Decision making on the inclusion of new provisions in the benefit package – a comparative study between the Netherlands and the Czech Republic

With a focus on the role of value for money considerations in pharmaceutical reimbursement decision making

by
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MINISTERSTVO ZDRAVOTNICTVÍ
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With a focus on the role of value for money considerations in pharmaceutical reimbursement decision making

A thesis submitted to the School of Management and Governance from the University of Twente in Enschede, the Netherlands, in partial fulfillment of the requirements for the degree of

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DEDICATION

Gewidmet meiner Mutti, ohne der ich im Leben nicht dort stehen würde, wo ich heute stehe.

Danke für alles!

Dedicated to my mother, without whom I would not where I am today.

Thanks for everything!

CONTENTS

PREFACE

The start of this paper can be brought back to the year 2009, when I decided to study abroad in combination with my final assignment. I chose Prague out of its good reputation, the fact of studying at one of the oldest universities in Europe in continuous operation, and by the challenge of learning a Slavic language. My topic was decided upon in mutual agreement between me, my first supervisor Prof. Dr. Hindrik Vondeling from the University of Twente in the Netherlands and my second supervisor Mgr. Petr Panýr from the Ministry of Health in the Czech Republic.

My personal presence in Prague was made possible by the ERASMUS-program of the European Union. I stayed one semester abroad in Prague during February till July 2010. I was accommodated in a student housing provided by the Charles University in Prague. Furthermore provided me my second supervisor Mgr. Petr Panýr with a working place in front of his own office to which I had unlimited access during the week. Concurrently to the final assignment did I follow three courses from the Charles University (in Health Economics, European Social Policy and Czech for Beginners).

This assignment is meant to fulfill a threefold objective: firstly, it is meant to inform the policy makers in the Czech Ministry of Health, Department of Health Care and Health Insurance, about the reimbursement systems in the Netherlands and its specific decision making on pharmaceuticals, to compare this with the situation in the Czech Republic and to finally draw recommendations for the Czech situation from the Dutch. Secondly, it can be looked also the other way round and considered whether the Dutch situation would be able to profit from characteristics of the Czech situation. A possible audience could be found in Dutch policy makers at the national government or at the national HTA-body. Thirdly, this assignment is written in the partial fulfillment of the requirements for the degree of "Bachelor of Science" in the Curriculum of Health Sciences from the University of Twente in Enschede, the Netherlands. The last requirement will be the successful completion of the colloquium planned on July 27th, 2010 at the University of Twente in Enschede.

This paper knows no conflict of interest. The funding and resources were provided by the Erasmus scholarship and the Ministry of Health in the Czech Republic.

Frank Gerd Sandmann

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First of all I want to thank my first supervisor Prof. dr. Hindrik Vondeling. His helpful comments and the overall guidance enabled me to write this thesis successfully on distance in Prague. Although we met during the whole time of writing only two times face-to-face, I had always the feeling of being well guided. We communicated at least every couple of weeks by email. The first meeting provided a good orientation on the Dutch situation, which seemed to be overwhelmingly described. He even offered to arrange a supervisor in Prague in the unlikely event that problems arise with the at that time unknown situation at the Ministry of Health. Fortunately, I did not need to come back on that offer because I was more than friendly welcomed at the Ministry. The second meeting was valuable in getting feedback on a draft version of my work and pointing at key factors for improvement.

Secondly, I want to thank the Deputy Minister for Health Care at the Ministry of Health in the Czech Republic with authority to direct the section for Health Care Insurance, MUDr. Markéta Hellerová, and especially her deputy Mgr. Petr Panýr, secretary of these sections. Mr. Panýr acted as my external supervisor from the Ministry of Health and he was my first contact for questions and practical issues. He arranged the two interviews with officials from the Ministry of Health and the State Institute of Drug Control, who were told to provide me any information necessary. I am very satisfied with his overall guidance and help by collecting the information for the Czech Republic. At the same time was he giving me the freedom to work independently and self-paced on my topic.

Furthermore I want to thank my interviewees from the Czech Republic, Mgr. Daniela Rrahmaniová, PharmDr. Marcela Heislerová, Ph.D. and MUDr. Mgr. Jindřich Kotrba. The interviews were valuable in orientating throughout the Czech situation. I also have to thank Mgr. Henrieta Maďarová, MS., who helped clarify the legislative situation among the criteria of reimbursement for the basic benefit package in the Czech Republic, although we never met personally. And special thanks go to the three female assistants from the Department of Health Care, Mrs. Magdalena Audová, Mrs. Anna Mottlová Malinová and Mrs. Andrea Panenková for solving practical problems.

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EXECUTIVE SUMMARY

Introduction

Europe's health care systems are characterized by the attempt of providing comprehensive care of high quality and available to all citizens. These three objectives are impossible to realize at the same time, given the scarcity of resources. One of them must be limited for the benefit of the others. Under this condition, the restriction seems to be the most promising solution. For an equal and just restriction is the use of a well tested and broadly accepted method necessary. This is fulfilled by health technology assessment (HTA). Without HTA is the uptake of new technologies at risk of being highly influenced by social, financial, professional and institutional factors instead of cost-effectiveness data. The Netherlands and Czech Republic are chosen for analysis as both are part of the European Union. The Netherlands is judged in international comparison to apply successful approaches of handling the threats in health care and gained experience in limiting the coverage of the benefit system during the last decades. The Czech Republic is an example of a new member state that joined the EU from a previous communist system who is adopting internationally tested means for cost containment.

Objectives

This assignment is meant to fulfill a threefold objective: firstly, it shall inform the policy makers in the Ministry of Health of the Czech Republic about the reimbursement system in the Netherlands and its specific decision making on pharmaceuticals, compare this with the situation in the Czech Republic and draw from this recommendations for the Czech situation. Secondly, it can also be considered whether the Dutch situation can profit from the Czech Republic. Thirdly, this assignment is written in the partial fulfillment of the requirements for the degree of "Bachelor of Science" in the Curriculum of Health Sciences from the University of Twente in Enschede, the Netherlands.

Methods

To answer above mentioned research questions was mainly qualitative desk research carried out during February till July 2010 in Prague, the Czech Republic. In addition were two interviews held with three officials from the Ministry of Health in the Czech Republic and the national assessment body called SÚKL (State Institute for Drug Control). The assignment is descriptive and explanatory in its scope. This paper has concentrated itself to study the gray literature, next to scientific articles and legal documents. The used literature was found by using search engines like Google, Scopus and

PubMed, next to the references of related articles and the hints of the supervisors. The searched terms were 'benefit package', 'uptake', 'inclusion', 'exclusion', 'provisions', 'criteria', 'cost effectiveness', 'threshold', 'ceiling', 'value', 'ratio', 'willingness to pay' and similar in interchanging order and together with 'Czech Republic' and/or '[the] Netherlands'.

Results

Both countries register new drugs by the criteria quality, efficacy and safety. The assessment of new drugs relies in the Netherlands on HTA, in the Czech Republic not. The relevant assessment body SÚKL is regulating the registration, maximum prices plus reimbursement rates, and takes the final decision for uptake. In the Netherlands is this divided upon the Board for the Evaluation of Drugs, the advisory assessment body CVZ (Health Care Insurance Board) and the Minister of Health. The criteria for inclusion show a high similarity in necessity, effectiveness and efficiency, but differ for affordability and safety. Societal questions are less apparent in the Czech system as in the Netherlands. Value for money considerations play an equal role in both countries. The Dutch recently stated an unbinding cost-effectiveness threshold from EUR 10,000 to EUR 80,000, while the Czech Republic considers a high cap in the amount of dialysis or kidney transplantation. Conditional reimbursement is applied in both countries as a method to ensure a wide package at the partial costs of the patients. Guidelines are predominating in the Dutch case while in the Czech case heterogeneous views on effectiveness and necessity prevail. In the Czech Republic plays political instability a major role for decision making, which is not the case for the Netherlands. Research shows the impossibility to adopt one universal method for prioritization. It is a learning process of incremental progress. Small modifications are made, as the metaphor suggests of a marathon versus a sprint.

Recommendations

The majority of six recommendations are applicable to the Czech Republic. They are related to the public support of prioritization, the promotion of transparency, the powerful position of SÚKL, the explicit naming of positively formulated criteria for the whole benefit package, the establishment of an independent HTA institution, the application of guidelines to support decentralized rationing, and the current situation regarding the partial reimbursement. The last two recommendations aim at policy makers in the Netherlands, as the temporary admission of innovative out-patient drugs should be considered as well as the use of co-payments to cross-subsidize more expensive new technologies.

This paper was not concerned with in-patient medicines, does not decide explicitly between cure and care, and has not have interviews with representatives from the Netherlands.

SAMENVATTING

Aanleiding

Europese zorgstelsel zijn gekenmerkt door het doel om een uitgebreid pakket van hoge kwaliteit voor alle burgers beschikbaar te stellen. Deze drie doelstellingen zijn niet op hetzelfde moment te realiseren, gezien de schaarste van middelen. Een van hen moet worden beperkt ten voordele van de anderen. Onder deze voorwaarde lijkt de afbakening van het pakket het meest veelbelovend. Voor een rechtvaardige afbakening is een breed geaccepteerde methode noodzakelijk. Dit is vervuld door health technology assessment (HTA). Zonder HTA dreigt de opname van nieuwe interventies te sterk worden beïnvloed door sociale, financiële, professionele en institutionele factoren in plaats van kosteneffectiviteit. Nederland en Tsjechië zijn gekozen omdat ze beide deel uitmaken van de Europese Unie. Nederland is in internationale vergelijking succesvol met het omgaan van problemen in de zorg. Zij hebben ervaring opgedaan in het beperken van het openbaar gefinancierde pakket gedurende de laatste decennia. Tsjechië is een voorbeeld van een nieuwe lidstaat van de EU uit een eerder communistisch systeem dat slechts internationaal geproefde methoden van kostenbeheersing toepast.

Doelen

Deze opdracht voorziet aan een drievoudig doel: ten eerste zullen de beleidsmakers worden geïnformeerd bij het Ministerie van Volksgezondheid in de Tsjechische Republiek over het Nederlandse vergoedingssysteem en de specifieke besluitvorming inzake medicijnen; dit wordt vergeleken met de situatie in Tsjechië en uiteindelijk aanbevelingen getrokken voor Tsjechië. Ten tweede wordt ook nagegaan of Nederland kan profiteren van de situatie in Tsjechië. Ten derde is deze scriptie geschreven in het kader van de studie Gezondheidswetenschappen aan de Universiteit Twente in Enschede om aan de vereisten te voldoen voor de academische graad van "Bachelor of Science".

Methoden

Voor het beantwoorden van de onderzoeksvragen is voornamelijk kwalitatief deskresearch uitgevoerd in de maanden februari t/m juli 2010 in Praag. Daarnaast werden twee interviews gevoerd met drie ambtenaren van het Ministerie van Volksgezondheid en het nationale instituut ter evaluatie van drugs (SÚKL). De opdracht is beschrijvend en verklarend. Naast grijze literatuur werden wetenschappelijke artikelen en juridische documenten bestudeerd. De literatuur werd gevonden via Google, Scopus en PubMed. Daarnaast waren de referenties in thematisch vergelijkbare artikelen en hints van mijn

begeleiders nuttig. De gezochte termen waren 'benefit package', 'uptake', 'inclusion', 'exclusion', 'provisions', 'criteria', 'cost effectiveness', 'threshold', 'ceiling', 'value', 'ratio', 'willingness to pay', 'Czech Republic', '[the] Netherlands' en vergelijkbare begrippen in onderlinge uitwisseling.

Resultaten

Beide landen registreren nieuwe geneesmiddelen op kwaliteit, werkzaamheid en veiligheid. De beoordeling van nieuwe medicijnen berust in Nederland op HTA, in Tsjechië niet. SÚKL reguleert de registratie, de maximum prijzen plus vergoedingstarieven, en neemt de beslissing voor opname. In Nederland wordt dit verdeeld over het College ter Beoordeling van Geneesmiddelen, het adviserende College voor Zorgverzekeringen, en de Minister van Volksgezondheid. De criteria voor opname komen sterk overeen voor noodzakelijkheid, effectiviteit en kosteneffectiviteit, maar verschillen voor de uitvoerbaarheid en veiligheid. Maatschappelijke overwegingen zijn minder zichtbaar in Tsjechië als in Nederland. Value for money overwegingen spelen een gelijkwaardige rol in beide landen. Nederland heeft onlangs een indicatieve bandbreedte verklaard van EUR 10.000 tot EUR 80.000, terwijl Tsjechië een ‘high cap’ overweegt van de kosten voor dialyse of niertransplantatie. Een voorwaardelijke vergoeding wordt toegepast in beide landen als een methode dat de breedte van het pakket garandeert tegen gedeelte kosten met de patiënt. Richtlijnen zijn overwegend in Nederland ter plaatse, terwijl in Tsjechië de heterogene opvattingen over effectiviteit en noodzaak prevaleren. In Tsjechië speelt politieke instabiliteit een belangrijke rol voor de besluitvorming, hetgeen niet het geval is voor Nederland. Onderzoek toont dat het onmogelijk is om een universele methode voor rantsoening op te stellen. Het is een leerproces van geleidelijke vooruitgang. Kleine wijzingen moeten volgen, zoals de metafoor suggereert van een marathon versus een sprint.

Aanbevelingen

Het merendeel van zes aanbevelingen is van toepassing op Tsjechië. Ze hebben betrekking op het maatschappelijk draagvlak voor afbakening, het bevorderen van transparantie, de controversiële positie van SÚKL, de expliciete benoeming van positieve criteria voor het hele pakket, de oprichting van een onafhankelijke HTA instelling, de toepassing van richtlijnen ter ondersteuning van rantsoenering, en de huidige situatie van gedeeltelijke vergoeding. De laatste twee aanbevelingen zijn gericht op beleidsmakers in Nederland, namelijk over de tijdelijke toelating van veelbelovende extramurale medicijnen, en het gebruik van bijbetalingen ter subsidiering van nieuwe technologieën.

Deze opdracht laat intramurale geneesmiddelen buiten beschouwing, maakt geen expliciet verschil tussen de cure en care, en heeft geen gesprekken gevoerd met ambtenaren uit Nederland.

LIST OF ABBREVIATIONS

Abbreviation	English name	Dutch name	Czech name
ACP	Advisory Package Commission	Adviescommissie Pakket	
CBG	Board for the Evaluation of Drugs	College ter Beoordeling van Geneesmiddelen	
CFH	Committee on Pharmaceutical Care	Commissie Farmaceutische Hulp	
CVZ	Health Care Insurance Board	College voor Zorgverzekeringen	
CZK	Czech crown	Tsjechische kroon	Koruna česká
DALY	Disability-adjusted life years		
EU	European Union	Europese Unie	Evropská unie
EUR	Euro (currency)		
GBP	Great Britain pound sterling	Pond sterling	Libra šterlinků
GDP	Gross Domestic Product	Bruto binnenlands product	Hrubý domácí produkt
GNI	Gross National Income	Bruto nationaal inkomen	Hrubý národní produkt
GVS	Pharmaceutical Reimbursement Scheme	Geneesmiddelen Vergoedings Systeem	
HTA	Health Technology Assessment		
MTA	Medical Technology Assessment		
MZCR	Ministry of Health of the Czech Republic		Ministerstvo zdravotnictví České republiky
NICE	National Institute for Health and Clinical Excellence (GB)		
NZa	Dutch Health Care Authority	Nederlandse zorgautoriteit	
OECD	Organisation for Economic Co-operation and Development		
QALY	Quality-adjusted life year	Voor kwaliteit gecorrigeerde levensjaren	Rok získaného života v plné (standardní) kvalitě
RVZ	Council for Public Health and	Raad voor de	

	Health Care	Volksgezondheid en Zorg	
SÚKL	State Institute for Drug Control		Státní ústav pro kontrolu léčiv
SZÚ	National Institute of Public Health		Státní zdravotní ústav
USD	United States dollar	Amerikaanse dollar	Americký dolar
VWS	Ministry of Health, Welfare and Sport	Ministerie van Volksgezond-heid, Welzijn en Sport	
VZP	General Health Insurance Fund		Všeobecná zdravotní pojišťovna
WHO	World Health Organization	Wereldgezondheids-organisatie	Světová zdravotnická organizace
ZFR	Health Insurance Funds Council	Ziekenfondsraad	
Zvw	Health Insurance Act	Zorgverzekeringswet	

1 INTRODUCTION

Europe's universal health care systems are characterized by the attempt of providing comprehensive health care of high quality and available to all citizens. Nevertheless, the three objectives of equal access, a broad benefit package and a good quality are impossible to realize at the same time, given the scarcity of resources. One of the three objectives must be limited for the benefit of the others (1). Under this condition, the restriction of the benefit package seems to be the most promising solution, when the alternative options are to accept a lower quality or a lack of equality in health care (2).

