Rationalisation of
Pharmaceutical Spending in
Hungary

THE IMPLEMENTATION OF PHARMACOECONOMIC EVALUATION IN THE DECISION-MAKING PROCESS OF REIMBURSEMENT OF MEDICINES

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I. Introduction

In my proposed research I wished to analyse the Hungarian pharmaceutical policy from its rationalisation process point of view. Owing to the limitation of the research under the wide range of policies that are meant under the rationalisation of pharmaceutical policy term I focused on the introduction of pharmaco-economic analysis into the decision-making process on reimbursement of medicines. In the first part of my research paper I plan to provide short background information of my proposed research. This includes the description why health and health policy is an important issue in Hungary and why pharmaceutical policy can be regarded an important health policy issue. This introduction is going to be followed by the detailed description of the suggested research topic, the applied methodology and results.

I.1. Health of the Hungarian population and response of Hungarian health policy

I.1.1. Health of the Hungarian Population

In this part I plan to review the literature about the health status of the Hungarian population and also the response of Hungarian health policy. By undertaking this I wish to argue that health is an important matter in Hungary and Health policy has a significant potential to influence health of the population to a great extent. I also wish to prove that pharmaceutical policy is an important part of health policy and a potential area of health policy research and analysis.

Health of the Hungarian population is among the worst in Europe. The reasons of this unfavourable health status have been the subject of extensive public health research for a few decades\(^1\text{-}^{17}\). The main conclusions of above studies are summarised in the following table.
### Table 1 Review of the conclusions of studies about the health status and health needs of the Hungarian population

1. On the basis of analysis mortality data of the Hungarian population the following issues have to be emphasised.

   - Mortality from all causes for the total Hungarian population is among the worst in Europe. Although, there has not been major age group protected from high mortality the population aged 35-64 showed the most unfavourable trends.

   - In 1999 more than ninety percent of the total mortality in Hungary is attributed to five main causes: heart and circulatory system diseases (49%), cancer (24%), external causes of death (8%), chronic respiratory diseases (4%) and chronic diseases of the digestive system (8%).

   - The excess in overall mortality is primarily due to the higher risk of middle aged men in causes such as cardiovascular diseases, cancers, injuries, suicides and chronic liver diseases. Certain types of preventable mortality still cause high risk of death (e.g. the cervix cancer among females).

   - Specific causes of mortality have been showing some favourable tendency during the last few years. The increase of lung cancer mortality and cirrhosis mortality has stopped and mortality in ischaemic heart diseases shows a stagnant tendency without any increase or decrease.

2. There is a lack of reliable information about the burden of morbidity in the population. On the basis of available data hypertension and diabetes are one of the most frequent chronic diseases.

3. The control of communicable diseases seems to be effective in the country. Most of the communicable disease has decreased since 1970. However, control of food borne diseases should be rearranged due to the unfavourable six-fold increase of incidence of salmonella cases. Control of TB should be revisited, too. Especially diagnostic and control measures need changes.

4. The measure of influence of social inequalities on health is unknown. It is assumed that growing economic inequalities increase existing social gaps, too. This tendency emphasises the increased role of inequalities in health and the need for more awareness of socially deprived population groups.

5. Most important life style factors are smoking, alcohol consumption and diet.

6. There is insufficient evidence about the effect of environmental factors on health. Major problems are such as air pollution, noise exposure, work places, dump and sewage disposal and the problem of workplace environment.
I.1.2. What is the message of poor health status of Hungarians to policy makers?

During the last decade intensive forces that have led to important changes of life of Hungarians have formulated Hungarian economic, cultural and social life. Political structure, economy and numerous aspects of social life were able to adapt rapidly to the new circumstances and produced internationally recognised improvements\(^ {21}\). However, other important dimensions of Hungarians’ life, which are far behind the desired state, can endanger this “success story”. Health of the population and health determinants is still among the poorest compared to economically well-established countries. Our present knowledge about health and causes of poor health status allows us to view present health policy strategies addressing health and proposing changes in a critical way.

On the basis of Dekker’s definition we can identify health policies focusing on the supply or demand side of health services\(^ {22}\). Health policy can have an important impact on both the demand and supply side of health services, which is further supported by the evidences about the effectiveness of health policy approach on improving the health of the population\(^ {23-27}\). If we look at the main health policy issues of the last few years we find that these are\(^ {28-31}\):

- **How to fix health care budget (emergence of cost-containment policies)**
- **Private and public role in funding health care services**
- **Private and public role in provision health care services**
- **Definition of the guaranteed health care package**
- **Introduction of competitive insurance**
- **Remuneration of primary health care physicians**
- **Remuneration of specialised health services**
- **Co-payment system**
- **Diffusion of medical technology with a special attention to pharmaceutical policy**
The importance of health policy and its analysis is further increased by the special Hungarian context. Hungarian health policy is a white spot on the map of health policy analysis literature. Up till now very little research is available on health policy issues. However, health policy analysis could play a dual role as it helps both the evaluation of the output and outcome of health policies and it also provides a good basis for the successful implementation of future health policies. Hungarian health policy has been improperly researched and explained. This area needs more research that supports the success of implementation of future health policies.

In this part I reviewed why health policy is an important issue. In the following part I demonstrate the importance of pharmaceutical policy in health policy.

I.1.3. The significance of pharmaceutical policy

Health care expenditures have risen since the nineteen seventies in most of the economically developed countries. Following chart shows how the total health care expenditures, calculated in US$ purchasing power parity, has changed

![Chart showing total health care expenditures over time](chart.png)
in a selection of European countries since the 1970. Neither of the examined countries avoided the rapidly escalating costs of health care services. Increasing costs of health services are mainly explained by the following reasons 29-31.

- Rapid diffusion of expensive medical technology (with special attention to pharmaceutical products);
- Ageing population with increasing demands for health care services;
- Increasing skills and specialisation in medical personnel;
- Shortages of supply, or artificially raised prices;
- Excess utilisation of existing resources.

Escalating pharmaceutical expenditures was a principal causative determinant of increasing health care expenditures common to all countries 29-31.

1. Graph Per capita pharmaceutical expenditures, calculated in the dollar purchasing power parity value, in a selection of European countries between 1970 and 2000

992707 Pharmaceutical expenditure, PPP$ per capita

- Austria
- United Kingdom
- Hungary
- Netherlands
- EU average
Above graph clearly demonstrates that pharmaceutical expenditures have increased in all of the examined countries since 1970. Hungary differs from all the other assessed countries by the steepness of the increase of expenditures. While most of the other countries had thirty years to reach the given level of expenditures, the lining up of Hungary took only 10 years. This rapid increase of pharmaceutical expenditures ran over the limits provided by the economic growth of the last decade. This obviously led to an increased pressure on pharmaceutical policy from all financer, provider and patient side. The involvement of all of the stakeholders placed pharmaceutical policy in the focus of health policy in Hungary.

It is also an interesting observation that while there was a gap between Hungarian and Western European per capita total health care expenditures this gap was less significant in the case of per capita pharmaceutical expenditures. This assumes that Hungarian pharmaceutical policy was less successful in cost containment polices than in controlling the increase of other health care cost. This assumption supports the importance of analysis of pharmaceutical policy further.

On the basis of the above information the following conclusions can be drawn.

- **Increasing health care cost is one of the main concerns of health policy.**

- **Rising pharmaceutical spending had resulted a significant escalation of health care expenditures and became an important health policy issue.**

- **Hungary seems to be less successful in achieving its policy objectives in controlling and rationalisation of pharmaceutical budget.**

In this part I reviewed the major evidences about the importance of pharmaceutical policy. In the following part I review the objectives of my policy research.
II. Objectives

In my research I plan to reach the following aims and objectives.

II.1. Research Aim

The aim of my research is to provide a background research for the introduction of rationalisation in the Hungarian pharmaceutical spending and to propose policy to implement on the basis of research’s results. This objective is going to be reached in three stages.

The first stage aims to examine how Hungarian pharmaceutical policy has been formulated (policy content, priority areas, process of decision making on pricing and reimbursement of pharmaceutical products) and what main actors have participated in policy process since the foundation of Health Insurance Fund in Hungary. In this stage I also carry through a review of international pharmaceutical policy initiatives to collect evidence about the experiences of implementation of different policy initiatives from the rationalisation of pharmaceutical expenditures point of view.

In the second stage I wish to describe and assess the present rationality Hungarian pharmaceutical policy by reviewing the content, context, process and actors of pharmaceutical policy in Hungary. In this part I plan to focus on a special policy initiative: the introduction of health economic evaluation in decision making of reimbursement of medicines.

In the final stage I plan to come to a conclusion and recommendations about Hungarian pharmaceutical policy formulation.
II.2. Research Questions

1. Stage questions:

1.1. What are the main pharmaceutical policy initiatives at international level?

1.2. How the effectiveness of these policies has been monitored and what are the major experiences about the effectiveness of these policies?

1.3. What main factors influenced the realisation of policies? How context, actors and process of policy making influenced the formulation and implementation of policies?

1.4. What were the main pharmaceutical policy initiatives in Hungary during the last decade?

1.5. What information is available about the effectiveness of pharmaceutical policy initiatives?

1.6. How policy was formulated? What main factors influenced the policy making?

2. Stage objectives:

2.1. What are the main pharmaceutical policies now in Hungary?

2.2. What is the present role of pharmaco-economic evaluation in decision making about medicinal products?

2.3. Description and analysis of present process of pharmaceutical policy making.

2.4. How far the introduction of pharmaco-economic evaluation can affect policy initiatives?

2.5. Analysis of stakeholders’ influence and power on decision making about pricing and reimbursement of medicines in the cases of selected initiatives.
2.6. Assessment the explicitness (transparency) of policy process in Hungary.

