

# Policy Interventions to Tackle Health Inequities in Macedonia: Patient Rights and Reference Pricing of Pharmaceuticals

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## Abstract

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**Background.** Health inequities refer to differences in the health status among the various groups of the population caused by modifiable external conditions and environment created in and around the health care system. The Government of Republic of Macedonia has adopted law of patient's rights and implemented referent pricing of the pharmaceuticals with primary purpose to deal with inequities in health care.

**Aim.** The aim of this paper is to present the challenges in implementation of two health policy interventions developed to reduce health inequities in Macedonia.

**Methods.** The study is descriptive analysis of two health policy interventions. The interventions selected for analysis were most popular health policies widely promoted by the Government. The paper reviews the process, adoption of the laws and implementation of the interventions. The initial impact of the interventions is assessed over media reports, responses of the medical community, patients and is compared to international experiences.

**Results.** Available information show that implementation of the law of patients rights has not achieved its primarily purpose, yet. The reference pricing has shifted the burden for financing of the pharmaceuticals from the Health insurance fund, to the patients.

**Conclusions.** More specific studies needs to be designed to assess the impact of these policies on the equity in the health care system in Macedonia.

## Introduction

Health inequities refer to differences in the health status among the various groups of the population caused by modifiable external conditions and environment created in and around the health care system [1]. There is growing movement and political pressure on governments to develop, promote, and implement policies aimed to reduce health inequities in the countries. This trend has been particularly strengthened following the publications of the report of Global Commission on Social Determinants of

Health [2], and the World Health Report 2008 [3]. These reports present strong evidence and knowledge base on the root causes for increased gap in health status among populations in different countries, regions as well as within countries. Available evidence show social gradient in the health status of the populations that depends of the societal ladder in the community. Numbers of recommendations are available to the governments what types of actions to take to reduce the inequities in health and to address social determinants of health. However,

sometimes countries with little experience in designing such interventions and contrary to the initial objectives and expectations erroneously can design and implement policies that may increase the inequities in health. The reasons for such problems are many, but usually they are consequence of inadequate design, poor timing and planning, lack of human resource capacities in implementing such policies.

## Interventions to tackle health inequities

The international pressure and civil sector movement alarmed the political elites to respond to the needs of the population. In 2006 one of the largest political party in the country in its election manifesto promoted very ambitious plan for health sector reforms "Safe, efficient and just health system"[4]. The need for comprehensive reform and reconfiguration of the health system was put at the forefront of the government policies. The key reforms were aimed to reduce inequities in health provision at the point of delivery according to the needs of the patients, and regardless of the ability to pay. The concept of the reforms intended to maintain the social health care system based on solidarity, to reduce out of pocket expenditure, to increase the autonomy of the health care providers, and significantly to improve the access to information for the patients and their participation in the medical treatment procedures. Among key agenda commitments of the manifesto was to improve and promote the rights of the patients by drafting and adopting the Law on patients' rights; and to improve the access and supply of pharmaceuticals by drafting new Law on pharmaceuticals. Also the plan envisaged developing reference price system for pharmaceuticals as cost contain measure in order to secure better supply and to provide choice to the patients.

### a) The law of patients' rights

The main purpose of the government policy to develop and implement law of patient rights was to improve the access to information for the patients and to reduce the inequities at the point of delivery of health care services. In Macedonia in the transition years there were number of situations in the hospitals when patient's rights were violated, patients felt unpleasant, and their privacy and dignity was harmed. Most of these reports were based on journalistic stories, and there are no available publications on this matter. Many patients were not informed by their doctors of the different possibilities of treatment, possible choices and possible risks of each option. The new Law of patient rights aimed to level up the position of the

patients at the level of health care providers, and to enable higher public and civil sector participation in promotion and protection of the patients' rights [5]. The first draft of the Law was completely opposed by the medical community represented and led by the Doctor's chamber. The law was adopted in the second phase by the parliament in 2008 after many public debates, talk shows and involvement of the civil society sector. In the end all political parties supported the final version of the law [6].

### b) Reference pricing of pharmaceuticals

The pharmaceutical market in Macedonia has slowly developed with limited competition due to the small market opportunity and very complicated procedures to register new products. Macedonia as small country of 2.1 million citizens was not very attractive for the big pharmaceutical companies. This was additionally complicated by number of bureaucratic obstacles, limitations and complicated administration to enter the market. Due to these circumstances the costs of some pharmaceuticals and medical devices had been much higher compared to the neighboring countries. There was constant lack of supply in drugs in the pharmacies included in the positive list financed by the Health Insurance Fund [7]. On the other hand, drugs were always available for private purchase by the patients. This has resulted in increase of private spending for health since cost of pharmaceuticals and medical devices constitutes the largest percentage of total health care consumption (68.5%) (see Table 1).