By controlling the benefit package is it possible to influence the costs of the health care system. Nevertheless, changing benefit coverage also affects the health of a population. If a country is selecting strictly the content of the package, costs are supposed to decrease while concurrently less health should be available for the population. To avoid this phenomenon must policy makers select the content of the package for the appropriate criteria (3).

Subsequently, an appropriate procedure must be found for using commonly accepted criteria in the real decision making of everyday practice. The best described methodology can be found for pharmaceutical products. They are the most prominent provision in the benefit packages and further the most rapidly changing and developing one (4). The detailed procedure for drugs can be brought back to the rapidly increasing growth of the pharmaceutical spending (although the pharmaceutical spending accounts still for less than one-fifth of most countries total health expenditure) (5) which is caused mainly by a high utilization and specific price and reimbursement policies. But also the fact that the pharmaceutical budget can mostly be easily identified makes it very attractive for financial constraints (6).

International regulations for limiting the basic benefit package are rarely found. The European Union (EU) is loosely influencing the pharmaceutical pricing and reimbursement since 1989 by the Council Directive 89/105/EEC, also known as the Transparency Directive (7). Despite specifying certain methods for ensuring the transparency of decisions is this Directive stating that any direct or indirect mechanism of profit control for manufacturers need to be explicitly declared, as well as the reasons for the uptake or denial of drugs on a national list for reimbursement (8). More explicitly described requirements about the specific compilation and content of the health care systems are not found, due to the remaining national responsibility of the organization of the health care system (9).

To get a deeper insight into the decision making regarding the general benefit package, its criteria and the procedure of uptake from new pharmaceuticals, an analysis at the national level is required. Therefore, two European countries will be compared in this paper: the Netherlands and the Czech Republic. The Netherlands is a country that has been one of the six founding member-states of the European Union in 1957, while the Czech Republic belongs to the countries of the EU enlargement in 2004. The Netherlands is judged in international comparison to apply successful approaches of handling the threats in health care (10) and has gained experience in limiting the coverage of the benefit system during the last decades. The Czech Republic is an example of a new member state that joined the EU from a previous communist system. It has adopted a variety of means for cost containment and strives for ensuring more transparency. Given these different historical developments in both societies, leading to different evolved decision making systems in the process of pricing and reimbursement, it seems interesting to compare these two diverse states of the EU.

Therefore, the main research question is formulated as follows:

How are decisions made on the inclusion/ uptake of new provisions (e.g. new pharmaceuticals) in the benefit package (so publicly financed health care) in the Netherlands and the Czech Republic?

This paper searches for general criteria in reimbursement decision making for the basic benefit package that can be applied to all kind of new medical technologies (therapy, diagnostic services, and pharmaceuticals). Moreover, the focus will lay on out-patient medicines, which have the best developed methodology of all provisions.

But the attention of this assignment will go beyond a mere description of the uptake process from new pharmaceuticals in these two countries. Special emphasize shall be given to the considerations of value for money in the decision making process. Economical data can support and steer priority setting through the demonstration of greater efficiency in new provisions. A practical example is found in the development of fictional ceiling ratios for the maximum willingness to pay for a quality-adjusted life year (QALY) of a society by the Ministry of Health. Whether or not these

information are taken into consideration, needs to be investigated. And if this is found to be true, the question rises how these considerations influence the decision making.

This leads to the sub-question of the paper:

What role (if any) do considerations of value for money play in the decision making process?

The further structure of the paper is as follows. Hereafter draws the introductory chapter some theoretical considerations regarding decision making of uptake from new provisions, followed by the historical developments in that field for the two selected countries. After that outlines the second chapter the used methodology. The third chapter will present the current state of decision making for both countries. Finally, the forth chapter will discuss the findings and compare the two decision making systems in the background of the earlier presented theory. Moreover, this chapter will conclude with recommendations for the policy makers in the Czech Republic.

THEORETICAL CONSIDERATIONS

Decision making about the coverage of the basic benefit package can be an unpopular task. Restrictions to the benefit package are conflicting with the principle of free choice in medical treatment and financial sustainability (11).

At the same time is the guarantee of equal access, a generous benefit package and a high quality impossible to ensure simultaneously. This is because of the scarcity of resources. Weale (1998) calls this an inconsistent triad. This means that only two of the three objectives can be fulfilled at the same time. One of the three objectives must therefore be sacrificed for the benefit of the others. Given this condition, the three evolving options are to accept (a) a low quality of care, (b) unequal access to care or (c) a less broad benefit package. Given these alternative options seems the third option to be the most appropriate (12).

The decision for a less broad benefit package directly influences the procedure of uptake from new provisions. For an equal and just restriction is the use of a well tested and broadly accepted method necessary. This is fulfilled by the use of health technology assessment (hereinafter called HTA).

HTA can be defined as a method that "examines systematically the consequences of the application of health technologies […] to support decision making in policy and practice" (13). Its ability in supporting a more efficient, effective and high quality health care is widely acknowledged in Europe (14). It has been used in many European countries since the late 1970s for supporting coverage and pricing decisions (15). Even European countries without a formal HTA system are adopting its means and set up informal programs to support decision making (14).

The whole HTA process can be divided into six steps: identification of the technology, health or health problems; the prioritization of possible assessments; the assessment; the dissemination of the findings and conclusions of assessments; the implementation of findings and conclusions in policy and practice; and the impact assessment of resulting change (16). The paper at hand shall mostly focus on the prioritization and the assessment process. Nevertheless, the dissemination of findings and the impact assessment are also affected. The authors of these six steps mention already that a strict separation of them is difficult to manage. Instead, when discussing one step are the others likewise involved (17).

One of the main objectives of HTA can be described as providing information for the process of coverage decision making (18). In that case is the assessment step in practice usually further subdivided into two phases: the assessment and appraisal phase. In the first phase is an assessment of the drug and its associated costs and benefits done, whereas in the second phase the focus lies on an appraisal of the found evidence (meaning interpretation and consideration) (15).

The use of HTA in health care decision making requires two conditions: firstly, the potential users (government, physicians, insurers, etc.) need to have a real interest in the outcome of these analyses. If the interest is only marginal (or worse hypocritical), than the use will be low and the correlated impact very small. At the end, the acceptance of HTA is one of the key factors for deciding whether or not decisions are put into practice (19). Because when professionals or patients do not accept the alternative of a cost-effectiveness analysis, rising costs could result by the inappropriate use of higher-cost substitutes (20). Secondly, the systematic application of economic evaluations requires a structure of priority setting, research facilities and procedures defining the structure and distribution of results (21).

Without the use of evidence-based methods like HTA and economic evaluations is the uptake of new technologies at risk of being highly influenced by social, financial, professional and institutional factors (22). The influence from the lobby of interest groups and the media can be much stronger than hard facts like cost-effectiveness. But in that case might resources not be used in the optimal way (23). Next to these, politicians could neglect their support for explicit priority setting (either hidden or not) because it is a controversial decision to confirm negative reimbursement decisions that can be influence the political future negatively. Therefore, they do not regret an implicit decision making process (24). And the pharmaceutical lobby is influencing decisions for their own profit. As a big employer do they have a great power on governments. Of course are thanks to biomedical research and the pharmaceutical industry major advances made in medicine to increase, restore or maintain the health of people. Nevertheless, the reimbursement of these new and high-cost innovations lacks in some cases a valid justification in terms of efficiency and evidence-based (25). New drugs that have no medical superiority and could be exposed to their low added value by economic evaluations are in some cases still reimbursed (26).

At this point of the paper follows after these introductory considerations some more concrete theory regarding the involved institutions for decision making, the used criteria for uptake of provisions, the

elements surrounding the procedure of inclusion from pharmaceuticals and the role of value for money considerations. The structure of these considerations will guide the setup of later chapters and form their framework.

Institutional configuration of decision making

At the beginning are the relevant actors in the decision making process and their institutional environment presented. The focus will lie on the most important directly involved stakeholders and not on indirectly involved parties. Next to all relevant parties is the legislation in force and the methods of reference pricing and the use of national formularies presented.

Because the special focus of this assignment will lie on pharmaceuticals, the first described bodies will be concerned with their licensing and registration. Manufacturers can only in that cases obtain a license when their new medicine meets the criteria of quality, efficacy and safety. Public health authorities must therefore establish an institute that tests these requirements. This is normally done by a series of toxicity, pharmacology and clinical tests that are complex and lengthy (27). These tests are not subject of this assignment. But only when the authority comes to a positive conclusion can the drug be authorized for the pharmaceutical market.

The relevant bodies governing the assessment of new provisions and their uptake can mostly be categorized as being either advisory or executive in its task. Advisory bodies formulate recommendations for reimbursement or pricing to the national or regional government, ministerial department or self-governing body. Regulatory bodies are responsible in making decisions for the listing and pricing of drugs, medical devices and other services. They are accountable to the Ministries of Health (28). While both types of bodies conduct or coordinate assessments, are only the regulatory bodies able to make decisions about the coverage and/or pricing (15).

The practice of setting common reimbursement amounts for similar products is known as the concept of reference pricing. Reference pricing groups pharmaceuticals into clusters with regard to their chemical, pharmacological or therapeutic equivalence. A single reimbursement level (the reference price) is set by the health care funder for a whole cluster (29). If patients demand to be treated by a more expensive drug, they have to pay the excess from the expensive drug and the reference price by themselves (30). Reference pricing is a practice by which payers seek to get good

value for money in pharmaceutical expenditure (31). Policy makers rely on this method because of its combination to limit public reimbursement while not restricting the availability of medicines (32).

National formularies are another method to influence the utilization and pricing of drugs (33) by the creation of lists which explicitly state all pharmaceuticals that are eligible for reimbursement (34). They can be divided into two groups: open and closed formularies, with the latter one subdivided into positive and negative lists. In schemes which are denoted as open formularies is every prescription drug covered which is approved for marketing (35). The majority of pharmaceuticals are automatically listed for reimbursement (36). Coverage schemes that are denoted as closed formularies are used widespread by most OECD countries (35). These formularies can be subdivided into negative and positive lists. Negative lists are explicitly mentioning technologies that are excluded from reimbursement. Much more common in Europe is the application of positive lists, which name all pharmaceuticals covered by the scheme and associated conditions, the level of reimbursement and potential cost sharing. The underlying principle of these lists is that pharmaceuticals which are proven to be ineffective or more expensive than equally effective and costly drugs should not be prescribed by physicians and are therefore not reimbursed (34).

In countries that use HTA is the Minister of Health often the responsible person that oversees the appraisal process. Nevertheless, independent institutions are involved in managing the main part of the assessment. In social insurance funded health care systems is the process mostly governed by insurance organizations. Nevertheless, even in these states provides the Ministry of Health some oversight (37).

Furthermore, a decision has to be taken within 90 days after the manufacturer has officially handed in a written proposal for uptake of a drug to the Health Minister, according to the already earlier mentioned Council Directive 89/105/EEC from 1988 on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (or in short: 'Transparency Directive') (7).

Decision making criteria for the uptake of new provisions

At the second sections follows a closer look at the nowadays applied criteria for inclusion into the basic benefit package. While the introduction drew a comprehensive view on the developments in the area of priority setting and criteria for inclusion in the past, are these sections looking at the latest state of the art. The connection of these criteria with the factual national procedure shall become apparent in the following sections and the focus will therefore lie on explicitly stated criteria.

In general are the criteria for inclusion varying, but mostly associated with therapeutic benefit, low risk factors plus price and budget impact (38). They may or may not include a formal assessment of the cost-effectiveness of a medicine compared to other therapeutic alternatives (35). Other criteria used are efficacy, necessity, affordability, public health impact, availability of alternative treatments, equity, projected product utilization and the innovation of product (e.g. pharmacological characteristics, ease of use) (39). Despite this full range of criteria are in most countries successively the relative therapeutic benefit of a drug and its cost-effectiveness the most important factors for the coverage decision (40).

Decision making process for uptake of new pharmaceuticals

The third sections will describe the procedure of inclusion from new out-patient pharmaceuticals. This is due to the fact that they have the best described methodology and a very restrictive legislation in most countries. For an explicit decision about the inclusion is the use of a well tested and broadly accepted method like health technology assessment recommended. As explained earlier involves decision making for uptake of new provisions based on HTA usually two phases: the assessment phase succeeded by the appraisal phase (15). Even European countries without formal HTA support adopt elements of it (14), the most prominent being the use of economic evaluations.

It is noted that the use of pharmacoeconomic assessment diffuses quickly in OECD countries because emphasize is shifting to the topic of generating better value for money for new drugs and related reimbursement and pricing issues (41). Systems using economic evaluations link the decision of reimbursement explicitly on the availability of economic data. This data has to be provided to the national body which is making the reimbursement decision (42). Only medicines for very severe diseases with a small patient population or in the case that there are no other treatment options (which is the case for orphan drugs) are covered even when they have a poor cost-effectiveness (43).

Without the use of such a tool as HTA that supports the evidence-based decision making is the uptake of technologies more at risk of being highly influenced by social, financial, professional and institutional factors (22). These might not act in a way that provides the best utilization of resources and for that reason generate a less optimum level of health than would be possible (22).

At the end of these sections will the communication of the decision be discussed. It is noted that the transparency and effective dissemination of recommendations depends on the used methods. As possible means can be considered the concrete policy, audits and peer review, clinical guidance, accreditation, standards, media campaigns, conferences and workshops, professional education and last but not least websites and newsletters (44).

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The role of value for money considerations

Finally, the forth sections look at the considerations of value for money. These considerations play a vital role in the whole health care sector. Yet, the focus here will rest on the use of HTA in the coverage decision making, the use of a cost-effectiveness ceiling ratio for defining the society's willingness to pay for a QALY, the practice of conditional reimbursement, the use of practice guidelines and cost-sharing approaches.

The use of HTA is ultimately done to determine the relative 'value for money' from new provisions (15). HTA supports evidence-based decision making (45) and indicates which provisions are more cost-effective than others (46). If applicable, the arguments speaking for or against the use or introduction of HTA shall be explained.

Another method for indicating a higher value for money of new provisions is the establishment of a cost-effectiveness threshold. A threshold is representing the amount of money that a society is willing to pay for an additional unit of health outcome (mostly described by the concept of quality-adjusted life year, or in short: QALY) (15). The use of such a threshold is a controversial topic but remains attractive to policy makers and researchers. Methods to define this ratio could be found in considering a high cap at the most expensive treatment, the value of a statistical life, a league table approach (which orders interventions), a multiple of the GDP or GNI, and a preference-elicitation approach (47).

The idea of using the cost of dialysis for setting the maximum willingness to pay is going back to the practice of the United States of America. They established in 1982 on the basis of the estimated cost effectiveness of renal dialysis the threshold of USD 50,000 per QALY. Interestingly was this threshold almost never corrected for inflation and is persisting the literature until today (48). Another consideration that can play a role is the value of a statistical life. Two American research articles estimated the value for a statistical life of about USD 7 million (49;50). If the average life expectancy is considered as being 79 years, the final value amounts to EUR 71,000 per year and could be used as a threshold. The concrete value of USD 150 per DALY is derived from a work of the World Bank in 1993 for low- and middle-income countries. Services with USD 150 per DALY are seen as having an 'attractive' cost-effectiveness, while USD 25 per DALY is 'highly attractive' for low-income countries, while these values lie for middle-income countries at USD 500 and USD 100 per DALY. Nevertheless, the applicability of this approach in practice is questioned (51). In 2002 suggested the WHO to take a cost-effectiveness ratio that is three times the gross domestic product (GDP) per capita of the population. They decided also three categories of cost-effectiveness: very cost-effective are those technologies that are lower than the GDP; cost-effective those that are between one time GDP and three times, and finally cost-ineffective for those greater than three times GDP (52). The preference elicitation method connects the threshold to individual preferences. It can take two perspectives, once the WTP for incremental improvements of health and once the amount of money people are willing-to-accept (WTA) as compensation for life threatening risks (53). The amounts for WTA are always higher than for WTP, so that people want more compensation for a loss than they are willing to pay for an equivalent gain. WTA also produces higher thresholds than those of discussion until now. For high-income countries are values calculated that lie at 3 to 20 times GNI (54).