2.7. Description and analysis of the main factors that are considered during setting up of priorities in formulating pharmaceutical policy. Description and evaluation of how these factors are prioritised. (E.g. what are the basic principles, which are considered in reimbursement and pricing decisions? How solidarity and efficiency are taken into consideration?)

3. Stage objectives:

3.1. What conclusions can be drawn from the international and Hungarian pharmaceutical policy making and what are the consequences on the future policy making?

3.2. What strategy can be advised upon?
III. Methods

In my method chapter, first, I introduce the theoretical framework of my research. Then I describe the analytical frame with the proposed methods.

III.1. Theoretical frame of the research

The aim of my research is to describe and analyse different aspects of Hungarian pharmaceutical policy, such as how the content of policy has changed, which stakeholders influenced the process, what the main priorities were etc. I evaluated a group of different frameworks, which have been developed for analysing health policy. As a result of this evaluation I selected to use a framework of Walt and Gilson, which provides the theoretical basis of the research. The main strength of this framework compared to the other ones is that it does not focus on specific aspects of the investigated health policy issue but it takes a comprehensive approach by evaluating the content, context, actors and process of policy making and their interactions with each other in the same model (most of the other reviewed health policy frameworks focus on the evaluation of specific segments of health policy, such as the process of decision making, setting priorities, the applied strategies and the power of certain stakeholders).

By using Walt and Gilson’s framework I provide a complex description of pharmaceutical policy formulation from a process (decision making process on pharmaceutical policy issues), actor (stakeholders affecting pharmaceutical policy decisions), context (economic, social, political and legal factors affecting pharmaceutical policy) and content (pharmaceutical policy priorities and their effect on improving cost-containment, efficiency and equity policies) point of view in each phase of the description. By applying this theoretical frame, not only the activities and
outputs of the system become available for description and analyses but those factors that hinder or facilitate the application of effective pharmaceutical policy, as well.

**III.2. Analytical frame of the research**

Research is planned to consist of three stages. Diagram on the following page provides an overview about the different stages and the recommended methods to realise objectives of each stages.

In the first stage I overview the Hungarian pharmaceutical policy of the last ten years and I review international evidence about the effect of different pharmaceutical policies. During the literature review I was looking for the following information:

- The content of pharmaceutical policy.
- The context of different policies and their influence.
- The main stakeholders influencing policy making.
- The policy process.

I plan to analyse content by reviewing what the main priorities and policy initiatives were (by the separate description of demand and supply strategies). Listing and assessing the main factors affecting pharmaceutical policy will provide a basis for the assessment of the context. Main stakeholders influencing pharmaceutical policy will be reviewed and their power and influence will be assessed through a stakeholder analysis. In this stage I plan to assess pharmaceutical policy by reviewing how the access to pharmaceutical products has changed and how policies could possible affect the access. In this study I use secondary data coming from the literature review.

In the second stage, the content of present pharmaceutical policy will be reviewed. Policy initiatives will be divided into supply and demand side strategies. It is planned to be examined how the different initiatives aim to maximise cost-containment,
efficiency and equity principles. By selecting a special policy initiative, pharmaco-economic evaluation in reimbursement of pharmaceuticals, the analysis of context of policy and the process of decision making is planned to be carried out. Main stakeholders are going to be examined by undertaking stakeholder analysis.

In the third stage and I plan to discuss the results of the previous part by making overall and special policy recommendations for Hungarian decision makers.

1. diagram The analytical frame of the research

- **Stage I.**
  - Review of literature on international and Hungarian pharmaceutical policies

- **Stage II.**
  - Qualitative and quantitative data collection on past and present policies.

- **Stage III.**
  - Assessment of present pharmaceutical policy. Recommendations for forming future pharmaceutical policy.
III.3. Data Collection and Analysis

Data collection and analysis was divided into the following main parts.

**Review of the literature**

Literature of pharmaceutical policy making was reviewed by using PUBMED and Science Direct.

The aim of this data collection was the collection of information on the following aspects of pharmaceutical policy making, such as content, context, actors and process.

To find literature PUBMED and Science Direct was searched by using the keywords:

- Pharmaceutical AND Policy
- Health Policy AND Pharmaceuticals.

The selected literature was collected and other relevant publications were selected by reviewing their references.

**Qualitative Data Collection and analysis**

The objective of this data collection was the identification of present pharmaceutical policies in Hungary with a special emphasis on the implementation of pharmaco-economic evaluation in decision-making on the reimbursement of pharmaceutical products.

An interview questionnaire was constructed to collect qualitative information about the different part of present Hungarian pharmaceutical policy. See the applied questionnaire, both in Hungarian and English, in Appendix 1.

To easy the analyses of data the interviews have been outlined in a special from (See in English and Hungarian in Appendix 1.). This form was constructed on the basis of the theoretical and analytical framework of the research. Main elements of the Data Analytic Sheet reflect the central themes of the theoretical and analytical framework. During the
analysis of interviews texts were outlined according to the thematic framework and these results were summarised in the result section.

Interviewees were selected on the basis to represent main actors of Hungarian Pharmaceutical policy making. Interviews had been contacted through telephone and after an appointment had been set an hour-long interview was carried through. See the final list of interviewees in Appendix 1.

Quantitative data analysis

In the assessment of pharmaceutical policy a special attention has been paid to the introduction and implementation of pharmaco-economic evaluation in the decision making process of reimbursement decisions. For the sake of understanding of this area a case study has been carried through.

In our study we aimed to evaluate and compare the cost-effectiveness of treatment of hypertension with a selection of drugs. Through the assessment of cost–effectiveness of these drugs we aimed to:

- Recognise the special factors and conditions that influence the introduction and implementation of economic evaluation in decision making about the reimbursement of medicines.
- We also aimed to understand how the present reimbursement practice should be changed by the introduction of the technology assessment into the decision making process.

To assess cost-effectiveness we built up a cost-effectiveness model in which we calculated the costs of hypertension treatment and the costs of treatment of hypertension related diseases (ischaemic heart disease, cerebrovascular diseases and pulmonary embolism). We modelled the effectiveness of hypertension treatment through the avoided morbidity and mortality owing to effective control of hypertension with the selected pharmaceuticals. Both average and incremental cost-effectiveness were calculated from a societal and Health Insurance Fund’s viewpoint for the year 2002.

There were important assumptions behind the building up of our model. The most important one refers to a condition when antihypertensive treatment covers the whole hypertensive
population, aged 35-74, and every patient complies with the antihypertensive treatment to 100%. Obviously, these assumptions do not depict the reality properly, however, they had to be set for the sake of modelling and the effect of the deviation of our assumptions from reality was considered in the conclusion, too.

See the detailed methodology in Appendix 2.
IV. Results

Results of the research are going to be presented in the following order.

First I summarise the results of the review of international literature on pharmaceutical policies. This is followed by the review of the Hungarian policy in the last decade. Then I summarise the results about the present pharmaceutical policy in Hungary, which is going to be followed by the case study about the implementation of pharmaco-economic evaluation in the decision making process on reimbursement of medicines.

IV.I. Review of the literature on pharmaceutical policy

In this literature review policies were divided into four interlinking part: such as content, context, process and actors. International literature review was undertaken through the examination of these aspects of policies. Following this logic I am looking for the answers of the following questions in this Appendix.

- What are the main issues of pharmaceuticals?
- What the main policy strategies are, based on the review of international literature?
- What are the effects of policies?
- What are the main factors that affect policy output and outcome?
IV.1.1. Main issues of international pharmaceutical policy

Issues related to pharmaceutical policy can be divided into two groups. The first group includes reasons that are not specific for the pharmaceutical area but applies to the basic problem of providing health services under constrained market conditions. The second group consists of those issues, which are specific to the pharmaceuticals.

The basic problems with health care services are reviewed in the following box.

- Presence and extent of uncertainty on both demand and supply sides.
- Existence of insurance (neither the decision maker about consumption of services – physicians - nor the patients pays directly for most of the health services).
- Information asymmetry (consumers of health care services do not own the needed information for rational decision making).
- Large role of non-profit firms.
- Restrictions on competition (major part of health care services is regulated).
- Role of need is not clearly defined.
- Government subsidies and public provision (even those services where patients have to pay directly for using the service the government is usually present to subsidize to various extents).

All of these issues are relevant for pharmaceuticals, too. However, there are special areas, which are specific problems of pharmaceutical policy. The four main issues related to pharmaceutical policy that does not apply to other areas of health care37:

1. Pharmaceuticals are regulated by law for safety, efficiency and quality.
2. Drugs have become increasingly expensive both for the individual consumer and society. However, the value – benefit – is not obvious in all cases.

3. Drugs are promoted by a powerful industry, which are a major employer and exporter in the economically developed countries.

4. Drugs are affected by policies in almost every area of health care.

Waley\textsuperscript{37} argues that there should be a single, clear policy on pharmaceuticals that unifies the various strands of relevant existing policies. He describes three typical situations when single pharmaceutical policy could result the avoidance of irrational decision-making. It is argued in this article that a common national policy is needed because it can resolve the conflict in interest among stakeholders. According to him the main stakeholders has a common interest to have safe, good quality and effective medicines. However, basic interests can be different and difficult to harmonise. The following table shows the differences in stakeholder interests.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Their interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government and its agencies (Department of Health; Department of Trade and Industry; NICE)</td>
<td>Regulates and support pharmaceutical industry; restrain its profit and ensures that drugs are reasonable priced for the NHS; promotes the further improvement of a research based industry.</td>
</tr>
<tr>
<td>Citizens – patients and taxpayers - -</td>
<td>They want equity and easy to access to effective medication; as taxpayers they are keen to control the cost of health care provisions; their want for medicines can be limitless that conflicts the capped budget for medicines.</td>
</tr>
<tr>
<td>Pharmaceutical Industry</td>
<td>Good rate of return on their investments.</td>
</tr>
<tr>
<td>Health Care Professional</td>
<td>Want to use safe and effective medicines; preserve professional privilege and power; can resent constraints on their prescribing practice.</td>
</tr>
<tr>
<td>Commissioners of health (health authorities; primary care groups or trusts)</td>
<td>The cost-effective use of resources to gain the maximum benefit from their budget.</td>
</tr>
<tr>
<td>Regulators (Medicines Control Agency; European Medicines Evaluation Agency)</td>
<td>Efficacious\textsuperscript{1} and safe medicines.</td>
</tr>
</tbody>
</table>

\textsuperscript{1} They use a narrow term for efficaciousness, as it does not cover the rigorous comparison of effectiveness of pharmaceuticals.
Lack of single and clear policy on pharmaceuticals results conflicting interests. Health care financers are more interested in costs and their containment than in the value of medications. Industry’s interest results activities that fuel the over-demand for their products. Governments are torn between the interests of improving the health of the population, supporting the industry, legacy within the law, keeping its political affluence.

