealand's Pharmaceutical Sector