Some jurisdictions also use restrictions to the access of drugs for specific conditions (56). Explicit exclusion of pharmaceuticals that clearly fail to meet earlier stated criteria for uptake in a sufficient way is in practice very seldom. Therefore, the use of additional conditions is established widespread. This means that a drug is only applicable in certain indications, patient groups or it can only be prescribed by certain health care providers or prior authorization (15;57). Related to this topic is also the partial reimbursement. This means that the insurance is reimbursing from comparable treatment options the price of the most favourable. If the patient chooses for a more expensive treatment needs the excess to be paid by the patients themselves.

Another method to restrict the utilization of drugs lies in the use of practice guidelines. These guidelines define special rules for description of specific drugs (58). A lot of health care is not

assessed in a formal and central way. Therefore, the use of practice guidelines can be helpful to determine on a lower level who is eligible for which care under which conditions (12;59). The objective is to steer available pharmaceuticals to the most efficient treatment (60). Furthermore are governments strengthening their position against pharmaceutical companies if they allow the limitation of drugs and exclude them for certain therapeutic areas (61). These guidelines can be established by governmental or professional organizations. But medical organizations tend to strengthen the clinical aspects and not to focus much on the financial implications (59).

The last discussed method here are cost-sharing approaches. They form part of private expenditures in health care, next to over-the-counter expenditures and user fees. Cost-sharing can be divided into mainly three types: co-payment, co-insurance and deductibles. Co-payment means that the patient is paying a certain fixed amount of money for a service at the time of receiving the care. Co-insurance means that the patient is paying a fixed proportion of the total costs, whereas the insurance company will pay the remaining proportion. And deductibles mean that the patient is paying for a fixed quantity of the costs, while the excess is paid by the insurance company (62). It is argued that cost sharing reduces the unnecessary utilization of health services and therefore raises the value for money. At the same time they serve as a cross-subsidy and ensure a larger benefit package (63). Research shows that people indeed lower their utilization when the prices are rising (64).

Conditional reimbursement, practice guidelines and cost-sharing approaches all have in common that they share the advantage that benefits are not fully excluded but still accessible to patients. The principles of solidarity and equal access are guaranteed while cost-ineffective treatment options are not publicly financed (65). This generates a higher value for money.

Before the results chapter presents the current situation, an outline of the history on priority setting is preceding for both countries. The description of the historical development up till today plays a crucial role for an adequate analysis of the current decision making and placing it into the context of its past. Decisions made today are based on decisions made in the past. This is also known as the concept of path-dependency (66). Thus for a better understanding of today's decision making regarding the benefit package and its compilation seems an outline of the history necessary.

HISTORICAL OVERVIEW OF PRIORITY SETTING: THE NETHERLANDS

The Dutch awareness for priority setting began to rise during the mid-1980s. The experienced cost explosion was one of the main reasons for considering adjustments to the basic benefit package. Other factors were the ageing of the population, advances in medical science and technology, epidemiological change and new public health problems like AIDS (67). The Netherlands are known for its argumentation that when the access to essential health care shall be ensured, withdrawing of certain care might be necessary given the scarcity of resources (68;69).

The two most recognized advisory reports addressing the decision making on the inclusion of new provision in the publicly financed benefit package were in the Netherlands written by the Committee on the Structure and Financing of Health Care (which is known as the Dekker-Committee after the chairman) in 1987, and the Government Committee on Choices in Health Care (known as the Dunning-Committee) in 1991. They initiated the discussion that led to the health system reforms in 2006 (70) and the beginning of priority setting with the exclusion of alternative medicine in 1993 (71).

The report of the Dekker Committee was focusing on restructuring the health care system, and in this respect it also recommended about the compilation of the basic benefit package. Two reasons would justify the inclusion of benefits into the insurance package: risks that were financially uninsurable and services that were substitution sensitive (meaning the risk that drugs which are not reimbursed are replaced by other drugs that are reimbursed, but not necessarily more cost-effective) (72). The committee suggested that around 85% of the costs of the health expenditure should be covered and publicly financed, including related social services. Proposed excluded services would be all drugs prescribed in a non-residential setting, all non-residential paramedical care (like physiotherapy, speech therapy and exercise therapy), dental care for people older than 18, care for children from one year upwards in child health centers, cosmetic surgery, in-vitro fertilization, abortion and sterilization (73).

In contrast to this rough criteria and the concrete suggestions for exclusion provided the Dunning Committee in 1991 with their advisory report a general methodology for the decision making on new provisions. All new medical technologies should pass a funnel of four cumulative criteria to be eligible for uptake (74). These criteria were in order of importance: necessity, effectiveness, efficiency

and individual responsibility (75). The recommendation for the inclusion of new provisions was easily to test each new provision on these four criteria by asking the following questions:

1. is the care necessary from a societal viewpoint (75)? Necessary care should enable individuals to share an existence with other members of society, and to maintain and, if possible, improve this co-existence (76).

2. is the effectiveness proven (75)? The range of effectiveness goes from confirmed and documented, via assumed but barely documented, to non-confirmed, and finally confirmed and demonstrated ineffectiveness. Only confirmed and documented effective care should be part of the benefit package (77).

3. is the care efficient (meaning cost-effective) (75)? Efficiency should be analyzed by using cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) (77).

4. is it possible to leave the care to individual financing and responsibility (75)? The last criterion of individual responsibility and financing is only applicable when the associated costs of a certain form of care are very high and at the same time the benefits very low (77;78).

Other recommendations of the Dunning-Committee included that medical devices and other new technologies should also be assessed for their effectiveness and safety before the inclusion, as in the case of pharmaceuticals, plus the committee stressed the importance of formulating protocols and guidelines for appropriate individual care (79).

It is important to recall that the criteria listed above are not the final criteria used today. Nevertheless, the report was successful in initiating a public discussion about the inevitable limitations for guaranteeing the financial sustainability of the health care system (67). This was intended by the Dunning committee as they recommended to set up a public campaign to create more awareness of the need and background in priority setting. The Dutch government was indeed able to achieve consensus about prioritization by starting an extensive public information campaign. A readable version of the xxx-pages report was disseminated between health professionals and hospitals for debate and critical comments. The media were widely reporting about it and interest groups and associations were

involved (80). Also several grey literature on priority setting was written thereupon, among others from the Committee for Criteria of Drug Selection in 1994, the Scientific Council for Government Policy in 1997, the Health Council in 2003 and by Rand Europe/Oortwijn in 2005 (81). Due to the scope of this assignment will they not be discussed here. Nevertheless, all of these reports have contributed to the discussing in the field of priority setting.

In total can be concluded that the Dunning Committee is one of the cornerstones in the developments of priority setting. It paved the way for today's criteria applied by the Health Care Insurance Board [College voor Zorgverzekeringen, CVZ], whose importance shall become clearer in the results chapter (see section 3.1.1, Institutional configuration).

As mentioned before, after these advisory reports started the practice of priority setting through the exclusion of services. Homeopathic and anthroposophical medicine were excluded in 1993; plasters, aspirin and nose drops as self-care products in 1994 (71); dental care for adults in 1995; prolonged physiotherapy in 1996 (82); then all physiotherapy and prolonged psychotherapy in 2004 (83-85). Also excluded are elective procedures like cosmetic plastic surgery without a medical indication (83). The reasons for these exclusions were the merely demonstrated effectiveness (71;86) and/or the low burden of disease that do not justify the appeal on funding by the society (71;87).

Between 1993 and 1998 was the Government restricting the inclusion of any new innovative drug without substitute into the social insurance coverage (88). The idea was to restrict the use of new drugs first to hospitals only, and when more information on cost-effectiveness has been gathered, to allow the use in the out-patient setting (89). This approach led to the rejection for uptake of 36 new drugs. After increased public pressure switched the government to a less restrictive policy in 1999 (88), with the concurrent inclusion of some of those and the costs for new drugs rose to the same level as before. Nevertheless, it is not reported about negative effects this policy have had (90).

The withdrawal of health technologies was not done without discussion and also often changed back. The best example for such a controversial decision regards oral contraceptives. After the unconditioned uptake in 1972 was the discussion of exclusion periodically coming back in 1983, 1986/87, 1992, 1993, 1995 and 1998. Finally was the exclusion for individuals older than 21 decided in 2004, which was reverted in 2008. Very recently in April 2010 was decided to exclude oral contraceptives totally, due to the low costs and low severity of disease (91).

HISTORICAL OVERVIEW OF PRIORITY SETTING: THE CZECH REPUBLIC

Priority setting has no long tradition in the Czech Republic, let alone the exclusion of benefits. The benefit package of the Czech Republic has been very broad since the establishment of a health insurance system up till today (92;93). But in recent years has the need for prioritization been realized due to the rising costs and the overutilization of health care services (94).

In the Czech Republic is less influential grey literature found as in the Netherlands. The applied approach ranged immediately on a higher level at the Ministry of Health and the legislative level. Prioritization started with the enacting of the Act on Public Health Insurance in 1997. Furthermore established the Ministry of Health in 2007 for two years a project called 'Round Table' to create awareness of the situation of the health care system and possible solutions to its threats. And in 2008 were proposals for three new bills presented, which would clarify the definition of the basic benefit package applied today by the SÚKL (see next chapter).

To establish more societal support for the reforms in the health system was in June 2007 (95) a public and political discussion initiated by the Ministry of Health, the so-called 'Round Table for the future path of healthcare in the Czech Republic with the main focus on its financial stability and sustainability' (96). It lasted until January 2009 (95) and its main task was to identify and quantify long-term problems of the performance of the Czech health care system, as well as to raise attention for these problems by experts, politicians and the public (95;96). Its main outcome was a number of reports on the sustainability of the health care system. The ten core members were from the political parties chosen specialists and experts. Furthermore are politicians as representatives of their party submitting comments and opinions to the reports of the Round Table. Last but not least, the public was invited to take part in the discussions via the website, scheduled seminars and conferences (97).

The proposals for the three new bills contained paragraphs that would have brought more clarity to the basic benefit package. Most important would have been the new Act on Health Services and Conditions for their Provision. It was intended to replace the 1966 Act on Care for People's Health. It would regulate the patient-provider relationship and specify specific rights and obligations of both parties (98). Furthermore, it would explicitly define health care benefits as entitlements, which strengthens the position of all involved actors (95). Because according to the new definition would only those services be covered by the public health insurance, which are:

(1.) responsive to the health needs of patients (addressing necessity),

(2.) based on the latest medical knowledge (addressing safety and effectiveness),

(3.) provided in compliance with the cost-effective utilization of health system resources (addressing efficiency) (95;99).

Furthermore, the definition was guided by a bylaw on the Catalogue of Health Services, and clinical guidelines which would ensure the most clinically effective care in individual circumstances (99).

Nevertheless, the proposed new legislation was not approved (Maďarová, e-mail from 08/06/2010, see appendix). The discussion in the Parliament about this definition revolved around the concern that full reimbursement would only apply to the most cost-effective treatments for the individual, depending on their needs (99). Also because health care services have always been free of charge, the resistance of politicians for accepting these laws must have been quite high.

For the future it will be interesting to observe the current political changes. At the last weekend of May 2010 took legislative elections place in the Czech Republic and the new government might redefine the basic benefit package. This can be assumed due to the great discussion about priority setting and the variety of available proposals (Maďarová, e-mail from 08/06/2010).

But apart from this setback is priority setting already done since the enacting of the Act on Public Health Insurance in 1997. This act is explicitly stating health procedures that are not reimbursed (100). Acupuncture, cosmetic surgery and some dental treatments are explicitly excluded (93;101), as well as some medical devices that are listed in Annex 3 of the law. Implicitly excluded are all medical services, treatments and drugs that do not maintain or improve the health of the individual (102). Examples are voluntary abortions and examinations requested by employers (93;102).

It can be argued that next to the history of decision making are also the general developments in health care important. This is not neglected by the author as this information would enable the reader to gain a more holistic view on the setting that influences health care decision making. But in line with the readability and text flow of this paper is a detailed description placed in the appendix. By deciding in this way, the focus of the main text remains at the topics of decision making and priority setting.

2 METHODS

To answer above mentioned research questions, how decisions are made on the inclusion/ uptake of new provisions (e.g. new pharmaceuticals) in the benefit package (so publicly financed health care) in the Netherlands and the Czech Republic, and what role (if any) do considerations of value for money play in the decision making process, mainly qualitative desk research was carried out.

The assignment is descriptive and explanatory in its scope. It describes the two different systems of decision making for inclusion of new provisions, with a focus on pharmaceuticals. It uses their history regarding the decision making and priority setting as a starting point to create an understanding of the current situation. It also explains which role value for money considerations are playing in reimbursement decision making processes in the two selected countries.

The units of analysis are the health care systems in the Netherlands and the Czech Republic, focusing on the decision making process and priority setting in benefit coverage packages. The research questions were answered by a literature study and by using interviews. The literature is mostly found in Dutch for the Netherlands and in English for the Czech Republic. In addition, two interviews with three officials from the Czech Republic helped the researcher to orientate in the national setting. Two interviews were held with once Mgr. Daniela Rrahmaniová, Ministry of Health of the Czech Republic, Deputy Director of the Department of Pharmacy and PharmDr. Marcela Heislerová, Ph.D., Ministry of Health of the Czech Republic, Department of Pharmacy on March 31th, 2010 at the Department of Pharmacy in the Ministry of Health, and once with MUDr. Mgr. Jindřich Kotrba, State Institute of Drug Control, Head of the Department for Price and Reimbursement Regulation on May 13th, 2010 at the Ministry of Health in the office provided for my own use.

The interviews were guided by semi-structured open questions, where the questions itself were only used as an instrumental aid. The interviewees were talking freely and answering questions that arose during their explanations in a sufficient way. During the interviews I make small sketchy notes to not distract my interviewees. After both interviews I rewrote my notes immediately. The intention was to give the interviewees not the impression of being recorded so that they behave and answer in a normal and natural way.

The first interview with Mgr. Daniela Rrahmaniová, and PharmDr. Marcela Heislerová, Ph.D., was more explorative to get a deeper insight into the Czech situation. The interview with MUDr. Mgr.

Jindřich Kotrba was more informative and his comments are incorporated in the text. Therefore these quotations underwent an authorization-procedure and are approved by him.

In addition to the interviewees was Mgr. Henrieta Maďarová, MS., approached, working in the private health care industry and as a teacher at the Charles University, who helped to clarify the legislative situation among the used criteria of reimbursement for the basic benefit package in the Czech Republic. She had described this situation earlier in a scientific paper and she replied immediately on an email, although she and the author have never met personally. The exact history of this contact is provided in the appendix.

The found data and interviews were analyzed in a thematically way. The literature was excerpted because of the unclearness about their usefulness. Later on were these notes screened and the most relevant passages used for this paper (103).

The main question of this assignment was answered by analyzing the criteria on which new provisions like new pharmaceuticals are getting into the benefit package of the countries. Also, the involved institutions and organizations and the process of pharmaceutical reimbursement decision making were analyzed. Besides that, the focus of this analysis will lie on the value for money considerations. The answer of the sub-question was subsequently derived from the main question. It was hereby analyzed whether these considerations play a role at all or, if not, whether they may play a role in the nearby future.

The main research question is addressed in the first three sections of the results chapter, while the sub-question is answered in the forth sections. The results chapter in general is based on the theoretical considerations and historical outline from the introductory chapter. The points of discussion there are used to further structure the whole paper.

The chapter ideas were elaborated from existing literature on descriptions and comparisons of decision making regarding the basic benefit packages in various countries. The structure of the assignment was adjusted after the second meeting between the first supervisor and the author. The concentration on priority setting was further worked out clearly in the theoretical considerations and the question was raised whether the Netherlands could learn something from the Czech Republic.

The working progress was established by working around three days a week on the assignment at either the Ministry of Health, the library of the Charles University or at the author's accommodation in Prague.

Relevant literature

This paper has concentrated itself to study the gray literature, next to scientific articles and legal documents. For the main body were for the Netherlands reports used from the Council for Public Health and Health Care (RVZ), the Health Care Insurance Board (CVZ) and the Health Council (Gezondheidsraad). For the Czech Republic, mostly legal documents and information of the State Institute for Drug Control have been taken into consideration. Additionally, information from the WHO on Health Systems in Transition was very helpful for both countries, as new versions were very recently published (for the Netherlands in 2010, for the Czech Republic in 2009).

The used literature was found on various search engines, namely by using Google, Scopus and PubMed. Furthermore were the references from other articles searched for appropriate sources. Additionally were the websites of the involved parties visited. The mainly used technical terms were 'benefit package', 'uptake', 'inclusion', 'exclusion', 'provisions', 'criteria' and similar in interchanging order. A more specific search algorithm included 'cost effectiveness', 'threshold', 'ceiling', 'value', 'ratio', 'willingness to pay' . Of course were these terms almost always used in combination with 'Czech Republic' and/or '[the] Netherlands'. Last but not least, the supervisors pointed to useful literature for their countries.