Although, many of the above issues have been widely recognised by policy analysts and policy makers for a long time, their significance was fuelled by the continuously increasing pharmaceutical expenditures.

In many of the cases health governments have created different policies to tackle different issues on an ad hoc basis or in a more planned manner. These policies and their effect are going to be summarised in the next part.
IV.1.2. Main policy strategies

Pharmaceutical policy in countries with established market economies has the following three main objectives:\(^{29-31}\):

- Containment of costs;
- Increasing of efficiency of financing pharmaceutical products;
- Keeping the right level of solidarity in access to medicines.

To reach the following objectives different policy measures were introduced. These policies could be divided into demand oriented policy strategies and supply side oriented policy strategies. The following table (Table 2) summarises the list of the different strategies and the place of their application.

<table>
<thead>
<tr>
<th>Table 2 Demand and Supply Side Strategies in the different European countries in 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demand side strategies:</strong></td>
</tr>
<tr>
<td>1. Cost sharing (all countries but the Netherlands)</td>
</tr>
<tr>
<td>2. Developing market for OTC products</td>
</tr>
<tr>
<td>3. Health education program (The Netherlands, UK)</td>
</tr>
<tr>
<td>4. Capitation or salary payment for first contact doctor (e.g. Ireland, UK, Sweden, Spain, Italy etc.)</td>
</tr>
<tr>
<td>5. Paying pharmacist on a flat rate, not on a percentage basis (UK, the Netherlands)</td>
</tr>
<tr>
<td>6. Fixed budgets for doctors (UK)</td>
</tr>
<tr>
<td>7. Indicative budget for doctors (Germany, Ireland)</td>
</tr>
<tr>
<td>8. Fixed budgets for pharmaceutical expenditures (Italy)</td>
</tr>
<tr>
<td>9. Practice guidelines (France)</td>
</tr>
</tbody>
</table>
10. Use of cost-effectiveness studies (UK, France, Sweden)

11. Information and feedback to physicians (UK, Denmark, Sweden)

12. Prescription auditing (several countries)

13. Disease management (France, UK)

14. Encouraging generic substitution (several countries)

15. Promoting the use of generics (the Netherlands, Denmark, Germany, UK)

### Supply side strategies

1. Price control (several countries)

2. Reference prices (Germany, Italy, Denmark, Sweden)

3. Profit control (UK)

4. Industry contributions when budgets are exceeded (Germany)

5. Revenue or fixed budget for the industry (Spain, France)

6. Positive and negative list (all countries)

7. Controlling the number of products (Norway, the Netherlands, Denmark)

8. Ceilings on promotion expenditure (UK)

9. Taxes on promotion expenditure (France, Sweden)

10. Development of market for parallel imports (UK, Germany, the Netherlands, Denmark)


There are various elements to influence demand for pharmaceutical products. Co-payment schemes are widely used in many countries and there is wide evidence about their effect on reducing drug consumption. However, even when moderate co-payment schemes were implemented the distortion of demand for pharmaceuticals was also detectable. In these cases it was observed that the socially deprived people
had not bought even essential medicines\textsuperscript{39-41}. It was also observed that the increase of the amount of co-payment schemes resulted the parallel increase of the use of other services owing to the decreased drug consumption. The decrease of reimbursement of medications for patients with major psychiatric diseases resulted such an increase in non-compliance rate in medication that costs of treatment became 17 times higher owing to the increased use of chronic mental health services. Withdrawing reimbursement of proven ineffective drugs can result the over-use of other, often more costly drugs\textsuperscript{42}.

British example shows that the introduction of prescription charges could reduce the prescription of both the efficient and less efficient medicines\textsuperscript{43-45}.

Over patient groups physicians have the major role in decision making on pharmaceutical consumption. Owing to this doctors are frequent target of policies aiming to change prescribing behaviour, such as providing data on prescribing analysis and cost, indicative prescribing budget, and managed care settings. The impact of these policies have not been extensively analysed but seems to be limited\textsuperscript{46}. In Germany budgetary restrictions was introduced in GP practices in 1993. Although, the restriction accounted for only 1\% of an average GP budget but it resulted a dramatic decrease in prescriptions and a considerable increase of the measure of generic substitution. It was estimated that this policy had resulted a 10\% saving in the drug budget\textsuperscript{47,48}. Individual GP budgets have been introduced in other countries: Britain, New Zealand and in Italy. In New Zealand it was found that the introduction of this policy slowed the rate of increase of prescription to a considerable extent. However, policy effects were severely restricted by the reluctance of physicians and patients to change medicines in the treatment of chronic illnesses\textsuperscript{49}.

It has been shown that providing prescribing guidelines for the doctors can change prescribing behaviour, too\textsuperscript{50-52}. Observational studies show that doctors’ prescribing behaviour can be changed with different educational outreach models, but more evaluative evidence from experimental studies still needed for evidence based decision-making.

Pharmaceutical policies often target the control of pharmaceutical expenditures through the regulation of the industry through various means: licensing,
reimbursement, price control, profit regulation and the encouragement of generic substitution.

Licensing of medicinal products cause a barrier into the entry into the pharmaceutical market but it does not affect the costs to a considerable amount. On the contrary, reimbursement decisions are more and more often linked to the evaluation of efficiency of drugs and a comparative assessment of its efficiency with others in the group. Although, there are numerous practical problems with the application of the total information provided by cost-effectiveness studies into the decision making process about reimbursement of medicines, their importance is growing continuously. Many government use negative and positive lists of drugs for the publicly financed medicines.

Prices of medicines are controlled in many different ways. Reference pricing is in function in many countries. However, there are differences in the way of definition of group of reference products. It has to be mentioned that price control is effective for controlling the prices and expenditures of publicly funded medicines. However, in most of the countries it was observed that the expenditures saved on the previous group of medicines was lost by the higher increase and sales of OTC products.

There are only two countries where profit regulation is in function, Britain and Spain. The applied mechanism of profit regulation is different and it is not very well explored what effect it has on efficient prescribing and pharmaceutical expenditures. There is a growing consensus about that price control is not very effective in regulating cost-effective prescribing practice.

Without the detailed and carefully monitored knowledge of economic effect of medicines and their effectiveness, price regulation remains a crude method for cost containment and maximisation of health benefit of drugs in the population. There is a growing acceptance of the following facts:

- Pricing and reimbursement of pharmaceuticals are very important from population health and welfare point of view.

- The government has to play an important role in pharmaceuticals pricing and reimbursement through the introduction of rational pharmaceutical policy.
• Evaluation of efficiency of pharmaceuticals has to be one of the most important pillars of decision making on pharmaceutical reimbursement.

On the basis of the pharmaceutical policy literature there are certain strategies, which proved to be effective on the inappropriate use of medicines based on the international literature. These are summarized in the next table:\(^{53}\):

<table>
<thead>
<tr>
<th>Results about the effectiveness of the policy program</th>
<th>Content of the policy program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proven effective in certain settings</td>
<td>• Standard treatment guidelines</td>
</tr>
<tr>
<td></td>
<td>• Essential drugs list</td>
</tr>
<tr>
<td></td>
<td>• Pharmacy and therapeutics committees</td>
</tr>
<tr>
<td></td>
<td>• Problem based basic professional training</td>
</tr>
<tr>
<td></td>
<td>• Targeted in service training of health workers</td>
</tr>
<tr>
<td>Need further testing</td>
<td>• Training drug sellers</td>
</tr>
<tr>
<td></td>
<td>• Education based on group processes</td>
</tr>
<tr>
<td></td>
<td>• Public education</td>
</tr>
<tr>
<td>Proven ineffective</td>
<td>• Disseminating prescribing information</td>
</tr>
<tr>
<td></td>
<td>• Clinical guidelines in written form only</td>
</tr>
</tbody>
</table>

In the above list the application of economic evaluation has not been detailed. Owing to the focus of present policy research this topic is going to be discussed in the following section separately.
IV.1.3. International experiences about the application of economic evaluation in decision making

Application of economic evaluation in decision making of reimbursement of medicines goes back to the middle 1990s and called as a fourth hurdle (the first three hurdle of marketing approval of medicines are: safety, efficacy and quality). Efficiency of medicines was considered in pricing and reimbursement of medicines first in Canada (Ontario state) and Australia in the World. By the late 1990s pharma-co-economic guidelines became widespread in many European countries and decision makers on pharmaceuticals started to learn the use of efficiency results in prioritisation among medicines in the case of reimbursement.

Kanavos et all. 54 found five different ways of using economic evaluations in pharmaceutical policy. These are the following:

1. Fourth hurdle to obtain market access (medicinal products are not allowed to be marketed without the proof of cost-efficiency results).

2. Hurdle to reimbursement decisions (medicines are not reimbursed without proof their value for money).

3. Influencing prescribing decisions of physicians.

4. Implicit use economic results in the decision making process on reimbursement.

5. Voluntary use of result, mainly for the sake of research.

Previous authors also summarised the main obstacles of applying economic evaluation to practice.

1. There is a challenge to ensure that economic evaluations are carried out scientifically without industrial or political bias.

2. There is still ongoing scientific discussion on many aspects of the transparent methodology.

3. Purchasers are usually make planning decisions on population level, whilst prescribers’
consider the interest of individual patients.

4. It is hard to ensure that economic evaluations are conducted from a societal point of view to be able to include all the costs and benefits of an intervention.

5. Practical application of results is hindered by the lack of understanding of results of economic evaluations among potential users.

However, the application of economic assessment of medicines is becoming a widely accepted practice in many European countries.

Kanavos et al. recommends the following framework to apply as a rational process.

**Policy Makers / Payers**

**Researchers**

**Health Care Providers**

**Pharmaceutical Companies**

Guidelines for economic evaluations

Commissioning of evaluations

Evaluations

Reimbursement

Practice guidelines

Disseminations through journals and databases

Audit of practice against guidelines
This framework clearly represents an ideal state of the process of actions related to the use of economic evaluations. Present practice of the different countries diverts from this state to different measure. To develop present policies the following objectives are recommended to be achieved in the future.

IV.1.4. Future development for pharmaceutical policy

Development of good and single pharmaceutical policy along the following principles.

1. Ensure that medicines are effective and as safe as possible.

2. Ensure clinically effective prescribing.

3. Audit prescribing and its outcomes.

4. Ensure the dissemination of good practice.

5. Maximise the health gain from resources used for prescribing.

6. Encourage equity and easy of access to pharmaceuticals across the NHS.

7. Ensure responsiveness to patients’ needs.

8. Provide a stable and suitable environment for a strong and profitable pharmaceutical industry.

In this part of the policy research the present pharmaceutical policy on international level has been reviewed. In the following part the results of research of Hungarian policy is going to be reviewed.
**IV.2. Hungarian pharmaceutical policy**

In the following sections I review the major findings of the qualitative data collection about the content, actors and process of pharmaceutical policy making in Hungary. Context of policy making is not going to be detailed in this part as it has already been discussed in the introduction part. Firstly, the policy content is going to be described. Secondly, the actors of pharmaceutical policy making is going to be reviewed and a stakeholder table is going to be constructed on the basis of the available information. In the third part process of pharmaceutical policy making is going to be described. Finally, the recent policy strategy of the government is going to be reviewed.

**IV.2.1. Content of Hungarian pharmaceutical policy**

Escalating pharmaceutical expenditures has not avoided the Hungarian health market either. Similarly to other countries, Hungarian health policy introduced different ad hoc measures to control rapidly rising pharmaceutical expenditures. Compared to the opportunities the number of these measures is very restricted. These policies are reviewed in the following table (Table 3).

| Table 3 Demand and Supply Side Strategies in Hungarian Pharmaceutical Policy |
|---|---|---|---|---|
| **Demand side strategies:** | 1. Cost sharing | 2. Developing market for OTC products | 3. Capitation or salary payment for first contact doctor | 4. Information and feed back to physicians (very limited for a short period of time) | 5. Prescription auditing (to a very limited extent) |
6. Promoting the use of generics (this happens in political rhetoric only)

**Supply side strategies**

1. Price control
2. Reference prices
3. Positive and negative list
4. Controlling the number of products

Obviously, Hungary has not utilised many of the available pharmaceutical policy strategies to control expenditures and due to the growing pressure on policy makers it cannot avoid the introduction of new measures. The successful application of international experiences is hindered by many circumstances.

- There is a very limited knowledge about the success of implementation of previous and present policies.
- Present pharmaceutical policy priorities are not transparent and explicit.
- Requirements and special consideration of the adaptation and application of new pharmaceutical policies are not explored.

**IV.2.2. Main Actors of Hungarian Pharmaceutical Policy**

Main actors of the Hungarian Pharmaceutical policy are the next:

1. Hungarian National Health Insurance Fund
2. County Health Insurance Funds
3. Public Health Service


5. Hungarian Ministry of Health (Special Advisory Committee on Strategy – “TATB”)

6. Hungarian Ministry of Finance

7. Medical Chamber

8. Pharmacists’ Chamber

9. Individual Physicians

10. Pharmacists

11. Wholesalers

12. Patients; Patient Organizations

13. Pharmaceutical Industry; Pharmaceutical Industry Societies

14. Media

The role of these stakeholders in pharmaceutical policy formulation has not been the topic of any research. During the interviews with stakeholders the following roles have been clarified for the aforementioned actors.

Responsibilities of the:

- **Ministry of Health**: development of pharmaceutical policy and implementation of it (it is responsible for the involvement of different actors in the pharmaceutical policy formulation to gain a wide social support for the implementation); evaluation of the effectiveness and efficiency in undertaking pharmaceutical policy. The Ministry of Health has a special committee (TATB) to advise upon the
pharmaceutical policy strategy. This committee includes representatives from the Ministry of Health, National Health Insurance Fund, Ministry of Finance, Medical professions and the Public Health Service. Delegated members of these organizations are responsible for the development of principles of reimbursement of medicines.

- **Ministry of Finance**: definition of budgetary constraints of pharmaceutical spending; contribution for the development of pharmaceutical policy.

- **National Health Insurance Fund**: coordination and participation in the realization of pharmaceutical policy in Hungary.

- **County Health Insurance Fund**: authority functions; their real functions on this area are very limited.

- **Public Health Service**: provision of professional background on certain areas of pharmaceutical market (etc. registration of products, authorization of clinical studies etc.). They have a role to provide professional supervision services over pharmacies on the field.

- **Hungarian government and Health committee of the Hungarian Parliament**: acceptance of pharmaceutical policies; regulation of pharmaceutical markets through the development of laws.

- **Medical Chamber**: provision of professional consultation on the effectiveness of pharmaceutical products through its professional boards.

- **Physicians**: the most important players in defining pharmaceutical spending through providing direct advices to patients on medicines.

- **Pharmacists**: potentially important players through providing advices patients on medications and through running the retailer pharmaceutical business.

- **Patients**: making the final decisions on pharmaceutical spending; some patient groups are very effective in advocacy work to realize their own interest, however, major part of them does have a very limited effect on pharmaceutical policy.
- **Pharmaceutical Industry**: a very strong interest group with the ability of influencing decisions at all level of the pharmaceutical field.

- **Hungarian Wholesalers**: an active player with a very narrow interest on pharmaceutical policy.

- **Media**: very active player with little definitive objectives.

<table>
<thead>
<tr>
<th>Actors</th>
<th>Interest</th>
<th>Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry of Health</td>
<td>▪ Control costs.</td>
<td>High at national level</td>
</tr>
<tr>
<td>National Health Insurance Fund</td>
<td>▪ Controlling the spread of modern medical technology.</td>
<td>Low at practice level</td>
</tr>
<tr>
<td></td>
<td>▪ The safety, quality and effectiveness of medicines.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Ensure equity and efficiency.</td>
<td></td>
</tr>
<tr>
<td>Ministry of Finance</td>
<td>▪ Control budget.</td>
<td>High</td>
</tr>
<tr>
<td>Medical Chamber</td>
<td>▪ Maximization of professional interest and the use of modern (if it is</td>
<td>Limited</td>
</tr>
<tr>
<td></td>
<td>possible the latest one) technology in medical practice.</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Companies</td>
<td>▪ Profit maximization</td>
<td>High both on national and local level</td>
</tr>
<tr>
<td></td>
<td>▪ Provision of high quality services in the field of pharmaceuticals.</td>
<td></td>
</tr>
<tr>
<td>Physicians</td>
<td>▪ Satisfy their patients’ needs and their professional interest</td>
<td>Very high at local level and very low at national level</td>
</tr>
<tr>
<td>Patients</td>
<td>▪ To get the best possible treatment at the lowest rate of contribution.</td>
<td>Very low at national and very high at local level</td>
</tr>
<tr>
<td></td>
<td>Maximization the effectiveness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>of care.</td>
<td>level</td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Wholesalers and</td>
<td>• Profit maximization.</td>
<td>Pharmacists have a high influence at lower level decisions.</td>
</tr>
<tr>
<td>pharmacists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>• Keep the attention of public high by exploring topics in the middle of</td>
<td>They have a high role in providing overall and not very detailed</td>
</tr>
<tr>
<td></td>
<td>public’s interest.</td>
<td>information among the public. They have an important role to form</td>
</tr>
<tr>
<td></td>
<td>• Provision of information.</td>
<td>the general perception of the public.</td>
</tr>
</tbody>
</table>

On the basis of the above results the following observations can be made:

1. There is not an actor whose priority interest would be the rational use of resources.

2. Primary interest of representatives of governmental bodies is cost-controlling. Government has an influence at national level, mainly through the development of legal context of pharmaceutical market. Although, by deciding about the reimbursement level of medicinal products, government has a very strong, but indirect influence at micro level decision making.

3. Those actors who have an influence at the micro level decision making of pharmaceutical consumption have similar interests. Physicians mainly want to satisfy the demand of the individual patients without considering the effect of uncritical use of expensive technology at population level. Pharmaceutical companies are traditionally very strong to influence both micro and macro level decisions on the pharmaceutical policy.
4. Although, patients have a major role in the decision making process of pharmaceutical consumption, their real role in the decision making process is undiscovered. It seems that they have a very limited power to decide about the medicinal products due to the information asymmetry on this field.

5. The role of media has not been explored very well. Their role is more reactive than productive.

6. Pharmacists have a potentially high influence on micro level decision making, however, according to the Hungarian practice they do not influence patients’ decisions about medicines. Rate of substitution is very low and most of the time they do not re-examine doctors’ prescriptions.