It is in retrospective clear without ambiguity that this paper would not have been possible to write by this author as it is written if it would have been written a few years ago. The information was not as good documented in English as it is now and it might be a supporting sign for the attempts of generating transparency when even a foreign student is able to analyze and study the Czech decision making process regarding the benefit package in a sufficient way without knowing much of the native language.

Timeframe

This research was written during February till July 2010 in Prague, the Czech Republic. The overall timeframe was divided into four phases: the first four weeks were used for writing a first version of the introduction and the methods section. The next eight weeks were used for the collection of material. Thereafter was a first full version written during the next four weeks. The last weeks were used for processing feedback and writing the final version.

Expected results

First of all, it was expected that the reimbursement systems of both country differ from each other. In the Czech Republic, a lot of changes were made after the fall of the iron velvet in the year 1989. In that respect the Netherlands did not face the same problems as the Czech Republic did (a changing political and economical system, together with societal and moral values). Recently, the Czech Republic started to reform the process of decision making in the pharmaceutical reimbursement system. It seemed interesting for the author to study the actual system in the Czech Republic and compare this to the (supposed to be much more experienced and sustainable) Netherlands structure.

Aside from this, it was expected that the value for money considerations are much more developed in the Netherlands than in the Czech Republic. Mostly the same arguments apply as already mentioned before. It was unclear in which way this research could be generalized as a case study for Western and Central European countries. It seems that the country's health care systems differ quite a lot from each other. Yet, certain trends are evolving in all these countries.

Furthermore, this assignment was intended to inform the Ministry of Health in the Czech Republic about the current situation in the Netherlands in comparison to the situation in their country. Some value for money considerations could be an interesting part to adopt in their system, and the same applies to the process of pharmaceutical reimbursement decision making.

3 RESULTS

In this chapter follows a look on the factual situation of decision making regarding new provisions, with a focus on out-patient pharmaceuticals. After the look at the historical developments regarding the health care system and priority setting in the introduction, follows in this chapter a closer look on the actual situation of decision making as it is made today. The structure will be overlapping to that of the earlier presented theoretical considerations. Therefore can the sections of this chapter globally be further divided into four parts, namely the institutional configuration, the criteria for decision making on the uptake of new provisions, the procedure of uptake from new pharmaceuticals in the benefit package, and the role of value for money considerations.

It is tried to achieve a similar structure in both parts, beginning with the Netherlands and ending with the Czech Republic for practical reasons of comparability. Nevertheless, the national differences force the author to specify points that are specific for only that country. Especially the process of uptake will differ because the used methodology is different and much better described for the Netherlands. With regards to the objective of informing the policy makers at the Ministry of Health, this is not seen as a major problem.

3.1 FRAMEWORK OF DECISION MAKING REGARDING THE BENEFIT PACKAGE IN THE NETHERLANDS

3.1.1 INSTITUTIONAL CONFIGURATION

Licensing of new pharmaceuticals entering the market

The Board for the Evaluation of Drugs [in Dutch: College ter Beoordeling van Geneesmiddelen, CBG] regulates the entrance of new pharmaceuticals into the market and authorizes the distribution as prescription or non-prescription drug (104;105). It makes use of the criteria quality, efficacy and safety to assign a trading license (106). Furthermore is the monitoring of pharmaceuticals on the Dutch market one of its tasks (105). The Board is set up as an independent organization and its members are appointed by the Minister of Health (107). The foundation of the Board for the Evaluation of Drugs goes back to the thalidomide-drama in 1963 (108).

Uptake of new provisions in the benefit package

The central position in the decision making process has the Health Care Insurance Board [College voor Zorgverzekeringen, hereinafter called CVZ]. It has the task to advise the Minister of Health about the compilation of the benefit package and about the uptake of new provisions. Most importantly, they evaluate all new pharmaceutical drugs for which manufacturers seek the uptake on the reimbursement list. For the evaluation are solely prescription drugs admitted. The CVZ is also giving unambiguous information to insured people, health insurers and health care providers about the scope of the package and serves as the contact for these third parties (109;110). The CVZ is the legal successor of the Health Insurance Funds Council [Ziekenfondsraad, ZFR] since 1999 (111).

For supporting the decision of whether new pharmaceuticals are eligible for inclusion into the benefit package is HTA in its two phases used. The CVZ has set up two Commissions to be concerned

with these phases. The Pharmaceutical Assistance Commission [Commissie Farmaceutische Hulp, hereinafter called CFH] is responsible for the assessment of the drug, while the Advisory Package Commission [Adviescommissie Pakket, hereinafter called ACP] is responsible for the appraisal (112). The CFH consists of 22 external and from the Ministry independent experts which are members of the commission for not more than eight years, to guarantee an independent evaluation process. Its foundation is related to the introduction of a national formulary in 1991 (described in a following paragraph). The ACP consists of six external experts and the three members from the Board of Directors. It consults the CVZ about the societal implications of its advice (113). It was founded in April 2008 (114). The Board of Directors will finalize the advice of the CVZ and send it together with political considerations to the Minister of Health.

While the reimbursement is regulated jointly by the CVZ and the Minister of Health, maximum prices are set by the Ministry of Health only (115). Since 2004 are in addition negotiations held between the Ministry of Health, the pharmacists and the manufacturer of generics (116).

Reimbursement is based on reference pricing in the so-called Medicines Reimbursement System [Geneesmiddelen Vergoedings Systeem, GVS], introduced in 1991 (117). This is at the same time a national formulary and determines which drugs and medical devices are allowed for reimbursement. It can be categorized as a positive list and it is managed by the CVZ. The included pharmaceuticals are divided in clusters of therapeutic equivalents (118;119). For each cluster is a reference price stated that serves as the reimbursement limit. A pharmaceutical is reimbursed up to this level and the possible excess has to be paid by the patient.

To determine the maximum price of a drug was in 1996 the use of an international price comparison introduced (88;108). The maximum price is since then calculated by using four countries as a reference basket: Germany, Belgium, France and the United Kingdom. The maximum price is derived by calculating the average of the average prices in these countries (120).

Legislative empowerment

The Dutch legal framework contains two laws that empower these organizations associated with the process of decision making: the Health Insurance Act [Zorgverzekeringswet, Zvw] from 2006 (109) and the Act on Medicines [Geneesmiddelenwet] from 2007 (104), which authorize the Health Care

Insurance Board and the Board for the Evaluation of Drugs respectively. The price setting for drugs is regulated by the Pharmaceutical Pricing Act [Wet geneesmiddelenprijzen].

Formal decision making authority

The Minister of Health is the legal person with the final responsibility in making the decisions regarding the inclusion of provisions. He (or she) heavily relies on the advice of the CVZ (109). Because the Minister is the final decision maker, needs a revision process to be done at the court. The legal remedies for manufacturers are communicated at the end of each decision (121).

The Minister decides about the maximum price within 90 days after he received the application. In case of a great number of requests for obtaining a price can the Minister postpone the decision one time for 60 days (122).

3.1.2 CRITERIA FOR DECISION MAKING ON THE UPTAKE OF NEW PROVISIONS

The criteria for uptake of new provisions into the benefit package are explicitly stated by the CVZ and their validity confirmed for several times (123-125). Furthermore, the CVZ takes as rationale that the used criteria are valid for all new provisions (126). The criteria are:

1. necessity: justifies the disease or the needed health care the claim of the solidarity?

2. effectiveness: is the expected effect from an intervention or supplied care reached?

3. cost-effectiveness: is the relation of costs to benefits acceptable? (containing efficiency).

4. feasibility (/affordability): is it now and later feasible and supportable to uptake the intervention?

Necessity, effectiveness and cost-effectiveness are answering the question whether or not a benefit should be included in the basic health insurance coverage. Feasibility is moreover specifying the conditions and consequences of this answer. It is not equivalent with cost-effectiveness as it considers the consequences on a macro level for the budget (127).

The overlap with the criteria from the Dunning-Committee should be obvious. A difference can be found in the recommended application. The four criteria of the CVZ are applied concurrently (123), while the Dunning-Committee constructed a funnel of criteria, which were supposed to be evaluated successively (128). The history shows further that the judgment of provisions can better be made on an integral level because the criteria were too often used like binary means in the past (75;129). For a deliberate decision, all four criteria should be considered.

Above mentioned four criteria can be found in specific application for the medical devices and the (out-patient) pharmaceuticals. The used criteria remain the same, only the focus differs. For the one is necessity more important while for the other one is the focus on cost-effectiveness (85). Moreover, the interpretation of necessity differs for them, as will now be explained in brief. For (out-patient) pharmaceuticals is necessity divided into two meanings, once the severity of a disease by using the concept burden of disease, and once the necessity to indeed insure a benefit (124;130). Disease burden can be defined as 'reduced quality of life or life span as a result of a disease or some other somatic or mental health problem in cases where no health care service would be utilized' (131), or as the percentage of remaining health expectancy that a patient could be expected to lose if his or her illness were or remain untreated (132). A low burden of disease is highly correlated to the individual responsibility (133). The necessity to indeed insure a benefit is a societal question. A more detailed description of the application can be found in the next two sections (134). For medical devices on the other hand is necessity further subdivided into the criteria 'commonly used' and 'financial accessible' (135). If this criteria are positive met, the remaining three criteria do not need to be assessed. The aim is nevertheless to let the different applications have a same basis (136).

For pharmaceuticals are additionally the criteria in the process of licensing pharmaceuticals relevant. The CVZ takes only those drugs into its consideration that have gained authorization as prescription drugs. Therefore, the criteria for entering the Dutch market are also determining the later uptake of pharmaceuticals. The three criteria are: pharmaceutical quality, efficacy and safety of the ingredients and the final drug (108). Especially the criterion safety seems to be worthwhile to consider explicitly for all provisions, as history shows. The most prominent example for pharmaceuticals can be found in the (inter-)national thalidomide-drama in 1963. For medical devices were in the Netherlands some problems reported about defective heart valve prostheses in the 1990s (131).

3.1.3 PROCEDURE OF UPTAKE FROM NEW PHARMACEUTICALS

When a manufacturer is appealing for uptake of his pharmaceutical into the Medicines Reimbursement System, he firstly needs it registered as a prescription drug by the Board for the Evaluation of Drugs. After that it is possible to make an appeal for uptake by the Minister of Health (137). He or she will ask the CVZ for advice on the uptake (138). Eventually will the Minister of Health make the final decision about the inclusion based on the advice of the CVZ.

The marketing authorization holder firstly needs to hand in a dossier with clinical and economical information (139). Since 2005 is the authorization holder obliged to transmit a cost-effectiveness analysis and budget impact analysis to the CVZ as part of the dossier for new pharmaceuticals that can not be clustered in a reference group of equivalent medicines (140). The manufacturer can ask for exemption of delivering a pharmacoeconomic evaluation only in the case of orphan drugs. This need to be declared as such by the EMEA and the exemption is granted by the Minister of Health in individual cases (141). In 1999 were by the CVZ pharmacoeconomic guidelines issued to strive for a standard methodology in research across the country (142).

For promising innovative but insufficient proven effectiveness of new interventions for indications with limited treatment options is an advice from the CVZ in preparation for a so-called temporary permission. The temporary permission would be connected to the obligation of gathering additional data to obtain the final permission (143). Certain medicines that are intended to treat life-threatening and seriously debilitating diseases with a progressive course is a previous evaluation possible. This is the case for medicines without alternative, other breakthrough drugs and those that have gotten a license after an accelerated procedure (144). As a small reminder should be mentioned that this situation describes only out-patient medicines.

In all other cases is the appealed drug in a first step assessed for the exchangeability with existing other drugs, which are already on the positive list (110). A pharmaceutical is considered to be exchangeable when both the new drug and those existing aim at the same disease, the same age group, share a comparable route of administration and the same clinical aspects (110).

When these criteria are matched in a positive way, the pharmaceutical is seen to be exchangeable with existing drugs on the list and can be placed in one of the clusters at the Medicines Reimbursement System. It therefore enters the first list with drugs which are reimbursed until the reimbursement limit of a clustered group (annex '1a') (145).

If at least one of above mentioned questions cannot be surely answered in a positive way, the drug is seen to be not exchangeable and cannot be clustered. The reference price system then does not apply and the process of using HTA is initiated. In that case is the evaluation divided into two parts: first comes the assessment phase, followed by the appraisal phase. The first phase evaluates the costs and benefits of a drug, while the second step is interpreting the findings and taking the public interest into consideration for the final decision (146).

Assessment phase

The assessment phase is carried out by the Pharmaceutical Assistance Commission [CFH]. Its task is to evaluate in a first step the added value of a new drug in comparison to the standard treatment or if not available, the usual care (147). After that is in a second step the cost-effectiveness of a medicine evaluated (148).

The added value is conceptualized as the therapeutic value of a drug, which is another description for the earlier mentioned criterion of effectiveness for out-patient pharmaceuticals (149). The therapeutic value is measured by controlling six criteria in order of importance (150): efficacy, effectiveness, side effects (how less severe the aimed disease, how less acceptable side effects are), experience (a sufficient amount of patients must have been treated for a sufficient time period), applicability (applicable for a wide patient group and no interactions with other drugs), and consumer-friendliness (an easier to take medicine is correlated to a higher compliance).

When the result of this test for the therapeutic value of the new drug is less than the standard treatment, the evaluation ends here and the CVZ advises to not include the drug in the benefit package. Costs have not been playing any role until this stage of the assessment (151). Only when the therapeutic value of the new drug is equal to or greater than the standard treatment, the CFH measures whether the new drug is cost-effective and the budget impact of the uptake (151;153).

For the cost-effectiveness applies that when the therapeutic value is equal to the standard care, a positive recommendation is only given when the price is the same. In case of higher therapeutic value combined with higher costs makes the Minister of Health a decision in respect to the public interest (154).

This assessment phase is finished with a preliminary recommendation for or against the uptake of a specific pharmaceutical. The CFH prepares a preliminary draft version of its report that is send to the market authorization holder with the possibility of adding comments. In the case that medicines should be reimbursed under certain conditions are also concept versions of the report send to the relevant associations from care providers, patients, and health insurers. All parties have one week time for their comments until it will be discussed in the next meeting of the CFH. The commission will then create its final report and send it again to the market authorization holder (155). After that phase ensues the appraisal phase.

Appraisal phase

The appraisal phase succeeds the assessment phase and is carried out by the Advisory Package Commission (156). The ACP is advising the CVZ about societal implications of its advice. It looks at societal values and norms that have not been taken into consideration during the assessment phase and that would influence the preliminary recommendation of the CFH. Also, legal and ethical restrictions are taken into consideration. The ACP is reviewing the draft report of the CFH and the reactions from the relevant involved parties. The question to be answered is whether it is desirable to insure the benefit from a societal point of view (156). In the case that the appraisal phase leads to other results than the assessment phase, must this explicitly be explained (123). In that case are amendments made to the original report of the CFH (157)

Administrative part from the Board of Directors

After the assessment and appraisal phases follows the administrative part from the Board of Directors. They finalize the report for the Minister in the first meeting after the ACP's meeting (158). The meetings of the Board of Directors are planned every couple of weeks. The Board of Directors takes next to the report of the CFH also political relevant aspects into their consideration. Both parts will then be send to the Minister. The political considerations are taken into account because the CVZ wants to emphasize its responsibility in the development of public conditions for the health insurance system (159).

The processing of this part from the Board of Directors knows two variants: in the first case can the board chairman decide to treat the appeal by himself, so that he sends the advice by himself to the Minister in the name of the Board of Directors. This is the case if the inquirer is requesting for uptake into appendix 1A of interchangeable drugs (160). The whole process of HTA with its two phases was then not passed through.

In all other cases needs the complete Board of Directors to gather and authorize the final report. In that case have all involved parties and the manufacturer again the possibility to react on the concept advice of the Board of Directors. This is to ensure a careful decision making. The concept advice of the Board can be commented in written form until a certain date. The CFH report is send again to take note of it, but not open for comments at this point of the process anymore. Furthermore can the board chairman decide that third parties can explain their written comments in a hearing.

Ministerial decision making

After this administrative part gives the CVZ a consolidated recommendation to the Minister of Health about the intervention and the uptake of the provision (110). When the advice is finalized and send to the Minister of Health is also a copy of all materials send to the market authorization holder and all heard organizations (161). The CVZ advice and CFH report plus appendix are further published on the website of the CVZ and freely accessible (162).

The Minister of Health then makes the final decision based on the advice of the CVZ. When the Minister comes to a positive decision, the drug can be placed on annex 1b, which knows no reimbursement limits (154). When the CVZ formulated additional conditions are the drugs likewise placed on 'annex 2' (163).