IV.2.3. The process of policy making

Based on the analysis of the interviews with key stakeholders the major characteristics of decision making of reimbursement of pharmaceuticals have been described. Reimbursement of pharmaceuticals has been chosen to be the focus of process description as this is one of the most important policy tools, it affects many areas of pharmaceutical policy and strategy and most of the previously described stakeholders have their interest on this area.

Decision making process on reimbursement has the following main characteristics.

1. The **process** of decision-making is **very implicit**. Most of the interviewed stakeholder could not describe who, where and along to what principles make the decisions on pharmaceuticals. Implicitness of the process has its roots in the structure of decision-making, the lack of prioritization on the field, the lack of the application of modern techniques and methodologies on this field.
2. Lack of mechanisms for the involvement of stakeholders. E.g. representatives of general population and patients are not involved into the process of decision making etc.

3. Even if a stakeholder is involved the way of involvement is very rigid. E.g.
   
a. the involvement of pharmaceutical companies into the discussion of reimbursement is restricted to a given time at a given stage. Even if the involvement would be fruitful at a later point it is ceased owing to the rigidity of the structure.

   b. Involvement of professional boards is also very limited. Professional boards are asked to give professional advice on the efficacy and effectiveness of medications but they are often not involved in the prioritization process where they could consider the effect of budgetary constraints. Owing to this situation professional boards have a reputation that they support every new technology without the consideration of costs.

4. The process follows irrational loops and badly managed. E.g. it happens very often those deadlines for the undertaking of a decision process if very short. Interested stakeholders have a few days only to deal with important questions after what their involvement ends. Options for change and discussion are very limited.
IV.2.4. Description of future strategy

In 2004 a new pharmaceutical policy initiative has been worked out and opened for discussion. The main objectives of this new initiative are the following:

- The new regulation has to be in accord with the publicised economic, social and health policy.
- A balance has to be found between the international obligation and the interest of the Hungarians.
- Special features of the pharmaceutical market have to be kept in mind.
- During the change of regulations the following factors have to be considered: the cost and efficiency of change; the benefit of the society; the publicised decentralisation process.
- The regulation has to be able to be the basis of further developments.
- Regulation has to provide the development of a transparent situation for all the interested parties.
- The regulation should be based on a normative basis to the maximum extent.

Main elements of the planned policy are reviewed in the next box.

- Ensuring the basis of safe pharmaceutical policy.
- Regulation of reimbursement of pharmaceuticals is going to be based on a comprehensive law.
- Transparency.
- Regulation of pricing of medicines.
- Life saving drugs and the need of elderly population has a preference in the reimbursement decisions.
- Vaccines and oral contraceptives are going to be reimbursed.
- The spread of generic products will be in the focus of policy.
- Stability of pharmacy network is going to be promoted. Network of family pharmacies will be developed.
- Authorisation of pharmacies is going to be liberalised.
- The social benefit list is going to be re-regulated.
- To encourage cost-effective subscription a model will be implemented among family physicians.
From the above list the most important elements of the future strategy is already obvious. However, from the above document is very little known

- how far this new policy departs from the present situation,
- and exactly how (through the application of what tools and programs) the above objectives are going to be reached.

Up till now Hungarian pharmaceutical policy and the application of efficiency criterions in the decision making process has been assessed from a theoretical point of view. In the next section I present the results and the experiences of the undertaking of an economic assessment study. This practice shows what are the practical obstacles of the use of economic evaluation in the decision making process of reimbursement of pharmaceuticals. This study also models the rationality of the present reimbursement system.
IV.3. Case study (Introduction of pharmaco-economic evaluation into the decision making process)

An economic evaluation of hypertension treatment was carried through to assess how rational the present rate of reimbursement system from economic point of view and to try out what are the major obstacles of the practical implementation of economic evaluations in Hungary (this research is reported in a more detailed manner in Appendix 2.). Firstly, the major findings are summarised, then I review the main conclusions of the case study.

IV.3.1. Economic evaluation of hypertension treatment

In our study we aimed to evaluate and compare the cost-effectiveness of a selection of different hypertension treatments. To assess cost-effectiveness we built up a cost-effectiveness model in which we calculated the costs of hypertension treatment and the costs of treatment of hypertension related diseases (ischaemic heart disease, cerebrovascular diseases and pulmonary embolism). We modelled the effectiveness of hypertension treatment through the avoided morbidity and mortality owing to effective control of hypertension with the selected pharmaceuticals. Both average and incremental cost-effectiveness were calculated from a societal and Health Insurance Fund’s viewpoint for the year 2002.

There were important assumptions behind the building up of our model. The most important one refers to a condition when antihypertensive treatment covers the whole hypertensive population, aged 35-74, and every patient complies with the antihypertensive treatment to 100%. Obviously, these assumptions do not depict the reality properly, however, they had to be set for the sake of modelling and the effect of the deviation of our assumptions from reality was considered in the conclusion, too.
Our results showed that the *average cost-effectiveness* of different products is different. And it was also showed that this rank is heavily influenced by the reimbursement of the different products. The other message of average cost-effectiveness was that more treatment options are more effective but more costly alternatives. To measure efficiency from this point of view we undertook an incremental analysis of efficiency of the selected treatments.

*Incremental cost-effectiveness* analysis showed that the marginal cost of gaining an extra life year or avoiding the controlling of an extra case of hypertension cost less in the case of Noliprel® treatment than in the cases of the following treatment alternatives: Lotensin HCT 10/12.5®, Coverex Comb®, Accuzide 20®, Inhibace Plus® and Noliprel Forte®. This list slightly changes if we consider the present conditions of reimbursement through undertaking the analysis from the Health Insurance Fund’s viewpoint. In this case the incremental cost-effectiveness of Noliprel® treatment was better than the incremental cost-effectiveness of the following treatments: Noliprel Forte®, Coverex Combination®, Accuzide®, Accuzide 20®, Lotensin HCT 10/12.5® and Inhibace Plus®.

Sensitivity analysis of the results did not cause the change of the above conclusions.

**IV.3.2. Rationality of present reimbursement system from economic point of view**

If we examine the incremental cost-effectiveness of the different hypertension treatments from the health insurance viewpoint (and from the societal viewpoint) we see that efficiency of treatment alternatives is very different. As the level of reimbursement was considered in the estimation of efficiency we found that reimbursement of the different treatments options do not correspond to the efficiency of the products. In many cases the reimbursement increased the differences in efficiency in a negative way.
IV.3.3. Main obstacles of practical implementation of economic evaluations in Hungary

There were many practical obstacles in undertaking the economic appraisal of the selected products.

Main obstacles are listed in the following box:

1. The unit costs of different interventions are missing. In most of the cases we had to use the National Health Insurance Fund’s reimbursement database for the estimation of the diseases specific unit costs.

2. In many cases we had to use efficacy data for the modelling of the effectiveness of medications. There was not available database for the estimation of the effectiveness of antihypertensive interventions not in a clinical setting.

3. Lack of officially adapted QUALY measurement tool makes the comparison of different medical technologies impossible.

4. Cost-effectiveness plain is not available in Hungary. The valuation of incremental efficiency is complicated and speculative.
V. Conclusions and Recommendations

Research results are hoped to be potentially used in the following ways:

- Results of this research provide a basis for stakeholders to initiate the further improvement of pharmaceutical decision-making. Description and analysis of the near past and present Hungarian pharmaceutical policy can improve policy makers understanding of good pharmaceutical policy.

- It provides a list of alternative policies that can be used in the Hungarian context after careful adaptation. One of the aims of the research is to provide a list of alternative strategies to improve Hungarian pharmaceutical policy. The goal of this is not the provision of a cookbook method of good pharmaceutical policy but the laying down of a good basis for discussion of further improvement of Hungarian pharmaceutical policy.

- It hopes to show further areas of policy studies to improve the basis for policy making. It is an important goal to show those areas where further research is essential and can support the efficiency of decision making to a great extent.

- The results of this research are hoped to encourage international comparison, which can improve our further knowledge at international level. It is also hoped that knowledge should be global, too. And the internationally relevant aspects of the analysis are planned to be emphasised.

Results showed that the main issues of the Hungarian pharmaceutical policy were the next:

1. Hungarian health care expenditures have increased exponentially during the last fifteen years. The scale of growth was much higher than the development of the GDP.

2. The uncontrolled increase of pharmaceutical expenditures plays a prominent role in loosing of control of health care expenditures. Opposite
to other health care costs the health government has not been able to
develop a policy to keep the increase of expenditures of medicinal
products under control.

3. The reasons of the growing costs are multifactorial and more or less have
been explored.

4. The budget impact of growing cost of medicinal product on society and
government has urged the introduction and implementation of newer and
newer governmental policies. However, most of these policies were
reactive without fitting into a non-existing long-term policy strategy.

5. Majority of policies aimed to decrease demand or supply of medicines
through the manipulation of subsidization policy. Although, costs could be
controlled temporarily, the long-term effect of policies was the increase of
implicitness of decision making in pricing and subsidization policy.

6. Recognizing the short and long-term drawbacks of reactive and badly
planned pharmaceutical policy, the government aims to develop a long-
term policy that provides the basis of a sustainable pharmaceutical policy
in the country and which gains the support of the interested
parties/stakeholders. The theoretical framework of the new policy is based
not only on the consideration of quality and efficacy of medicinal products
in decisions about subsidization but the extensive use of effectiveness and
efficiency results, as well.

7. Cost-containment policies and the role of economic evaluation of
pharmaceutical products are important elements of the new policy.

Determinants of ineffectual pharmaceutical policy in Hungary were found to be the
following:

1. Very little understanding of modern pharmaceutical policy at decision-making
level.
2. Lack of human resources for efficient policy making. The lack of human resource development problem that could prepare the decision making level to be able to develop short and long term pharmaceutical policy.

3. Unplanned liberalization of pharmaceutical market in Hungary without the understanding and consideration of further consequences.


5. Tendency to overuse pharmaceutical products. Increasing demand for pharmaceutical products.

6. Rapid and unplanned introduction of expensive pharmaceuticals into the Hungarian market and the lack of strategy in the subsidization of these technologies.

7. The lack of motivation for the rational use of medicines at micro level of the decision making process of pharmaceutical consumption.

8. Lack of tool to monitor and to evaluate the characteristics of use of pharmaceuticals. Owing to this there is a very little understanding of the present pharmaceutical market.

Based on these facts I argued that the careful and stepwise introduction of economic evaluation had to be the basis of the new pharmaceutical policy in Hungary that could lead the rationalization on public spending on pharmaceutical products in the country.

To apply health economic evaluations into the decision making process of pharmaceuticals the following theoretical and practical issues has to be dealt with:

**Theoretical Issues**

1. There is a challenge to ensure that economic evaluations are carried out scientifically without industrial or political bias.
2. There is still ongoing scientific discussion on many aspects of the transparent methodology.

3. Purchasers are usually make planning decisions on population level, whilst prescribers’ consider the interest of individual patients.

4. It is hard to ensure that economic evaluations are conducted from a societal point of view to be able to include all the costs and benefits of an intervention.

5. Practical application of results is hindered by the lack of understanding of results of economic evaluations among potential users.

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**Practical Issues**

1. The unit costs of different interventions are missing. In most of the cases the National Health Insurance Fund’s reimbursement database have to be used for the estimation of the diseases specific unit costs.

2. In many cases efficacy data have to be used for the modeling of the effectiveness of medications. There is not available database for the estimation of the effectiveness of most of the interventions out of clinical settings.

3. Lack of officially adapted QUALY measurement tool makes the comparison of different medical technologies impossible.

4. Cost-effectiveness plain is not available in Hungary. The valuation of incremental efficiency is complicated and speculative.
Implementation of economic evaluation assumes the following structural and procedural elements as it was developed by Kanavos et al.

**Policy Makers / Payers**

**Researchers**

**Health Care Providers**

**Pharmaceutical Companies**

- Guidelines for economic evaluations
- Commissioning of evaluations
- Evaluations
- Reimbursement
- Practice guidelines
- Disseminations through journals and databases
- Audit of practice against guidelines
On the basis of these findings the following short and medium-term program is recommended.

**V.1. Short-term recommendations**

In the short run the following recommendations are made:

1. Prioritisation of therapeutic areas has to be carried through. Those areas, which are the most important ones from the population health point of view, have to be defined. The way of priority setting has to be transparent.

2. Guideline of economic evaluations has to be updated according to the application experiences in Hungary.

3. An open databank of epidemiological data, effectiveness data and cost data has to be developed.

4. Economic evaluations have to be publicly available for open discussion.

5. The practical application of quality adjusted life years methodology has to be developed in Hungary for practical application. In the lack of this method the comparability of results of health economic evaluations become impossible.

6. Cost-effectiveness plane has to be constructed on the available data and the line of incremental cost-effectiveness, of which financing is publicly viable has to be defined from year to year.

7. Not only new but therapies of the most prioritized therapeutic areas have to be assessed from efficiency point of view.

8. Regarding the process of application a structure and process recommended by Kanavos et al. has to be developed.

9. Human resources of economic evaluation has to be developed centrally in the administrative sector.
10. The ability of interpretation of economic results have to be made widespread in the society.

V.2. Long-term recommendations

In the long run the objective is the development of good and single pharmaceutical policy along the following principles.

1. Ensuring that medicines are effective and as safe as possible.

2. Ensuring clinically effective prescribing.

3. Auditing prescribing and its outcomes.

4. Ensuring the dissemination of good practice.

5. Maximising the health gain from resources used for prescribing.

6. Encouraging equity and easy of access to pharmaceuticals across the NHS.

7. Ensuring responsiveness to patients’ needs.

8. Providing a stable and suitable environment for a strong and profitable pharmaceutical industry.
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Appendix 1. – Qualitative Data Collection

List of interviewees

1. Csaba Dózsa (Health Insurance Fund)
2. Miklós Bacskai (Health Insurance Fund)
3. László Szabó (Ministry of Finance)
4. Zsolt Mogyorósi (International Expert)
5. Kerpel Frónius (International Expert)
6. Zoltán Kaló (Health economists, Novartis Hungary)
7. László Búzás (President of the Hungarian Association of Pharmaceutical Companies)
8. Teréz Amberger (Expert of pharmaceutical policy in Hungary, Hungarian Agency of Economic competition)
9. Imre Somody (Expert)
10. János Demeter (CEO of a Pharmaceutical company)
11. Csilla Kiss Pethoné (Ministry of Health)
12. Tamás Dávid (Health Insurance Fund)
13. Róbert Kiss (expert)
14. Mihály Makara (Ministry of Economics)
15. Judit Laám (Ministry of Economics)
Interview questionnaire in Hungarian

Bevezetés: bemutatkozás és az adatgyűjtés céljának összefoglalása.

Megkérde az interjúalanyt, hogy mutassa be magát és szervezetét.

Korábbi gyógyszer-politikai elképzelések és intézkedések:

1. Kérem mondja el, hogy ön szerint melyek voltak az elmúlt évtized legfontosabb gyógyszerpolitikai tervei és intézkedései és mik voltak ezek?

2. Mennyire voltak ezek sikeresek ön szerint?

3. Mik azok a tényezők, amelyek alapvetően meghatározták a sikerességüket?

4. Melyek azok az intézkedések, amelyeket meg kellett valósítani, de nem kerültek megvalósításra?

5. Mik voltak a megvalósítás akadályának legfontosabb okai?

6. Kik voltak ezeknek az intézkedéseknek a legfontosabb szereplői?

7. Mi volt a szerepük a folyamatban (stratégia megalkotása, döntéshozatal, megvalósítás és ellenorzés).

8. Mennyiben volt kritikus a szerepük a siker szempontjából?

Jelen helyzet:

9. Hogyan értékelné a jelenlegi gyógyszerpolitikát?

10. Mik ön szerint a legfontosabb problémák, amikre a választ meg kellene találni?
11. Mi az oka ön szerint, hogy ezek a problémák kialakultak?

12. Kik ön szerint a legfontosabb szereploí a gyógyszerpolitikának?

Új intézkedések:

13. Milyen új gyógyszer-politikai intézkedéseket terveznek az elkövetkező években?

14. Mi az oka ezen intézkedések bevezetésének ön szerint?

15. Kik dolgozták ki ezeket az intézkedéseket?

16. Mi ezekrol a véleménye és az ön ill. szervezetének szerepe a megvalósításban?

17. Mit gondol, milyen tényezők fogják még befolyásolni e politikák sikerét? Mik ön szerint a sikeres megvalósítás feltételei?

Tudna még olyan interjúalanyokat ajánlani, akik ön szerint tudnának segíteni a kutatásban?

Köszönöm a segítségét.

*Lásd a felméréshez használt urlapot.*
Qualitative Data Analytic Sheet in Hungarian

This is a sample to present how the results of interview questionnaires have been used and processed further (the original sheet leaves more space for notes and citation!).

<table>
<thead>
<tr>
<th>Intézkedés tartalma és ideje:</th>
<th>Megjegyzések</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Fázis</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategia megalkotása:</td>
<td>Megalkotás oka:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Szereplék:</td>
</tr>
<tr>
<td></td>
<td>Befolyásoló tényezék:</td>
</tr>
<tr>
<td>Döntés az alkalmazandó politikáról:</td>
<td>Döntés megszületett:</td>
</tr>
<tr>
<td></td>
<td>Szereplék:</td>
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<tr>
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<td>Befolyásoló tényezék:</td>
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<table>
<thead>
<tr>
<th>Megjegyzések</th>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Strategia alkalmazása:</th>
<th>Alkalmazás periódusa:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Szereplék:</td>
</tr>
<tr>
<td></td>
<td>Befolyásoló tényezék:</td>
</tr>
<tr>
<td>Politika értékelése:</td>
<td>Értékelés megtörtént?</td>
</tr>
<tr>
<td></td>
<td>Szereplék:</td>
</tr>
<tr>
<td></td>
<td>Befolyásoló tényezék:</td>
</tr>
</tbody>
</table>
Interview questionnaire in English

Introduction: introduction of myself and the research.

I ask the interviewee to introduce him or herself and the organisation he is working for.

Previous pharmaceutical policy in Hungary:

1. Please tell me about the most important pharmaceutical policies and policy decisions in Hungary.

2. How successful were these policies according to your opinion?

3. What are the factors that determined the success of failure of these policies?

4. Which are those policy decisions that should have been introduced and realised?

5. What were the main hindering factors of the realisation of these policies?

6. Who were the most important actors of these policies?

7. What were the role and tasks of these stakeholders?

8. How critical was their contribution to the success of the policy process?

Present state of policy making:

9. How would you evaluate the present pharmaceutical policy?

10. What do you think are the most important issues and problems?

11. Why do you think these problems have evolved?

12. Who are the most important actors of pharmaceutical policy at the present?
New policies to be introduced:

13. What new pharmaceutical policies are planned to be introduced?

14. What are the main reasons behind the introduction of these policies?

15. Who are involved in the development of these policies?

16. What is your opinion about it and what is the role of your organisation in this process?

17. What factors do you think are going to influence the success of these new policies?

Could you recommend me further potential interviewees?

Thanks for your help.

On the following page I show a questionnaire form that I use during the interviews.
**Qualitative Data Analytic Sheet in English**

This is a sample to present how the results of interview questionnaires have been used and processed further (the original sheet leaves more space for notes and citation!).