The decisions are legally valid when the GVS is changed. The GVS is updated each time that the Minister of Health accepts the uptake of a new provision (164). Each year are on average around 40 appeals made for uptake in the system. The CFH evaluates around 80 percent as interchangeable (165). The changes are published each month in the 'Staatscourant', the national communication platform, together with other changes that did not need an evaluation by the CVZ (162). The Minister of Health is communicating his decision about the appeal in written form with the market authorization holder. Next to the advice of the CVZ plus the attached CFH report is also the motivation for the decision included and the possibility for taking legal remedies (162;166).

If an inquirer does not accept the decision of the Ministry of Health about the uptake, he needs to go to the court. As the Minister of Health makes the final decision is normally an appeal at the Ministry of Health after his or her final decision not scheduled. Instead, the manufacturers have had earlier a couple of times the possibility to make comments on preliminary versions of the decision during the process of evaluation by the CVZ.

3.1.4 THE ROLE OF VALUE FOR MONEY CONSIDERATIONS

HTA in coverage decision making

As should be clear now is the decision making for inclusion and reimbursement supported by HTA. Its use lies in generating evidence-based information about the appropriate use of medical benefits and the policy decision regarding the uptake into the benefits package (167).

As described earlier can the process of uptake for new pharmaceuticals without therapeutical equivalents be divided into two phases: a more quantitative assessment phase, followed by a more qualitative appraisal phase (124). The usefulness can be found in what the CVZ calls an integrally evaluation. Integrally evaluation means that the CVZ strives to let the burden of disease and cost-effectiveness not play the crucial factors for the final recommendation, although they are important. But societal considerations should always play an important role as well (168). Examples of such arguments that recommend the uptake are orphan drugs, the absence of medical alternatives and negative externalities for the public health (169).

The practical usefulness of this separation can also be seen when looking at the criterion of necessity. The CVZ had experienced much difficulty with distinguishing the necessity criterion in its two different meanings already in the assessment phase when evaluating pharmaceuticals. The question whether a benefit is necessary to insure, was seen as being difficult to answer during the assessment phase. Thus while the burden of disease remains to be the topic of the assessment phase, the necessity to indeed insure a benefit will be part of the appraisal phase (170).

Cost-effectiveness threshold

In the assessment phase are three criteria expressed in numbers: the effects and the costs of a treatment plus the necessity for a treatment (123).

To calculate the cost-effectiveness is at first an incremental cost-effectiveness ratio computed. The costs of a certain intervention are calculated in comparison to a relevant alternative and divided through the same calculation of effects. The concept known as burden of disease then plots this ratio against necessity. The more severe a disease, the higher is the so gained cost-effectiveness threshold. And if the consequences of a disease are very serious and urgent, they strongly justify an appeal on the society. Decisions based solely on efficiency would ignore aspects of distribution, and therefore a connection between efficiency and severity was sought. With this calculation could a cost-effectiveness threshold be established, which is subject to discussion in the use as a ceiling ratio for the maximum willingness to pay.

The discussion about such a threshold was stimulated by the Council for Public Health and Health Care (RVZ), which picked up the idea of a flexible threshold that varies with the severity of a disease (171). Their idea was that higher costs per QALY are accepted for more serious diseases than for less serious ones. The suggestion is to take a ceiling of 0.1 for the burden of disease as the minimum and a maximum of EUR 80,000 per QALY per year for a burden of disease at 1.0 (172). So the treatment of a disease with a burden of 0.1 or smaller is not reimbursed, while diseases of a burden of 1.0 are reimbursed up to EUR 80,000 per QALY and per year. These numbers were calculated on the basis of considering the value of a statistical life and the concept of the WHO from 2002 to use a cost-effectiveness ratio that is three times the gross domestic product (GDP) per capita of a population (173;174). Given these considerations seemed a value of EUR 80,000 to be reasonable for the RVZ.

The RVZ is aware of limitations to the concept but wants to encourage the development of a transparent and explicit method. It compares the current situation with those times when in the navigation the Beaufort Wind Force Scale was used. This scale was a method to categorize the wind forces in several groups, which is in the light of today's technical highly sophisticated methods a very primitive instrument. Nevertheless, back then it helped to save the life of seamen by letting them communicate in an explicit manner about the weather (175).

Another notably fact is that the RVZ suggested that the application of a threshold is unavoidable and needs to be explicitly establishment by the Minister of Health (176). Nevertheless, the Minister at that time had announced that he would not treat the proposed EUR 80,000 threshold as an ultimate value (177).

Also no specific cost-effectiveness threshold as a ceiling ratio was established by the CVZ until recently (178). In 2009 established the CVZ for the assessment of the cost-effectiveness a unbinding range of EUR 10,000 for a low burden of disease and a value of around EUR 80,000 for very severe diseases. These values are comparable with those that the RVZ had suggested (173;174).

Conditional reimbursement

Because of strong societal resistance against the explicit exclusion of services (182) was the Dutch government switching from explicit exclusion to a limiting coverage for only special groups that would most likely benefit from an intervention (183). Examples for conditions to be formulated by the CVZ are for example that the reimbursement is restricted to specific patient populations, is limited to the prescription by a specific specialist, needs the preceding approval of the insurance company or underlies a certain treatment protocol (163). An example for this type of reimbursement is in-vitro fertilization, which is only reimbursed for the first three attempts (117).

A further advantage of the Dutch system is the partial reimbursement. Services up to the basic coverage have to be reimbursed by health insurers, even for more expensive treatments. But at the same time they do not need to reimburse more than is considered as being reasonable for the Dutch health care market, meaning more than the standard treatment (184).

Use of practice guidelines

The Netherlands are relying on practice guidelines to limit the benefit package on a lower level. These guidelines indicate which care is the most appropriate form for which patient group. The treating physician (and/or the health insurer) is then the responsible person for making decisions about the offered medical services (185).

The development of these guidelines is mainly a task for medical and paramedical scientific associations. They make use of the information collected and analyzed by the Cochrane Collaboration or other institutes. Since 1997 are these guidelines also considering cost-effectiveness. Nevertheless, the widespread use of cost-effective information in guidelines is still lacking (186). Instead, safety and effectiveness are the prevailing criteria (187).

The Minister of Health also plans to let the guidelines of associations from care providers play a more important role on the decision making of uptake. But the CVZ remarked that the quality of the cost-effectiveness is very diverse and that these guidelines are aiming at another objective than decision making on reimbursement and inclusion of new provisions (187).

Cost-sharing approaches

The Netherlands are also relying on cost-sharing approaches. In general are three forms of private expenditure prevailing: (a) expenses for over-the-counter medicines and excluded services, (b) co-payments on medical devices and prescription drugs that exceed the reimbursement limit set by the Medicines Reimbursement System (GVS), and (c) a compulsory deductible of EUR 155 for persons aged 18 or above. The deductible was introduced to make the population more aware of the costs in health care and to prevent moral hazard, which is defined as the use of expensive medical services because the expenditures are paid for by the insurance (188).

3.2 FRAMEWORK OF DECISION MAKING REGARDING THE BENEFIT PACKAGE IN THE CZECH REPUBLIC

3.2.1 INSTITUTIONAL CONFIGURATION

Licensing of new pharmaceuticals entering the market

The State Institute for Drug Control [in Czech: Státní ústav pro kontrolu léčiv, hereinafter called SÚKL] is the relevant legal body that approves and licenses pharmaceuticals and medical aids. The state institute is assessing each pharmaceutical on its quality, efficacy and safety (190). It also has to monitor pharmaceuticals, once they are on the market. The institute is under direct control of the Ministry of Health and financed from the state budget (190). The Minister of Health approves the statute of the SÚKL and has the power to appoint and dismiss its director (191). Today's institute was established in 1952 after the organisational reorganisation at the National Institute of Public Health [Státní zdravotní ústav, SZÚ] (190). Its foundation reaches back into the year 1918, when a predecessor of the SÚKL was founded: the Institute for the Examination of Pharmaceuticals [Ústav pro zkoumání léčiv] (192).

Uptake of new provisions in the benefit package

The main actor of the decision making for the uptake from new pharmaceuticals is again SÚKL. It has the executive task to decide on the compilation of the benefit package and the depth of coverage, as all proposals for uptake of new pharmaceuticals in the positive list are evaluated (193). The reimbursement rates are only set for pharmaceuticals which have been registered before, or under very strict special regulation for unauthorized drugs specified in §39b (194). The institute is providing open information to the state administration and the public (195).

The Czech Republic is not explicitly using health technology assessment yet and thus not dividing its process of inclusion into an assessment and appraisal phase. Nevertheless, they adopt certain aspects that can be found in the HTA process and they are also thinking about the formal introduction of HTA (96).

Since 2008 is SÚKL responsible for setting maximum prices and defining reimbursement rates for pharmaceuticals, which are covered by the social health insurance (192). Before that were maximum prices defined by the Ministry of Finance and reimbursement rates set by the Ministry of Health (192). This change of competence was intended to ensure transparency in the whole process of reimbursement and price-setting (106).

Reimbursement limits are set by using a reference pricing system since 1995 (197). The Act on Public Health Insurance [in Czech: Zákon č. 48/1997 Sb., o veřejném zdravotním pojištění] contains an informative list of active substances from which at least one pharmaceutical should always be fully covered (198). This list in the appendix of the law is the basis for SÚKL to apply a positive list for pharmaceuticals. They cluster medicines in groups according to their active substances. The reimbursement limit is set at the level of the least expensive drug in one cluster to fulfill on the legal requirement of one pharmaceutical being fully reimbursed in each cluster (198). In practice are around 57 % of the pharmaceuticals in these clusters fully reimbursed (199).

Next to that positive list for pharmaceuticals is the law also providing a list of medical devices and dental aids that are covered. This list is governed by the General Health Insurance Fund [in Czech: Všeobecná zdravotní pojišťovna, VZP] (200). Because of the general kind of the lists in the law are they thus complemented by these positive lists, containing all approved drugs, medical devices and dental aids that can be reimbursed (200). For pharmaceuticals is the list set by SÚKL, while the list for medical devices and dental aids is governed by the General Health Insurance Fund (200). Even a third positive list exists with the so-called Catalogue of Health Services [Seznam zdravotních výkonů], whose responsibility lies at the Ministry of Health (201). This list is a fee schedule and contains the rates of annual co-payment for more than 3600 items (202).

All of these lists are not final in their power as even benefits outside of them can be reimbursed, dependent on the needs of the patient (203;204). The reason that the lists are split to the authority of the SÚKL and the General Health Insurance Funds can be found in the recent changes of competencies. Until 2008 existed only the list of the VZP. With the beginning of 2008 got SÚKL its power of today and established an own list [called Seznam hrazených léčivých přípravků, SCAU], but the VZP list still exists and prevails with doctors. SCAU changes each month two times on the first and the fifth working day of a month due to the legal obligation to allow for revision by the producer at the end of each month (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague).

The maximum ex factory price for pharmaceuticals is derived from an international price comparison since 2008. The prices are calculated by using a reference basket consisting of Estonia,

France, Italy, Lithuania, Hungary, Portugal, Greece and Spain (205). The maximum price is defined by comparing the prices for a certain individual pharmaceutical in all eight countries and calculating the average of the three lowest (123).

Legislative empowerment

The authority of SÚKL is given through two laws, once the Act on Pharmaceuticals no. 378/2007 Coll. [Zákon č. 378/2007 Sb., o léčivech] (206) and on the other hand the earlier mentioned Act on Public Health Insurance from 1997. The Act of Pharmaceuticals regulates the activities of registering and licensing new drugs by SÚKL, whereas the Act on Public Health Insurance regulates the decision making on reimbursement and the maximum price-setting conducted by SÚKL (207;208).

Formal decision making authority

SÚKL has the informative and legal right in the decision making regarding reimbursement for the out-patient settings. As for the hospital use, this is defined in general by the law (209). Health insurance companies are entitled to fine-tune the details. The Ministry of Health acts as the second body in appealed cases confirming SÚKL´s decisions or cancelling them and returning them for revision back to SÚKL. The revised decision is again made by SÚKL and possibly reviewed again by the Ministry of Health. The Minister of Health is not involved as the final actor of the decision. Only when an "irregular" revision process of an Ministry of Health decision on the second level is encouraged by a participant to the proceeding (market authorization holder or health insurance company) has the Minister to decide about the motion and whether the Ministry of Health has or has not to revise its decision (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague).

SÚKL decides on the maximum price and the reimbursement level within 75 days starting the date when proceedings were initiated (210;211). In case of an extremely large number of requests for price setting can SÚKL postpone its decision one time for 60 days (212).

3.2.2 CRITERIA FOR DECISION MAKING ON THE UPTAKE OF NEW PROVISIONS

The criteria for inclusion into the benefit coverage are fragmented and judged as being ad hoc and difficult to manage (213). This is partly because those criteria, which are set by the Act on Public Health Insurance, can be dated back to the year 1966 when the Act on Care for People's Health was established (214). A variety of its articles were later just taken over into the law of 1997, while it still remains valid (215). Today, 34 out of its originally 84 paragraphs have been repealed (216). Nevertheless, the Act on Public Health Insurance is explicit in setting criteria for the exclusion of medicines (217). The law says that SÚKL does not grant reimbursement in the case that the pharmaceutical products

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(a) are labeled as supportive and complementary (necessity),

(b) whose use is inappropriate from a professional point of view (safety),

(c) do not have sufficient evidence of therapeutic efficacy (effectiveness), and

(d) do not meet the conditions of cost-effective therapeutic interventions (efficiency).

It can be said that the last three points are specifying the criteria safety, effectiveness and efficiency (218). This is explicitly explained as such in the law. Point (c) is regarding both the concept of efficacy and effectiveness, because it also considers the effects in everyday clinical practice. Point (d) is specified as regarding the most efficient and safest treatments while being cost-effective (217).

The overlap with the proposed new definition from 2008 is apparent. The differences lie in the fact that the new proposed criteria would have been valid for all health services and not only pharmaceutical products. Furthermore, the new criteria would have been formulated in a positive way and describing which services are included in the benefit package, not negative and excluding as it is mainly under current law (see for example efficiency described in the proposed new law as 'services that are provided in compliance with the cost-effective utilization of health system resources' [are

included] versus in the current law as 'drugs that do not meet the conditions of cost-effective therapeutic' [are excluded]).

For medical devices it is much more complicated to find criteria for uptake. The current law is stating for all medical services and treatments (thus including medical devices) that insurance holders are entitled to all medical care, which is provided to maintain or improve their health (219). Implicitly excluded are all medical services, treatments and drugs that do not maintain or improve the health of the individual (220). Moreover, it can be insightful to look at the requirements for conditional reimbursement. Conditional admission can be granted for medical devices if the benefit is prescribed for the continuation of a treatment process, to promote the stabilization of the health condition and significantly repel its decrease, and to mitigate the consequences of health defects, including the replacement of anatomical or physiological processes (221). These criteria are in line with the definition of entitlement to maintain or improve the health.

For pharmaceuticals and medical aids are also again the criteria of registration and licensing interesting. For prescription drugs is the prior authorization necessary if they pursue the uptake into the benefit package. This authorization is based on the criteria quality, safety and efficacy for each individual pharmaceutical (222;223). For medical aids is also looked at the safety, quality and rational use (224). These factors are complementing above stated criteria.

3.2.3 PROCEDURE OF UPTAKE FROM NEW PHARMACEUTICALS

It is possible to initiate the process of determining a maximum price and the reimbursement rates by the manufacturer of a prescription medicine, by the health insurance company (225), and in rare cases by the SÚKL itself when the uptake and reimbursement would be in the best public interest (226). The request for uptake and pricing must be made for each pharmaceutical or medical product individually (227). The evaluation is then carried out by the SÚKL who sets the amount and conditions of reimbursement. They are only set for registered pharmaceuticals, or under very strict special regulation for unauthorized drugs specified in §39b (194). As described earlier is the registration of new drugs also a task of SÚKL (see section 3.2.1, Institutional configuration).

All applications should include the results of clinical trials and economic evaluations, especially cost-effectiveness analysis and analysis of the budget impact (228). In the Czech Republic is the use of economic evaluations mandatory. Although the translation of foreign studies into the national context is possible, this decision must be reasonable. For example must be proven that the foreign studies match the Czech medical practice. This is usually the case for orphan or ultra-orphan products. SÚKL even supports the conduction of economic analysis in these cases, as the manufacturer can get a temporary admission for the medicine for one year. After that a submission for permanent reimbursement must contain the full range of prerequisites – among them also CEA and BIA (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague). The condition for this temporary reimbursement is only that the drug is part from at least one other country in the reference basket. This temporary admission can be prolonged up to three years (229).