<table>
<thead>
<tr>
<th>Phase</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy strategy and its time:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Development of strategy:</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Remarks</td>
</tr>
<tr>
<td>Determinants of policy:</td>
<td></td>
</tr>
<tr>
<td>Stakeholders:</td>
<td></td>
</tr>
<tr>
<td>Period of decision:</td>
<td></td>
</tr>
<tr>
<td>Stakeholders:</td>
<td></td>
</tr>
<tr>
<td>Determinants of the decision:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Implementation:</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Remarks</td>
</tr>
<tr>
<td>Stakeholders:</td>
<td></td>
</tr>
<tr>
<td>Period of implementation:</td>
<td></td>
</tr>
<tr>
<td>Determinants of implementation:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation of policy:</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Remarks</td>
</tr>
<tr>
<td>Was the evaluation undertaken?</td>
<td></td>
</tr>
<tr>
<td>Actors:</td>
<td></td>
</tr>
<tr>
<td>Determinants of evaluation:</td>
<td></td>
</tr>
</tbody>
</table>

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Appendix 2. The economic evaluation of hypertension treatment (a case study)

In this study an economic evaluation of a selection of hypertension treatment was carried to examine:

- What are the special conditions of the carrying through and implementation of economic evaluation of a treatment group focusing on an important disease group?

- What are the consequences of the results of economic evaluations on present reimbursement practice?

In the following part I introduce the topic and justify the selection of the disease area.

Introduction

During the last few decades the public health importance of hypertension has become one of the first priorities, because of several reasons. These are the following:

1. Essential primary hypertension is the most prevalent non-communicable chronic disease for which effective treatment is available [1, 2]. Although, the hidden morbidity is assessed to be considerable in the case of hypertension it is estimated that it affects one third of the elderly population in economically developed countries [3].

2. Hypertension predisposes to all of the major atherosclerotic cardiovascular diseases, including heart failure, stroke, coronary artery disease and peripheral artery disease [4 - 9].
3. Reducing blood pressure pharmacologically has been proved to reduce the risk of development of cardiovascular, cerebrovascular and renal disease [9].

Although, hypertension treatment and control is considered a successful medical intervention and the decrease of the incidence of morbidity and mortality of associated diseases is recognised as one of the result of successful hypertension control, three main concerns has arisen.

Firstly, according to survey results the majority of hypertension patients is still poorly controlled and their hypertension do not reach the required level [10-12].

Secondly, incidence of stroke and ischaemic heart diseases started to rise again, which is thought to be the result of declining awareness of adequate hypertension control [9].

Thirdly, hypertension management accounts for a large and growing part of health care budget spending. If the adequateness of hypertension management improves in the future the cost of treatment of hypertension will increase to a considerable amount [13, 14]. Owing to this fact, the efficiency of hypertension management becomes more and more significant. It is unavoidable that over the effectiveness of anty-hypertensive treatment their costs have to be adequately measured and evaluated. This helps the rational choice between cheaper but less effective and more costly but more effective treatment alternatives.

In our study we faced a similar situation. We tried to find the answer whether extra costs of modern fixed combination treatments was justified by its extra benefits compared to fixed combination anty-hypertensive treatments and traditional metoprolol treatment.
Objectives

The general objective of the study is the comparative assessment of cost-effectiveness of a selection of traditional and new antihypertensive treatments.

In our study we wished to reach the following objectives:

*Obj.1.* We calculated the unit cost of treatment of hypertension and hypertension related diseases (stroke, ischaemic heart disease and pulmonary embolism).

*Obj.2.* Comparison of the effectiveness of different antihypertensive treatments through modelling

- the controlled number of hypertensive patients and
- the long-term savings through the calculation of life years saved by the avoided mortality in stroke, cardiovascular diseases and pulmonary hear diseases owing to effective hypertension treatment.

*Obj.3.* Comparative assessment of the efficiency of selected treatments through the calculation of the average and incremental cost-effectiveness of hypertension treatment.
Methods

To reach the stated objectives we applied the following methodology. To assess the cost-effectiveness of hypertension treatment we applied both a societal and health insurance fund viewpoint.

Cost effectiveness was calculated for the year 2002.

Data sources

Modelling the outcomes

To model the outcome of the treatment of hypertensive patients we had to assess:

- the effectiveness of hypertensive treatment,
- the controlled number of hypertensive patients,
- the avoided number of deaths in ischaemic heart diseases, cerebrovascular diseases and pulmonary embolism.

Modelling the effectiveness of antihypertensive treatments

In our study we modelled the effectiveness of the following antihypertensive treatments, such as:

<table>
<thead>
<tr>
<th>Noliprel®</th>
<th>Co-Renitec®</th>
<th>Enap HL®</th>
<th>Accuzide®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noliprel Forte®</td>
<td>Renitec Plus® 20/6</td>
<td>Coverex Komb®.</td>
<td>Accuzide 20®</td>
</tr>
<tr>
<td>Betaloc® (50mg)</td>
<td>Lotensin HCT® 5/6.25</td>
<td>Lotensin HCT® 10/12.5</td>
<td>Inhibace Plus®</td>
</tr>
</tbody>
</table>
These medications were selected as all of them belong to the fixed combination of modern antihypertensive group. Betaloc was selected as one of the most widespread used generic and traditional anty-hypertensive treatments.

To gain effectiveness data of the above selection of antyhypertensive treatments we undertook a non-systematic literature search. The objective of the search was to assess how effective the above treatments were in normalising the blood pressure of hypertensive patients. For literature search we used the following two databases:

- Cochrane library,
- Medline.

As a result of literature search we found that [15-32]:

- Superiority of effectiveness of modern fixed dose combination treatments in the control of hypertension had been demonstrated;
- It could be assumed that modern fixed dose combination therapies had similar effectiveness.

Owing to these findings we assumed that traditional treatments controlled 50% of hypertension patients successfully and modern fixed dose combination therapies had an incremental effectiveness of double of the traditional metoprolol therapy.

**Controlled number of hypertensive patients**

To calculate the controlled number of hypertensive patients we assessed the prevalence of hypertensive patients in Hungary. We gained prevalence data from the HMAP program in which prevalence and incidence of non-communicable chronic diseases are collected from general practitioners [33]. This database covers a representative sample of the Hungarian population. As these results show the prevalence of hypertension of a sample of the Hungarian adult population (aged 35 – 74) we extrapolated these prevalence for the whole population by calculating the age group specific prevalence figures. According to these results, the estimated prevalence of hypertension by age groups in 2000 is shown in the following table.
The above table shows the uncertainties of extrapolated prevalence data by showing the lower level and upper level of 95% Confidence Intervals of prevalence.

Controlled number of hypertensive patients was calculated based on the effectiveness information and the above information of prevalence of hypertensive patients.

### Modelling the avoided number of deaths

To model the avoided number of deaths attributed to effective hypertension control we examined the association between hypertension and the following diseases:

- I10 – I15.9: Hypertensive disease;
- I20.0 – I25.9: Ischaemic heart disease;
- I26.0 – I28.9: Pulmonary heart disease;
- I60.0 – I69.8: Stroke;
- I70.0 – I70.9: Diseases of arterias, arteriolas and capillaries;
- I74.0 – I74.9: Embolisation and thrombosis of arteriolas.

To model the saved years of life by the avoided number of deaths from the above diseases we had to describe:

- the potential years of life lost due to the above diseases,
- and the Relative Risk of morbidity or mortality due to hypertension.
Owing to these data we could calculate the *Population Attributable Fraction (PAF)* [30] of deaths due to hypertension and the years saved due to avoiding a certain amount of deaths depending on the effectiveness of hypertension control.

In our model we used the following Relative Risk figures [27] (Table 1.).

**Table 1. Relative Risk of hypertension associated diseases and their 95% Confidence Intervals**

<table>
<thead>
<tr>
<th>Disease type (BNO Code)</th>
<th>Relative Risk</th>
<th>Mean</th>
<th>Lower 95% CI</th>
<th>Higher 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>i20</td>
<td>1.91</td>
<td>1.79</td>
<td>2.04</td>
<td></td>
</tr>
<tr>
<td>i10</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>i60</td>
<td>1.56</td>
<td>1.3</td>
<td>1.71</td>
<td></td>
</tr>
<tr>
<td>i26</td>
<td>1.87</td>
<td>1.77</td>
<td>1.99</td>
<td></td>
</tr>
</tbody>
</table>

**Modelling the costs**

In our model we calculated the following cost items:

- Cost of treatment of hypertension;
- Cost of medication of hypertensive patients;
- Cost of treatment of attributable diseases due to hypertension (ischaemic heart disease, cerebrovascular diseases and pulmonary embolism);
- Cost of years of life saved.
Calculation the cost of hypertension treatment and medication costs

Hypertension treatment costs and cost of medication was calculated separately for the sake of modelling (in this way in our model we could examine cost of treatment of any kind of hypertensive medication).

Over the medication costs the following cost items were included in the calculation of the cost of hypertension treatment (Table 2.).

Table 2. Sources and year of relevance of cost items

<table>
<thead>
<tr>
<th>Cost item</th>
<th>Source</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute and Chronic Inpatient Care</td>
<td>GYOGINFOK</td>
<td>2000-2002</td>
</tr>
<tr>
<td>Outpatient Care</td>
<td>GYOGINFOK</td>
<td>2000-2002</td>
</tr>
<tr>
<td>Sickness Benefit Allowance</td>
<td>Health Insurance Fund</td>
<td>2000-2001</td>
</tr>
<tr>
<td>CT/MRI diagnosis</td>
<td>GYOGINFOK</td>
<td>2000-2002</td>
</tr>
</tbody>
</table>

These cost items are prices paid by the National Health Insurance Fund and not real costs. However, the main advantage of them is that they include nationwide statistics and not the result of a sampled data collection. Some of the important cost items could not be included in the costing due to the lack of indication specific cost data.