There is no binding guideline for pharmacoeconomical analysis at present that SÚKL would require that economic evaluations would adhere to. If prompted for guidance, SÚKL points to the Czech pharmacoeconomic society guidelines that complying with these would be advisable. The analysis must be logical, measuring direct costs and include a section for the budget impact. The analysis will be checked for its logical consistence and design layout by SÚKL (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague).

It is difficult to give a detailed description of the process as was done for the Netherlands. The Czech Republic is not relying on HTA (yet). In the legislation is only a list of the following criteria found for determining the reimbursement and considering the uptake into the benefit package (194;230):

(a.) the therapeutic efficacy and safety

(b.) the severity of disease

(c.) cost-effectiveness and cost-benefit of treatment

(d.) the public interest (defined as the interest of the public in ensuring the quality and availability of health care, a functioning health system and its stability within the financial capacity of public health insurance system) (231)

(e.) the suitability of the route of administration, dosage form, strength and pack size

(f.) the usual therapeutic dosage

(g.) the necessary length of treatment

(h.) the intensity of compliance and adherence from the patient to the treatment

(i.) substitution through other reimbursed medicinal products

(j.) the budget impact

(k.) recommended guidelines and standard procedure from the perspective of cost-effectiveness and budget impact

In one of the interviews was further revealed that the process would be done in a logical manner. First they assess efficacy, safety and clinical use and when the provision passed this positively then the financial considerations enter the assessment (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague).

SÚKL is also following certain steps in the process of evaluation. Apart from the legal acts and ministerial decrees, the employees are following the SÚKL methodology that is published on the

SÚKL web page (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague). Nevertheless, this methodology is defining the way of how to control for above stated criteria. The methodology is not stating the chronological order of the criteria among each other (232).

In practice, when the SÚKL experts draft a report, they fill in templates of an internal software for administrative proceedings in medicinal products that are exported with electronic signature in PDF/A format or in the Microsoft Word format and then electronically signed and converted into PDF/A formats. Such documents are then inserted into electronic administrative proceedings files and all the steps of the proceedings inclusively evaluation reports can be seen by anybody holding an electronic signature online through the SÚKL website. An electronic signature (an equivalent of handwritten signature in electronic communication) is a common thing for electronic submissions to or electronic communication with the state administration in the Czech Republic (eGovernment project) in accordance with EC directive 1999/93/EC. The communication to SÚKL is usually done electronically (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague).

Holders of an electronic signature can see all the steps of the procedure. Thus full transparency of the process is granted which is [regarded as being (added by author)] one of the best among the state administration bodies. There is a need to have the full identification of persons entering the electronic files and an electronic protocol is made out of it - this is required by law. On the other hand, SÚKLs decisions (with incorporated evaluation reports) are fully published and they can be seen by anybody via the website of SÚKL (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague). Each individual has even the legal right to get insight into the decisions of the SÚKL (233).

SÚKL publishes an updated list of medicines covered by health insurance together with the maximum price, the possible conditions for reimbursement, and the reference groups and its reimbursement level (234). This list changes each month two times on the first and the fifth working day of a month due to the legal obligation to allow for revision by the producer at the end of each month (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague).

If someone is not accepting the decision, he can make an appeal with the Ministry of Health. The Ministry acts as the second body in appealed cases confirming SÚKL´s decisions or cancelling them and returning them for revision back to SÚKL. The revised decision is again made by SÚKL and possibly reviewed again by the Ministry. Only when an “irregular” revision process of an Ministry decision on the second level is encouraged by a participant to the proceeding (market authorization holder or health insurance company) has the Minister to decide about the motion and whether the Ministry has or has not to revise its decision (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague).

3.2.4 THE ROLE OF VALUE FOR MONEY CONSIDERATIONS

HTA in coverage decision making

The inclusion of benefits and reimbursement rate is not guided by health technology assessments, although certain elements of HTA have been taken over. SÚKL requires indeed the evidence of clinical and cost-effectiveness for pharmaceutical products, as well as calculations regarding the uptake for the budget impact (194). Also when the manufacturer applies for uptake in the fee-schedule called Catalogue of Health Services is he required to submit an evidence-based dossier with data on the efficacy, the comparable technologies, a forecast of the costs for the budget and an overview of international mechanisms for reimbursement (235). Nevertheless, in practice are formal and transparent procedures missing that weight these data during the process of decision making (235).

Although the legislation provides general conditions for using HTA (like cost-effectiveness, quality and safety in health care) (194;236), exist certain barriers for the development of HTA in the new Member States of the EU. This include the incomplete legislation, lack of responsible institutions, short supply of HTA specialists, low training for professionals, paternalistic, authoritative and command-and-control based traditions without trust in HTA, and passive consumers in health care (236;237).

Cost-effectiveness threshold

The Czech Republic is not applying any cost-effectiveness threshold yet and as outlined earlier is the benefit package covering almost each treatment and are only very few limitations made.

The willingness-to-pay is neither implicitly nor explicitly stated (238). This is seen as a shortcoming of the existing law and SÚKL is waiting for a principal case that would be decided by the Ministry of Health as the appealing body at the second level. That decision would have the persuasive power to act as a precedence case, unless a legislative definition is present (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague).

Even though the method [from the WHO] of three times GDP is still considered as one of the options, the establishment of a high cap was suggested, where the most expensive treatment of today would define the limit. As such a benchmark, the treatment of dialysis was suggested and kidney

transplantation is still under investigation, which actually poses similar thresholds as three times GDP. Nevertheless, such a high cap for the most expensive treatment is seen to be better justifiable due to that it is something that is already in place and reimbursed from the public health insurance. A draft of an amendment to the existing Public Health Insurance Act contains the most expensive treatment as such cap recommendation, but it has not been passed through the parliament yet (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague).

Furthermore, an informal working group on WTP was established after a meeting from the Round Table with the presence of Ministry of Health representatives on October 20th to continue analyzing the best option for a WTP setup. The informal working group on WTP found out that the WHO methodology has not been changed since 2002 and SÚKL knows of no evidence in using this method alone in practice. Therefore, an official query to the WHO will be sent out and a further detailed investigation into the Hungarian and Polish approach will be done (MUDr. Mgr. Jindřich Kotrba, Head of the Department for Price and Reimbursement Regulation, State Institute of Drug Control – Interview of May 13th, 2010 in Prague).

Conditional reimbursement

The Act on Public Health Insurance is also stating explicitly health procedures that are reimbursed only under certain conditions (239). Examples for conditions include that the reimbursement is dependent on the diagnosis of the patient, the specialty of the prescribing physician or needs approval by a review doctor of the insurance company (240). A concrete example for conditioned reimbursement is in-vitro fertilization, which must be recommended by a gynecologist and only applies for women between the age of 18-39 (241). A further specification is given through the Catalogue of Health Services. This fee schedule for example specifies further that in-vitro fertilization is only reimbursed up to three times in a lifetime and that spa treatment needs to be indicated and prescribed by a physician. Additional for spa treatment or some dental procedures is the approval of a review doctor necessary, who is working for the health insurance (242).

A special disadvantage of the law in force is that the partial reimbursement up to the level of the standard treatment is not allowed. This fact arose out of good intentions. Until 1997 were health insurance companies allowed to offer additional services that were above the basic coverage (243). But because the insurers were competing for clients by offering services above the basic package that the companies actually could not afford and which lead to rising debts and their inability to cover even

the standard treatment, law-makers decided for these restrictions of reimbursement (244). Since 1997 can only preventive benefits be offered or a patient has to pay the more expensive treatment totally by himself. The before mentioned new laws would have brought a change to this situation (245).

Use of practice guidelines

The Czech Republic is not relying heavily on practice guidelines yet. This development could have been hampered by the fact that a lot of medical associations, who are responsible in other countries for the establishment, were not founded again until the Velvet revolution plus the lack of HTA in supporting these guidelines (22;246).

Another more implicit and decentralized form of limitation is given through the payment of individual providers. Their annual budget is dependent on the collected resources from citizens. The funding of resources is based for almost 80% on income-based contributions, which make the system sensitive to an economical recession (247). When the contributions are decreasing, is the budget for the providers decreasing as well. As a consequence have providers to ration their resources on a secretly and quiet way, based on their opinion of the individual severity of the disease and the necessity for treatment, or even on a first-come first-served basis (248). In the worst case are providers closing their practice at the end of the month because they have used up their budget, as happened in 2006 (249).

Cost-sharing approaches

The Czech Republic is applying three sources for private expenditure: (a) over-the-counter pharmaceuticals and excluded procedures, (b) co-payments on medical aids and prescription drugs that exceeds the reference price of the cluster in the positive list, and (c) user fees for visiting doctors, the prescription of medicines, staying in hospitals and the use of ambulatory services out of standard office hours (250). These cost-sharing approaches have been introduced to reduce the overutilization of health services as well as to save costs. This is because the utilization in the Czech Republic is one of the highest in the WHO European Region and the costs still steadily rising (251).

4 DISCUSSION AND RECOMMENDATIONS

This chapter will discuss the main findings for both decision making systems and place them in an international context when appropriate. Firstly, it is looking on the general introduction and discussion about priority setting. Thereafter comes a comparison of the national decision making systems for inclusion of new benefits, in order to answer the main research question. After that, the sub-question on the role of value for money considerations is addressed. Furthermore, this chapter will point at elements that need consideration from policy makers in the Czech Republic and make recommendations.

At the beginning of this paper was a historical outline given for both countries in the field of priority setting. Both systems have recognized the cost inflation and resulting need for prioritization, although with a delay in the Czech Republic to the time after the Velvet Revolution. Since then is the Czech system marked by following approaches, instead of being on top of the innovations (see Appendix).

In the Netherlands started the discussion about priority setting in the late 1980s to become translated into concrete action and policies. They argue that the access to essential health care can only be assured if certain (unnecessary) care is withdrawn. Nevertheless, the policy on exclusion of certain treatments is shaped by regular changes back into the coverage. This is also related to the fact that explicit priority setting is a continuous process and not responding well to definite 'once and for all' decisions. The metaphor of priority setting being more of a marathon than a sprint seems to be appropriate here (252). Therefore, the differences in the systems cannot be judged in a binary way of good or bad. The differences among them emerged due to historical, political and cultural developments.

Internationally has been a great discussion in other European countries about the quality and efficiency of health care systems, and the specific compilation of the general benefit coverage (253). It is a fact that a lot of committees around the world have given recommendations on national priority setting. Their factual implementation is very low. Reasons are among others: the difficult conceptualization of criteria, the lack of data on effectiveness of interventions, the problem that systematic assessments come to conclusions which have no support in society, the lack of the policy to make decisions based on these assessments, the lack of transparency, and the freedom of actors on the

micro-level who can fill-in decisions which results in differences (254). These factors have to overcome if the prioritization is suggested to be successful.

In the Netherlands tried the Dunning Committee to achieve consensus about the problem of scarcity, priority setting and patient selection in 1991. The debate following this report showed great support from the public for the general need of prioritization. The Netherlands thereafter started discussions, public campaigns and very recently the CVZ initiated debates about health care that is necessary to insure in 2009 (255).

For the Czech Republic, the establishment of the Round Table in 2007 formed a begin for creating awareness of prioritization to a broader audience. This project also promoted a discussion about the funding and future of health care. It is acknowledged in practice and research that HTA is only in that case useful in supporting decision making if the process is carried out on time, the resulting recommendations are used by policy makers and decisions are really implemented (123). If also other stakeholders (insurances, physicians and patients) are not or only on an opportunistic way accepting HTA, its added value is marginally at its best. A substitution effect can occur from non-reimbursed to more expensive but reimbursed technologies, leading to the waste of resources. Thus even when the discussions on priority setting are controversial, is it better to hold an open dialogue for ensuring transparency (256).

Furthermore are there at this moment in time concrete indications that the Czech Republic has no broad societal support for prioritization. Because although the Round Table found the different used methods for prioritization in international context interesting, they highly questioned the portability of these approaches to the Czech Republic, given the historical development, the economic opportunities of the country and most importantly the interests of the involved actors (84).

For the future, the current political changes in the Czech Republic will be interesting to observe. The new government might redefine the basic benefit package and its criteria due to the great discussion about priority setting and the variety of available proposals (Maďarová, e-mail from 08/06/2010, see appendix). Maybe the rejected proposals for new laws from 2008 will be discussed again. The situation of today seems to be highly unsatisfying, with the criteria fragmented and their application difficult to manage. An explicit and unified appearance would support the further discussions on priority setting. The Dutch case shows that the criteria established by the Dunning-Committee were always used as some kind of reference point. Whether the debaters agreed or not, they were at least talking on the same basis and the same assumptions. Moreover, political instability is playing no major role in the Netherlands.

Recommendation # 1: Policy makers wishing to implement HTA successfully need to enhance the acceptance of it by key stakeholders. Discussions are therefore necessary to create societal support and a stronger commitment for the use of HTA by the different stakeholders.

Furthermore, that country that wants to implement HTA in decision making processes needs to ensure a existing structure of priority setting, research facilities and procedures defining the structure and distribution of results (21). For the existing bodies in Central and Eastern Europe is observed that they face the problems of lacking qualified personnel and funds for assessment, mainly because their establishment has no long history (257).

Without the use of a method like HTA is the inclusion of new benefits at risk of being highly influenced by social, financial, professional and institutional factors (22). The Dutch case shows that the influence from the lobby of interest groups, media and the pharmaceuticals industry were in the past much stronger than hard facts like cost-effectiveness data. As a result, resources were not used in the best way (23). Furthermore, the process of priority setting is to some degree open for technical manipulation by governments and pharmaceutical companies through determining the methods used for calculating costs and benefits. International experience shows for example in Great Britain, that all approvals to NICE (the responsible HTA body) cost a maximum of GBP 30,000 per QALY, because this is the unspoken threshold limit used (258).

The ambivalent role of the pharmaceutical companies towards economic evaluation can also be seen during the last decades in the Netherlands. A paper from the year 1997 reported that the pharmaceutical industry is heavily supporting the conduct of economic evaluations. Their main reasons for doing so would be that they want to be prepared for discussions with the government about the pricing and reimbursement of their products, and because they can use the results from independent research for the marketing of their products to prove the good quality or even superiority of their products (259). Nevertheless, a more recent document from 2006 states that it can be observed that in the Netherlands the pharmaceutical companies would have no interest in doing research about the cost-effectiveness of their products in the care sector (260). Reasons are not stated but could be found in the fact that the thought stronger position in negotiations with the government was not met and in the fear of the real practice of exclusion. But the pharmaceutical sector can also profit from the establishment of HTA-institutes. In Great Britain was one of the reasons to set up the HTA-institute NICE because the uptake of new provisions had been to slow, although there was sufficient data available regarding the clinical effectiveness and cost-effectiveness (261).

With this background information, the found information in the results chapter can be placed in context. This seems necessary to explain the differences between both countries. At the beginning, the main research question was tried to answer, which was formulated as 'how are decisions made on the inclusion/ uptake of new provisions in the benefit package in the Netherlands and the Czech Republic.'

Institutional configuration of decision making

The systems for decision making and the policy environments in the Netherlands and the Czech Republic share a certain degree of similarities and differences (see also table 2 in the appendix). Both countries have established regulatory authorities that register new pharmaceutical products and their ingredients with respect to the three conditions of quality, efficacy and safety. This is in line with all OECD countries (262). Moreover, the EU is harmonizing the test requirements between Member States to guarantee a high level of protection for the public health (27). A difference regarding the market authorization is only found in the time when the institutes were assigned with their task. The Dutch CBG was founded in 1963 as a response to the thalidomide-drama, while the Czech pendant was founded already in 1918 and later reorganized into the current organization in 1952.

Both countries use closed national formularies to define the benefits that are eligible for reimbursement. Again, the point in time of establishment differs: the Netherlands established its list in 1991, the Czech Republic its in 1995. The formulary of the Czech Republic is further separated due to recent changes in responsibility of the involved authorities. The application of a positive list as a fee-schedule is overlaying the other two lists. In general were selected lists implemented throughout Europe with little consistency (263).

Recommendation # 2: The application of three positive lists in the Czech Republic is not promoting transparency. Policy makers should consider merging the two separated lists for pharmaceuticals and medical devices under one authority.

The reference baskets differ due to the different economical powers and the comparability of the countries in the basket to the related country.

For setting the reimbursement limit apply both a reference pricing system and for defining the maximum price of individual pharmaceuticals are both relying on international price comparisons. Their effect was visible in both countries. As a result of the reference pricing and international price comparison decreased in the Netherlands the average price of pharmaceuticals by 8 % between 2007 and 2008 (116). The share of pharmaceutical expenditure on the total health care expenditure was only about 11% in 2007, after it had risen from 9 % in 1980 to 15 % in 2000 (88). In the Czech Republic helped the reference pricing system to slow the growth in pharmaceutical expenditure to around 10 % since 1996, where it has been 39 % in 1994 and 43 % in 1995 (264). The total pharmaceutical expenditure is still high with about 21 %, mainly due to a overutilization of pharmaceuticals and the use of more expensive new drugs (265). Nevertheless, the pharmaceutical industry is misusing these approaches of cost containment. For example was in the Netherlands observed that during short time the prices of drugs below the reference price were raised to this limit, and in some therapeutic clusters were the cheapest drugs withdrawn from the market (90).

The most evident difference between both systems is found in the competence of the relevant bodies concerned with the assessment of new provisions, namely the CVZ and the SÚKL. While SÚKL can be classified as a regulatory body, the CVZ is an advisory body. SÚKL is responsible for the registering of drugs, setting maximum prices and reimbursement limits and taking the final decision for uptake. The CVZ on the other hand is only advising about the content of the benefit package. The registering of drugs is done by another institute (the Board for the Evaluation of Drugs, CBG), maximum prices are set by the Ministry of Health and the final decision for uptake is made by the Minister of Health. He (or she) heavily relies on the advice of the CVZ and is also overseeing the appraisal process (109). In the Czech Republic is the Ministry of Health overseeing the process only in appealed cases. It then has to confirm or cancel the decision made by SÚKL.

This concentration of power in the case of SÚKL is at least controversial. The institute registers drugs for which it decides about the uptake and associated with that the prices and reimbursement limits. To prevent malpractice are all decisions made in a transparent way and can be freely assessed on the website. This is in line with the Transparency Directive of the EU and true for both states. The reason for taking the pricing and reimbursement out of the hands of respectively the Ministry of Finance and Health in the Czech Republic was exactly to ensure this: the transparency in the process of uptake.

Looking at the international level, it is already uncommon that the registration and reimbursement of drugs are found in the same institution (245). The practice of establishing an executive body is even more interesting when looking at other countries of Central and Eastern

Europe. Although not all countries have established a HTA body, those who are discussing about it or where they are under development consider mostly an advisory role for them (75). The reform in 2008 was thus an exception from this trend in that area and its sustainability might be reconsidered.

Recommendation # 3: The concentration of the whole process of uptake and registering from drugs at the State Institute of Drug Control, who also sets the prices, is at least controversial. Policy makers should consider a separation of these processes in different and from each other independent bodies.

Decision making criteria on the uptake of new provisions in the benefit package

The used criteria for decision making about the uptake of new pharmaceuticals show in both countries a high degree of similarity. Both state explicitly the criteria of necessity, effectiveness and efficiency. As an explicit criterion is the Netherlands also taking the affordability into account, while the Czech Republic names safety. Remarkably are both countries also stating the opposite factor in a more implicit way. But if an explicit framework is stated, priorities can not only be seen because more important is the transparency in trade-offs. Priority setting rests on decisions made by evidence, and with the help of an explicit framework can decision makers be held accountable for their decisions (252).In general is the Dutch system more concrete and explicit in defining criteria while the Czech criteria are more fragmented and judged to be ad hoc and difficult to manage.

The Dutch criteria are further also applicable for the whole benefit package, while the Czech criteria are only regarding pharmaceutical products. Criteria for medical devices are only implicitly formulated in that they need to maintain or improve the health of insurance holders. Furthermore is SÚKL controlling medical aids on their safety, quality and rational use. It is noticeable that the Czech criteria for pharmaceuticals are formulated in a negative and excluding way, while the Dutch criteria are stated in a positive and inclusive way. It is misleading that the criteria are stated in a negative and exclusive way for a list that is meant to be a positive formulary. This would have changed in the Czech Republic by the proposals of new laws from 2008, which did not pass the parliament. Instead, the criteria defined by an act from 1966 are still valid with amendments through the Act on Health Care Insurance.

Recommendation # 4: The Czech Republic should think about naming the criterion affordability explicitly. Furthermore does it seem to be more appropriate to formulate the criteria for the positive list in a positive way. And policy makers in the Czech Republic should consider establishing criteria that are valid for the whole benefit package.

Decision making process of uptake from new pharmaceuticals in the benefit package

A very important difference between both countries lies in the use of HTA in supporting decision making. It should be obvious by now that the Netherlands are applying a system that can be characterized as at least more complex than that of the Czech Republic. In the Netherlands is the process of making coverage decisions subdivided into four parts: the two phases of HTA (a more quantitative assessment and a more qualitative appraisal phase), the succeeding administrative part from the Board of Directors and finally the ministerial decision making. The division into an assessment and appraisal phase is characteristic for countries that use HTA as a method for controlling the benefit package (15). This explicit use of HTA is missing in the Czech framework, while the lack of a ministerial part is not considered as being a disadvantage for an executive body.

More complex does not necessarily mean advanced. Nevertheless, the practice of establishing HTA as a supporting tool was done in many European countries in the past because it is widely acknowledged for its ability to identify efficient, effective and high quality health provisions (14-15). The first country to begin in Central and Eastern Europe was actually Hungary in the early 1990s (14). But it is an important fact that even countries without the formal application of HTA are relying on informal programs or practices (14). The use of economic evaluations and budget impact analyses is implemented in their decision making, like it is also done in the Czech Republic.

More problematic is that many countries rarely specify explicitly the relative importance and weight of the criteria used for recommendations, especially in the case of societal and non-quantifiable elements. Instead, the importance of efficacy and cost-effectiveness is stressed for the final decision making (39). This seems also to be true for the Czech Republic, as the considerations on societal factors in the decision making are rarely found.

Nevertheless, also the Dutch practice of assessing new benefits knows its limitations and critics. For example is there also the fear from people of reducing incalculable values (like solidarity, responsibility, equality and security) to monetary terms. The CVZ is not denying the importance of economical data, but it emphasizes the crucial role of social desirability for the uptake of benefits

through the appraisal phase (112;113). This can also be seen in its recent attempts for letting societal factors play a more vital role, like the establishment of the ACP, the participation of stakeholders during different moments in time and the integrally approach. Furthermore, the Minister of Health has the discretionary power to evaluate the advice of the CVZ with regard to the importance of public health and the public interest. The final decision making lies in his person and he can therefore explicitly balance the cost-effectiveness and the severity of a disease against the public desire (266). The functioning of this system has been approved in Great Britain that have a similar system as the Netherlands and where the Minister of Health approved two medicines out of social reasons, which had gotten negative recommendations from the British national assessment body NICE (267).

Another negative aspect of the Dutch system comes from this appraisal procedure. Because by letting societal values weight a decision, the decision seems to return from an explicit priority setting on objective facts to implicit prioritization. Where a more explicit policy approach was sought and would be needed is the decision making again getting more implicit. Nevertheless, sufficient explicit approaches are still underdeveloped and hard to establish that fulfill to achieve the aims of objectivity and explicitly (258). This is also due to the fact that it is unknown for a lot of therapies and interventions whether they work at all (268). Therefore it is said that an adequate and appropriate explicit decision making on priorities is almost impossible to achieve at this moment.

The RVZ is comparing this situation to the times of the Beaufort Wind Force Scale. Today, this scale is indeed very rough. But in the past times, it helped to survive a lot of seamen (175). The use of HTA in an explicit decision making system might not help survive individuals (as the Wind Force Scale did for seamen), but it can help support decisions that decide about the survival of the health care system by being sustainable and making efficient use of scarce resources.

In conclusion, the Dutch framework has its limitations but is advanced in comparison to other European countries. A good cooperation between the field of science and policy is important to overcome limitations in practice by solutions provided by theory. For example, in the Netherlands is the responsible HTA-body CVZ closely cooperating with researchers in Rotterdam (269).

Recommendation # 5: Given the high overlap of used criteria in the procedure of uptake, which are embedded in HTA for the Netherlands but not the Czech Republic, should be considered to introduce HTA in the Czech Republic. The involvement of from SÚKL independent external experts into the process seems promising, when looking at the committees in the Netherlands. The Czech Republic should even consider to set up an independent research institute for HTA, as it is done already in a lot of other countries in Central and Eastern Europe.

Next to the general decision making on the inclusion of new provisions, the sub-question is answered that was formulated as 'which role, if any, would considerations of value for money play in the decision making process'. The compared parts here are the use of HTA, the establishment of a cost-effectiveness threshold for defining a society's maximum willingness to pay per QALY, the practice of conditional reimbursement, the use of practice guidelines and cost-sharing approaches.

The considerations of value for money

Value for money considerations play an equal role in both countries. As outlined earlier is HTA playing a greater role in the Netherlands than in the Czech Republic. Because it consumes many resources to evaluate each provision of the whole benefit package, the translation of foreign studies was suggested. This possesses problems as economical data is often context-specific and cannot be easily transferred between countries (257). One solution to this issue could be a closer international cooperation that aims at sharing resources (270).

Another difference lies in the use of a cost-effectiveness threshold. The CVZ in the Netherlands has recently published an unbinding explicit threshold ranging from EUR 10,000 for mild and EUR 80,000 for severe diseases per QALY. These values come close to that earlier recommended by the RVZ, who took a variety of considerations into account, among them the approach of the WHO and the value of a statistical life. In the Czech Republic is no explicit threshold stated but a discussion ongoing about implementing one. It is unclear whether the Czech Republic has taken methods like the league table approach or the preference-elicitation approach into consideration. The approach of taking three times the GDP as the threshold was found to be not applicable in the Czech Republic. Instead, a high cap at the level of the most expensive treatment was suggested. That would be dialysis or kidney transplantation, which almost comes near to the rate of three times GDP (MUDr. Mgr. Jindřich Kotrba – Interview of May 13th, 2010 in Prague). Although those countries in Central and Eastern Europe, that apply HTA, are concerned with this issue has as of 2009 none an explicitly stated threshold (257).

Although the reader might have gotten the image that the exclusion of certain care is the only way of prioritization, is the question for inclusion not binary. The conditional reimbursement of care under certain circumstances can be a much more appropriate approach to keep the health care system sustainable by providing a broad package of health care in high quality and for all in need accessible. Both countries apply this method of conditional reimbursement, with the difference that the Netherlands are in addition to the Czech Republic also relying on treatment protocols and guidelines as a condition. These guidelines indicate which care is the most appropriate form of care for certain

patients and in doing that they harmonize the heterogeneous views on effectiveness and necessity (256). For decision makers seems the use of HTA more likely in the case that there are policy instruments established like practice guidelines and the commitment to use them (271).

Although the Czech Republic is not relying heavily on guidelines yet, they apply also a form of decentralized rationing by health care providers. They have to ration their resources on a secretly and quiet basis without evidence-based guidelines, relying on their own opinion of the severity of a disease and the necessity for treatment. On this way is the topic of rationing disappearing from the visible surface (256). This issue is arising due to the financial dependency of the providers' budget from the overall economy, which is related to income-based contributions and makes it vulnerable in economical recessions. The dislike about this situation was shown in 2006 when providers closed their practice at the end of the month. It is highly questionable to leave rationing at actors without supporting them by evidence-based guidance, as is the current mode of funding.

Furthermore is the partial reimbursement having unintended effects in the Czech Republic. They were restricting this type of reimbursement, that refunds higher treatments only up to the most favourable provision that is fully covered, because the government wanted to ensure that health insurers can pay for basic provisions and do not offer advantageous treatments to attract clients but which they cannot really afford. Since 1997 is thus the partial reimbursement not allowed which poses to be a big disadvantage in the Czech Republic.

Apart from that is the Czech Republic more focused on introducing cost-sharing approaches to reduce the overutilization, which is one of the highest in the WHO European Region (251). The introduction of co-payments in 2008 was successfully implemented but controversial. Thereafter has the share of private expenditure been increasing (272), while the out-patient visits decreased with 15 % and the number of emergency department visits with 35 % (251). But more important is the re-allocation of resources. Although the overall expenditure for pharmaceuticals did not change, so did their allocation. Drugs that cost less then CZK 60, which would be equal to the fee for visiting a physician and receiving a prescription (both CZK 30 each), are now privately paid. This publicly saved money can then be used for the reimbursement of more expensive drugs (251).

Recommendation # 6: It should be considered to establish evidence-based guidelines that explicitly support physicians in their treatment decisions by formulating which care is the most appropriate form for which patients group. In this way, heterogeneous views on effectiveness and necessity are harmonized. Moreover, the Czech policy on partial reimbursement should be considered to change.

It would be easy to conclude that the Netherlands cannot learn anything from the Czech Republic, given their advance and forerunning. However, I believe that the Netherlands might learn from observing the Czech Republic, especially in two respects.

Recommendation # 7: An interesting difference regards the temporary admission of innovative drugs. This instrument is in the Czech Republic already established while the Netherlands are still considering it. Only for the in-patient sector are temporary admissions allowed with conditions.

Recommendation # 8: The practice of introducing co-payments for freeing resources to fund more expensive health care technologies should be taken into consideration by Dutch policy makers.

In general should two factors be taken into consideration. First, prioritization is a learning process with incremental improvements. Small modifications have to be made, as the metaphor suggests of a marathon instead of a sprint. A universal golden standard for all countries is not existent (273). Second, it can be argued that all efforts for cost containment are only as serious as the public and the political support would allow them to be (274). If an explicit framework is stated, priorities can be seen but more important is the transparency in trade-offs. Priority setting rests on decisions made by evidence, and with the help of an explicit framework can decision makers be held accountable for their decisions (252), which is not always in their best interest. These are important facts to bear in mind that also apply to these two countries.

Shortcomings of this paper

This research was not looking at in-patient pharmaceuticals and generics and made no explicit distinction between cure and care. The lack of the author to understand in an appropriate way the Czech language might have been a barrier to access certain documents. Nevertheless, this bottleneck was tried to handle with the help of interviews and by the use of up-to-date information in English. Another shortcoming is that there was no time for an interview with responsible persons from the Netherlands. But because their situation was much better documented in a language that the author understands without problems, this should not have a too big impact on the work at hands.

Appendix

APPENDIX A: Table 1 – General description of both countries

APPENDIX B: Outline of the national histories in health care policy

APPENDIX C: Table 2 – The focus of national health care policy

APPENDIX D: Timeline of events in the recent history of health care

APPENDIX E: Table 3 – Comparison from the main elements of decision making

APPENDIX F: Interview Mgr. Daniela Rrahmaniová and PharmDr. Marcela Heislerová, Ph.D.

APPENDIX G: Interview MUDr. Mgr. Jindřich Kotrba

APPENDIX H: Email correspondence with Mgr. Henrieta Maďarová, MS.

APPENDIX A: Table 1 – General description of both countries

Table 1 - General description of both countries for latest available data (WHO 2007, unless other stated)		
	Czech Republic	The Netherlands
Citizens (in millions)	10,429,692 (2008)	16,524,296 (2008)
Real GDP (US$ PPP per capita)	22,004 (2006)	36,099 (2006)
Total health expenditure (% of GDP)	6.8	9.8
Public expenditure on health (% of GDP)	6.3 (2005)	6.0 (2005)
Total pharmaceutical expenditure (% of total health expenditure)	21.05.10	11.0
Public pharma. expenditure (% of total pharmaceutical expenditure)	66.0	83.1
Pharmaceutical expenditure (US$ per capita)	349	422

Table 1 gives an indication of the general conditions in both countries. A lack of this table is the differences in time on some parameter and that they do not measure recent reforms. But a global picture can be gained. The Netherlands has a bigger and richer population than the Czech Republic. The Total health expenditure is three percent higher in the Netherlands than in the Czech Republic, although the utilization in the Czech Republic is one of the highest in the WHO European Region and the costs still steadily rising (251). But of course is a higher total expenditure nothing saying about the efficiency of a health care system. The Public expenditure on health is in both countries comparable. The Total pharmaceutical expenditure is almost twice as much in the Czech Republic as it is in the Netherlands, which is a true sign for the overutilization of pharmaceutical products. Surprisingly is the Public pharmaceutical expenditure lower in the Czech Republic than in the Netherlands. This means that the private expenditure is higher in the Czech Republic than in the Netherlands. These data is not taking the Czech co-payments reform from 2008 into its consideration. Thus must the explanation lie in the fact that the Czech population consumes more not-prescribed over-the-counter drugs and medicines that exceed the reference price level and therefore require a co-payment. The Pharmaceutical expenditure per capita lies at USD 349 per capita for the Czech Republic compared to USD 422 per capita in the Netherlands. This gap is not very high and lies compared to the EU in the middle of the range. This value confirms that the Czech Republic is spending much money for drugs.