Cost of one day medication is shown in the following table (Table 3.).

Table 3. Cost of one day treatment of compared medications (in HUF)

<table>
<thead>
<tr>
<th>Cost of one day treatment</th>
<th>Total cost in HUF</th>
<th>Reimbursed cost by HIF in HUF</th>
<th>Paid by patient in HUF</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO-RENITEC</td>
<td>54</td>
<td>43</td>
<td>11</td>
</tr>
<tr>
<td>RENITEC PLUS 20/6</td>
<td>54</td>
<td>43</td>
<td>11</td>
</tr>
<tr>
<td>ENAP HL</td>
<td>52</td>
<td>43</td>
<td>9</td>
</tr>
<tr>
<td>NOLIPREL</td>
<td>106</td>
<td>47</td>
<td>59</td>
</tr>
<tr>
<td>NOLIPREL FORTE</td>
<td>127</td>
<td>56</td>
<td>71</td>
</tr>
<tr>
<td>COVEREX KOMB</td>
<td>127</td>
<td>56</td>
<td>71</td>
</tr>
<tr>
<td>ACCUZIDE</td>
<td>73</td>
<td>48</td>
<td>25</td>
</tr>
</tbody>
</table>
Modelling the cost of treatment of attributable diseases

To model the cost of attributable diseases we calculated:

- the unit cost of treatment of attributable diseases,
- the Population Attributable Fraction (PAF) of diseases at the present prevalence of hypertension.

Unit costs of the previously described diseases were calculated in the same way what we have already described in the case of calculation of unit cost of treatment of hypertension. The only difference was in the calculation of cost of medication of attributable diseases. In this case we used IMS indication specific drug usage statistics to calculate indication specific medication costs.

PAF was calculated in the same way as it was described in the case of modelling of avoidable mortality.

Calculating the costs of years of life saved

In this calculation we used the human capital approach [35] to calculate the value of a saved life year. We assumed that the total monthly revenue before taxation of an average Hungarian in 2002 was 130 000 HUF. Based on this figure we could assess the loss of HUF due to an early death at a given age during the productive life period.
Calculating Cost-Effectiveness Ratios

In our calculation we both calculated the average and incremental cost-effectiveness [35] of the selected hypertension treatments.

In the case of average cost-effectiveness we calculated the cost per life years saved and cost per number of controlled cases of hypertension.

Incremental cost per incremental life years saved and incremental cost per incremental number of controlled cases of hypertension was also calculated. In calculating the incremental cost-effectiveness ratios we assessed the efficiency of financing extra effect of more expensive treatments. See the more detailed explanation of the use of incremental cost-effectiveness ratio in the Result section.

Basic Assumptions of the applied model

In our model we applied the following assumptions:

1. Each patient suffering from hypertension is treated and each treated patient is 100% compliant with the treatment regime.

2. This is not the first year of the treatment but the model reflects a steady state situation after many years of the introduction of treatment.

3. To model controlled morbidity and avoided mortality we applied a prevalence model, which can describe real flow of events to a limited extent.

4. An average patient takes the Daily Defined Dose (DDD) equivalent amount of anti-hypertensive medication.
In our study we compared the cost-effectiveness of a selection of hypertension treatments. Our results are going to be presented in two parts. Firstly, we show the average cost-effectiveness of the analysed treatments. Secondly, we look at the incremental cost-effectiveness of treatments. Incremental cost-effectiveness is analysed owing to the special situation we faced during the comparison of treatments, i.e. modern treatments are more effective but more expensive treatments than traditional treatments. Under these conditions, through applying incremental cost-effectiveness analysis, we can evaluate how additional money can be spent more efficiently to gain additional health.

Average Cost-effectiveness

To measure the average cost-effectiveness of treatments we used both the societal and Health Insurance Fund viewpoint and we also analysed the cost-effectiveness through measuring the cost per life years saved and cost per number of avoided morbidity. Results are shown for all these cases.
Average Cost-effectiveness (Societal viewpoint)

Cost per life years saved

The following graph (Graph 1.) shows the average cost per life years saved.

Graph 1. Average cost-effectiveness (cost – HUF - per life years saved) of hypertension treatment for a selection of medications

It is shown that there is a wide variation in the average cost-effectiveness of the different hypertension treatments. The lowest cost-effectiveness ratio is related to the Betaloc® treatment.
Cost per number of controlled cases of hypertension

The following graph (Graph 2.) shows the average cost per controlled morbidity specific for the analysed treatments.

Graph 2. Average cost-effectiveness (cost – HUF - per number of controlled morbidity) of hypertension treatment for a selection of medications

Case is similar to the previous one. Average cost-effectiveness of different medications shows a wide variety. The cost- effectiveness of Betaloc® was negative due to the method of cost calculation (avoided costs of treatment of hypertension related diseases were deduced from the cost of hypertension treatment without discounting).
Average Cost-effectiveness (Health Insurance Fund’s viewpoint)

If we look at the results from a Health Insurance Fund’s viewpoint the situation changes due to the different level of reimbursement of medications.

Cost per life years saved

The following graph (Graph 3.) shows the average cost per life years saved.

Graph 3. Average cost-effectiveness (cost – HUF - per life years saved) of hypertension treatment for a selection of medications

Now, the rank of average cost effectiveness of products is different from the case when counted cost-effectiveness from a societal viewpoint. Due to the fact the previous situation does not change by examining the cost per avoided morbidity it is not going to be presented here.
Incremental Cost-effectiveness

In the previous section we presented the results of the evaluation of average cost-effectiveness of hypertension treatment. This approach for the calculation of efficiency of medical technologies could influence decision-making on reimbursement if the effectiveness of treatments is not the primary objective of policymakers. However, if the decision maker faces a situation when a new medical treatment provides additional treatment benefits by extra cost an incremental cost effectiveness analysis has to be carried through to evaluate which treatment alternative provides the most efficient incremental outcome. Due to the fact that we face this situation we assessed the incremental cost-effectiveness of modern hypertension treatments. To be able to assess the efficiency we chose the Betaloc® treatment as a comparator point.

Incremental Cost-effectiveness (Societal viewpoint)

Cost per life years saved

The following graph (Graph 4.) shows the incremental cost per life years saved

This graph proves that the incremental cost-effectiveness of different treatments are different. This means that on the basis of incremental efficiency drugs can be ranked from the most dominant to the least dominant treatment. This obviously carries an important message for both decision makers on the provider, financer and patient side.
This observation means that the subsidisation of different products has to be undertaken at different level.

Due to the fact that the previous argument does not change by looking at incremental cost per avoided incremental morbidity these results will not be shown here.

**Graph 4. Incremental cost-effectiveness (cost – HUF - per life years saved) of hypertension treatment for a selection of medications**

On the following graph we show how this result is modified if we measure efficiency from the Health Insurance Fund’s viewpoint.
Incremental Cost-effectiveness (Health Insurance Fund’s viewpoint)

Cost per number of controlled cases of hypertension

The following graph (Graph 5.) shows the incremental cost per number of controlled cases of morbidity specified for the analysed treatment alternatives.

Graph 5. Incremental cost-effectiveness (cost – HUF - per number of controlled cases of hypertension) of hypertension treatment for a selection of medications

The importance of these results is that it shows that reimbursement of medicines produces an unequal situation from efficiency point of view.

This observation means that at the present level of reimbursement the incremental cost-effectiveness of certain products is better than the incremental efficiency of other above list is medications. This means that the incremental gain of therapeutic effect is
more efficiently gained in the case of Noliprel® treatment than in the cases of the other treatment alternatives.
**Discussion**

In our study we aimed to evaluate and compare the cost-effectiveness of a selection of different hypertension treatments. To assess cost-effectiveness we built up a cost-effectiveness model in which we calculated the costs of hypertension treatment and the costs of treatment of hypertension related diseases (ischaemic heart disease, cerebrovascular diseases and pulmonary embolism). We modelled the effectiveness of hypertension treatment through the avoided morbidity and mortality owing to effective control of hypertension with the selected pharmaceuticals. Both average and incremental cost-effectiveness were calculated from a societal and Health Insurance Fund’s viewpoint for the year 2002.

There were important assumptions behind the building up of our model. The most important one refers to a condition when antihypertensive treatment covers the whole hypertensive population, aged 35-74, and every patient complies with the antihypertensive treatment to 100%. Obviously, these assumptions do not depict the reality properly, however, they had to be set for the sake of modelling and the effect of the deviation of our assumptions from reality was considered in the conclusion, too.

Our results showed that the *average cost-effectiveness* of different products are different. And it was also showed that this rank is heavily influenced by the reimbursement of the different products. The other message of average cost-effectiveness was that more treatment options are more effective but more costly alternatives. To measure efficiency from this point of view we undertook an incremental analysis of efficiency of the selected treatments.

*Incremental cost-effectiveness* analysis showed that the marginal cost of gaining an extra life year or avoiding the controlling of an extra case of hypertension cost less in the case of Noliprel® treatment than in the cases of the following treatment alternatives: Lotensin HCT 10/12.5®, Coverex Comb®, Accuzide 20®, Inhibace Plus® and Noliprel Forte®. This list slightly changes if we consider the present...
conditions of reimbursement through undertaking the analysis from the Health Insurance Fund’s viewpoint. In this case the incremental cost-effectiveness of Noliprel® treatment was better than the incremental cost-effectiveness of the following treatments: Noliprel Forte®, Coverex Combination®, Accuzide®, Accuzide 20®, Lotensin HCT 10/12.5® and Inhibace Plus®.

Sensitivity analysis of the results did not cause the change of the above conclusions.
References