APPENDIX B: Outline of the national histories in health care policy

The Netherlands

The Netherlands health care system is based on the Bismarckian model. After its introduction in 1941 was almost two-thirds of the population insured. The focus of the health care policy underwent substantial changes during the last decades. From the beginning of the 20th century until the 1970s aimed the government to ensure a certain minimum of quality (e.g. by professional licenses). During the 1970s and 1980s was the guarantee of universal access to health insurance the main objective. In the 1980s shifted the emphasis to cost containment, due to the observed cost inflation (275). But the cost containment led to a rising tension between ensuring the universal financial and physical access to health care services. Financial access means that no rationing by price is done, while physical access means that no rationing by quantity is applied (276). Increasing waiting lists and lack of medical personnel showed a threat especially for the physical access. A way to improve both the universal financial and physical access was found in an increased efficiency of the health system. Another way would be to terminate unnecessary, ineffective, inefficient or 'easily affordable care' from the social health insurance coverage (276). This was recommended by the Government Committee on Choices in Health Care in 1991. So finally is since the mid-1990s the improving of the responsiveness and efficiency of the health care system on the political agenda (275,276).

Another cornerstone was the introduction of one single general insurance scheme for all residents in 2006 (277). This reform replaced the dual insurance system and it ideas can be traced back to the advisory report of the Committee on the Structure and Financing of Health Care in 1987 (16). Next to one compulsory insurance was also the idea of a regulated market competition included. In this way the government tries to establish more distance between itself and the health-care funding through deregulation (277,278). This does not imply that the state should do completely nothing. Rather it meant stopping a too intensive interference while keeping the responsibility for the overall strategy and progress monitoring in the hands of the state (279). To prevent undesired market effects were “watchdog” agencies (like the Dutch Health Care Authority, NZa) installed (280). The new system is further characterized as being demand-induced and patient-centered (281).

The Czech Republic

The Czech Republic was in the late 19th century part of the Austro-Hungarian Empire and its health care system was also based on the Bismarckian model. Characteristic for it was a compulsory health insurance that had been expanded over the first decades on the ratio of solidarity (282). After the Second World War followed four decades of communist rule which established a centralized and universal health care system (283). The performance of the new system's quality was rapidly decreasing over time due to its inflexibility and centralist design (284). The whole economy was facing the problem that the supply did not correctly reflect the actual need of the people (285). For the health care sector meant this that the system was incapable to adjust itself to a changing demand due to a changing structure of diseases, mainly caused by the lifestyle (286).

After the Velvet Revolution in 1989 turned the economy away from central planning to market liberalization. The health care system was reformed again according to a Bismarckian type of social health insurance (287). This reform included the introduction of compulsory membership in a health insurance fund, the transformation from an ineffective command-control to privatization and deregulation, and an increase in free choices for patients (287,288).

During the early 1990s was the health expenditure rising steadily and started the attention for cost containment (289). Along with the growing pharmaceutical expenses have purchases of medical equipment been rising between 1991 and 2001. The number of computerized tomography scanners rose from 22 to 117, whereas the necessity of these purchases remains unclear (290). Nevertheless are changes in the health legislation only slowly introduced, e.g. is the Act on Care for People's Health from 1966 valid up until today, although amendments have been made and almost 40 percent of its paragraphs have been repealed (291).

Due to the high overutilization of health services is efficiency a concern since the last few years (292). Remarkably is the introduction of cost-sharing in 2008 (293). Each patient has to pay 30 Czech crowns (about 1.20 Euro) (294) for a visit to the doctor or for a prescription, 60 crowns for each day of hospitalization and 90 crowns for an emergency room visit. 57 % of the prescribed drug packages do not require any co-payment, except for the CZK 30 user fee (295). Nevertheless, for the main population has health care always been free of charge (296).

APPENDIX C: Table 2 – The focus of national health care policy

Table 2 - The focus of national health care policy (HsiT, both countries)		
	The Netherlands	The Czech Republic
Quality	till 1970s	till 1990s
Universal access	1960s till 1980s	1940s
Cost containment	1980s	1990s
Efficiency	1990s	2000s

In the Netherlands was quality in the focus till the 1970s, e.g. through professional licensing. As could be assumed was quality a major concern in the Czech Republic until the new state of the Czech Republic was founded in 1993.

The universal access was established in the Netherlands with the introduction of the Exceptional Medical Expenses Act [Algemene Wet Bijzondere Ziektekosten, AWBZ] in 1967 and the Health Insurance Access Act [Wet op de toegang tot ziektekostenverzekeringen, WTZ] in 1986. In the Czech Republic was the universal access already guaranteed since 1948 when the communist principles were adopted.

The need for cost containment began to rose in the Netherlands during the 1980s when the health expenditure was rapidly growing. In the Czech Republic rose this awareness after the Velvet Revolution in 1989, when the liberalization allowed the costs to become more prominent and reach the focus.

Finally, efficiency is a concern in the Netherlands since the 1990s when the improvement in efficiency was seen to be a valid solution for the problem of guaranteeing universal financial and physical access. In the Czech Republic is the health care policy focused on cost containment since the 2000s, with a remarkably cornerstone in 2008 when co-payments were introduced.

APPENDIX D: Timeline of events in the recent history of health care

Timeline of events in the recent history of health care (Author's own work, based on earlier stated sources)		
The Netherlands	**Year(s) of event**	**The Czech Republic**
	1918	Institute for the Examination of Pharmaceuticals
	1952	State Institute of Drug Control
EU accession	1957	
Board for the Evaluation of Drugs	1963 Thalidomide drama	
	1966	Act on Care for People's Health
	1982 US renal dialysis for threshold maximum willingness to pay	
Dekker-Committee	1987	
	1989 Transparency Directive	Velvet Revolution
Dunning-Committee Positive list (GVS) Reference pricing	1991	
Begin of exclusion	1993	
Exclusion of all innovative (out-patient) drugs	1993-1998	
	1995	Reference pricing introduced First positive list
International price comparison	1996	
	1997	48/1997 Act on Public Health Insurance

CVZ is the legal predecessor of the ZFR	1999	
	2002 WHO	
Negotiations introduced	2004	EU accession
Use of cost-effectiveness mandatory	2005	
Universal health insurance Health Insurance Act/ CVZ	2006	Closed practices
Act on Medicines	2007	Act on Pharmaceuticals
	2007-2009	Round Tables
ACP founded for more societal implications First package-scan for diabetes	2008	Introduction co-payments SUKL new competencies Proposals for new bills International price comparison
CVZ established CE-threshold of EUR 10,000 to EUR 80,000 Discussions started about necessary to insure health care	2009	
Full exclusion of oral contraceptives	2010	Legislative elections

This timeline shows all mentioned dates of the paper. Next to the dates that can be connected to one of the countries are also events concerning both states added in the central line.

There are a few remarkable events that should be pointed out. The foundation of the Board for the Evaluation of Drugs was in 1963 after the thalidomide-drama, while the first Czech Institute for the Examination of Pharmaceuticals was founded in 1918 after World War One. A reference pricing system and the first positive list were established in the Netherlands in 1991, in the Czech Republic four years later in 1995. Furthermore, the International price comparisons were introduced in the Netherlands in 1996 and in the Czech Republic 12 years later at 2008. The last comparison regards the use of HTA in reimbursement decision making, which was introduced in 1999 in the Netherlands and is 11 years later still not introduced formally in the Czech Republic.

APPENDIX E: Table 3 – Comparison from the main elements of decision making

Table 3: Comparison from the main elements of decision making (own work)		
	The Netherlands	**The Czech Republic**
Institute that registers drugs	CBG	SÚKL
Registering criteria	Quality, efficacy, safety	Quality, efficacy, safety
Prices set by	Ministry of Health	SÚKL
Price setting method	Positive list, reference pricing	Positive list, reference pricing
Pharmaceutical evaluation ('assessment body')	CFH (CVZ)	SÚKL
Formal decision making authority	Minister of Health	SÚKL
Type of assessment body	advisory (gives recommendations)	regulatory/executive (makes decisions)
Explicit decision making criteria	Necessity, effectiveness, efficiency and feasibility	Necessity, effectiveness, efficiency and safety

This comparison shows the concentration on SÚKL in the system of the Czech Republic. Where in the Netherlands four different parties are involved, are in the Czech Republic only one institution responsible for all of the tasks.

From the comparison of criteria can be seen that their exists a great overlap between both countries. Only feasibility is not explicitly stated in the framework of the Czech Republic.

APPENDIX F: Interview Mgr. Daniela Rrahmaniová and PharmDr. Marcela Heislerová, Ph.D.

Department of Pharmacy in the Ministry of Health on March 31th, 2010

This interview was planned with a semi-open structure and an explorative character. As this interview took place around one and a half month after my arrival did I know already some information about the Czech situation beforehand. That is the reason why some questions are already quite detailed. The beginning formed a general introduction by Mgr. Daniela Rrahmaniová and PharmDr. Marcela Heislerová, Ph.D. on the pricing and reimbursement policy of pharmaceuticals in the Czech Republic. A lot of my answers were answered during this part while others arose. Especially identifying out-dated information was useful in this part. The interview lasted for approximately one hour at the Department of Pharmacy in the Ministry of Health. The interview was disturbed only once for a short time because my interviewees asked a colleague about some technical terms and their translation in English. During the interview I made sketchy notes while I was listening and answering questions back to ensure the right understanding. Immediately after the interview was I re-writing my notes at my office. The initial questions I wanted to ask are listed down here. Some of the questions listed were not answered and I was directed to talk to someone from SÚKL, who would be able to give more reliable information on that topic. That is the reason why these questions will also appear for the following interview partner.

1. Is priority setting done in the Czech Republic? If yes, how is it done?

2. Which criteria are defining the basic benefit package?

3. Does the Czech Republic apply a positive or negative list (or both) for its provisions?

4. Do considerations of value for money play a role in the decision making process? If yes, which role and which considerations?

5. Has the Ministry of Health (or SÚKL) stated a maximum willingness to pay for a QALY (e.g. three times GDP)?

6. How is the project going to set up a HTA institute? [This was a misunderstanding from my side. There are only plannings for a project to set up a HTA institute, but no concrete institute yet. Both interviewees were surprised about this question that suggested the establishment of such an institute already.]

7. Would there be some infrastructure available for conducting HTA and economic evaluations (e.g. at SÚKL)? [I have to admit that at the time of this interview I was not fully aware of the full competencies of SÚKL]

8. How is the acceptance from the people for the already done changes in the system? How will the acceptance be for priority setting? [This question was aiming at the fact that the people of the Czech Republic were used for decades to obtain their health care for free, while a paper from Madarova suggested that there would be great consensus for changes in Health Care]

9. For setting maximum prices are international price comparisons made. What are the countries of comparison and why were they chosen?

10. In the reimbursement list of SÚKL is stated that one drug is reimbursed in every group. How are you defining the reimbursed one?

11. Is the reason for the rising health expenditure and especially drug expenditure found in importing more expensive foreign products? [This was suggested in a paper from Prokes]

12. Does the categorization committee at the Ministry of Health still exist? And if so, what is its task nowadays? [aiming at a possible supervisory task, but the committee stopped to exist after SÚKL took over the responsibility from the Ministry]

APPENDIX G: Interview MUDr. Mgr. Jindřich Kotrba

Department of Health Care and Health Care Insurance in the Ministry of Health, my office, on May 13th, 2010

This interview was also planned with a semi-open structure and had an informative character. At the time of this interview was the paper already in an advanced stadium. The questions were used as a guidance for the interview. Again was also out-dated information identified. The interview lasted for approximately one hour at my office in the Ministry of Health. The interview was disturbed only once for a short phone call by my interviewee. I used that time to complement my notes, which I again made only in a sketchy way. Again was I immediately after the interview re-writing my notes at my office. The initial questions I wanted to ask are listed down here. Some of the questions listed were not answered and became obsolete. I was using the information from this interview as quotations throughout the assignment. I asked Mr. Kotrba for authorization and he made amendments by email.

1.A Which criteria are defining the basic benefit package?

1.B How is defined which pharmaceutical is reimbursed?

1.C Is priority setting done in the Czech Republic? If yes, how is it done?

2. Do considerations of value for money play a role in the decision making process? If yes, which role and which considerations?

3.A Has the Ministry of Health (or SÚKL) stated a maximum willingness to pay for a QALY (e.g. three times GDP)?

3.B Is there research conducted about an unofficial maximum willingness to pay per QALY for the Czech Republic?

4. Which role play economic evaluations for the reimbursement system of the Czech Republic?

5. Who makes the last decision? Is that still officially the Minister of Health?

6. How much time is available for SÚKL to assess a proposal for a new pharmaceutical?

APPENDIX H: Email correspondence with Mgr. Henrieta Maďarová, MS.

First email from 12/06/2010:

Dear Frank,

see my answers below in capitals,
best regards,

Henrieta

Original Message from 09/06/2010:

[Introduction]

> My question therefore is: may I use your answer to my email, as well as the document for the think tank Timbro, as a source for my paper [underlining by author!]? It would be a great help as they are explaining factors that are not mentioned elsewhere (in English at least).

YES, YOU CAN USE THEM.

> If it is not to much effort I would also appreciate to receive a copy of these proposals. Although they are only in Czech, I will have the important parts be translated.

SEE THE ATTACHMENTS, IN DOCUMENT 1, IN PARAGRAPHES 63 TO 68 YOU FIND THE DEFINITION OF ENTITLEMENTS, THE FOLLOWING PARAGRAPHES SPECIFY SOME OF THE RIGHTS AND OBLIGATIONS OF HEALTH INSURANCE COMPANIES AND INSUREES CONCERNING THE CONSUMPTION OF THESE ENTITLEMENTS DOCUMENT 2 CONTAINS MORE PRECISE SPECIFICATION OF THE SCOPE OF SERVICES

COVERED - E.G. LIST OF SERVICES EXCLUDED, LIST OF SERVICES COVERED ONLY UNDER CERTAIN CIRCUMSTANCES, ETC.

DOCUMENT 3 CONTAINS THE EXPLANATORY NOTES - FIRST PART IS GENERAL, THE SECOND PART CONTAINS EXPLANATORY NOTES TO EVERY PARAGRAPH

>

> I have further one last question: when you say that "There is a lot of discussion about it and many proposals is on the table." do you mean that there are other proposals then these three taken into consideration? Is that somewhere stated so that I could read the ideas for proposals?

AT THE MOMENT THE COALITION IS BEING CREATED SO IT IS UNCLEAR WHAT WILL BE THE CONSENSUS. THREE PARTIES ARE INVOLVED, YOU CAN FIND THEIR PROGRAM CONCERNING HEALTH CARE HERE.

SORRY, AGAIN ONLY IN CZECH.

- ODS: http://www.ods.cz/volby2010/reseni-pro-moderni-a-vstricne-zdravotnictvi.html
- TOP 09: http://www.top09.cz/proc-nas-volit/volebni-program/volebni-program-2010/?clanek=1355
- Věci veřejné: http://www.veciverejne.cz/program-vv-zdravotnictvi.html

MORE WILL BE KNOWN FROM THE GOVERNMENT MANIFESTO WHICH WILL TAKE TIME TO PREPARE AND HAVE APPROVED

[Greetings]

Second email from 08/06/2010:

Dear Frank,
See my answers in the bold below.
Sorry for the delay.
Best regards,

Henrieta Madarova

Original Message from 31/05/2010

[Introduction of myself and reason for writing.]

First of all it would be interesting to know, whether the proposed changes in the law were accepted or not. I could not find any answer to this question.

The proposed law were not approved. In the meantime, there were elections in Czech Republic (weekend 28-29 May) and the coming government might go into redefinition of BBP. There is a lot of discussion about it and many proposals is on the table.

Secondly, I asked myself about the definition of the basic package (according to your article are these for health services: responsive to health needs of patients, based on latest medical knowledge and provided in compliance with cost-effective utilization of health system resources), where I could find them specifically? I was unable to find them in the bills, maybe you could send me a paragraph or point to me at which law I should look at?

These were the proposals in the new bills that were not approved as I have mentioned. If it is helpful for you, I can send them to you but I have them only in Czech.

Furthermore, this seem to be only the reimbursement conditions for health care services. I found other conditions only for drugs in § 15 (5 & 6) of the Law 48/1997 on Public Health Insurance, and of course § 39. Are there no general criteria which define the whole benefit package as such, containing both drugs and services?

Enclosed I am sending you the document that I have prepared for the Swedish think tank Timbro which also contains descriptions of BBP in Czech republic

Also I am sending you the link to the most up-to-date report of WHO about Czech republic – Health in transition 2009 which might contain some information http://www.euro.who.int/en/where-we-work/member-states/czech-republic

[Greetings]

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