**Table 1: Total annual household expenditure for health care 2008.**

<i>Personal Expenditure</i>	<i>Per person in MKD</i>	<i>%</i>
Total consumption on health care	2949	100
Drugs and medical devices	2020	68.5
Outpatient services	829	28.1
Hospital services	93	3.4

Source: Statistical yearbook 2008.

In order to overcome the problems in supply of pharmaceuticals and to reduce the out of pocket expenditure the government has introduced set of interventions in the pharmaceutical sector including adoption of the new law on pharmaceuticals. The new policy was aimed to relax the conditions of the big producers from EU and USA more easily to enter the market with new products and substantially to reduce the waiting times and bureaucratic procedures for registration. According to the law, ministry of health sets the prices of the drugs at same level regardless of the pharmacy where

drug would be purchased. Each package of drugs contained sticker with the set price for the patients to see. The government also decided to introduce reference price system in Macedonia with ambition to reduce the out of pocket expenditure and to provide more choice and availability of pharmaceuticals at the market [8].

## Results

The adoption of the law of patient rights set the basis for achieving the initial objectives to improve the access of information and to level up the position of the patients. Quite contrary to the expectations, its adoption went under very long procedure of public hearings, parliamentary and media debates. The perception of the medical community towards the law remained unchanged and it was accepted as instrument to reduce the power of the doctors. The doctors did not understand the law as good opportunity to improve the communication between the medical personnel and patients. The medical community feared that the law would now encourage the patients to challenge doctors' decisions on treatments, performance of the operations what would lead towards performing more defensive medicine. However, even after two years since the law was adopted there are no official studies on the impact of its implementation. We still witness poor quality of services and lack of information for the patients in health care facilities. The adoption of the law has not yet initiated development of necessary by-laws and rulebooks by the ministry of health that should assure its proper implementation. The communication of the law to the patient is problematic particularly for the less educated portions of the population.

The development of reference prices of pharmaceuticals in Macedonia was based on erroneous government assumption to set low prices what have created opposite effect. The costs of certain pharmaceuticals were set lower than the cost of same drugs in the neighboring countries. Macedonian pharmaceutical producers also export its products to the neighboring markets. The new pricing system created business problem for producers, since proposed reference prices were set lower than the export prices of the same products. Producers were not willing to supply the drugs for the referent prices set by the government [9]. Thus, if the patient wanted to take the drug per selected referent price, it was not available. The patients were forced to purchase drug of another producer with additional and usually higher copayment (Table 2) [10].

As one can observe from the table the absolute

**Table 2: Generic and brand names of selected drugs; reference and set price, and difference in co-payment.**

No	Name of the medicine (form, strength, producer)	Referent price in denars including VAT*	Set price in denars**	Co-payment required to be paid by the patients	Absolute Difference in Set/referent price
1	Skopyl tbl.5mg x 20 Generic name: Lisinopril Alkaloid	18.19	105.84	87.65	5.8 times
2	Skopyl tbl.10mg x 20 Alkaloid	25.20	122.22	97.02	4.96 times
3	Skopyl tbl.20mg x 20 Alkaloid Citaler tbl.500mg x 10	25.41	165.38	141.18	6.05 times
4	Generic name: Ciprofloxacin Alkaloid	27.79	214.20	189.72	7.7 times
5	Atoris tbl.10mg x 30 Generic name: Atorvastatin Krka	47.10	546.49	4	11.6 times
6	Atoris tbl.20mg x 30 Krka	61.80	625.97	729.46	10.1 times
7	Atoris tbl.40mg x 30 Krka	124.80	1,284.78	1,165.92	10.3 times

Sources:

\*The Health Insurance Fund determines reference price of the drugs ([http://www.fzo.org.mk/WBStorage/Files/Priracnik%20Ref\\_Ceni.pdf](http://www.fzo.org.mk/WBStorage/Files/Priracnik%20Ref_Ceni.pdf));

\*\* Price of drugs is set by the Bureau of pharmaceuticals (for all registered drugs and set prices visit [www.reglek.com.mk](http://www.reglek.com.mk)).

difference in prices between the referent and the set price for the selected drugs differs from minimum 5, up to more than 11 times higher price. Thus in practice the user charges for pharmaceuticals increased shifting the cost of previously public funding, towards more private out of pocket sources.

## Discussion

For the proper implementation of the Law of patient rights the key challenge remains in finding innovative strategies for communication of the law both with the patients on their rights, how can be achieved, protected and promoted, and with the medical community. This challenge will be bigger in communication with less educated, vulnerable and disadvantaged people in the society. It may take additional few years to implement the law in practice, and to see the benefits for the patients. However, it is to be expected that its proper implementation would reduce inequities at the point of delivery of the health care services.

The introduction of the reference price system in Macedonia was deficient in clear public and professional debate, what resulted in poor understanding of its purpose. However, lack of public debate made it easier for the politicians to sell this policy to the public as success. Internationally there is ongoing debate on the positive and negative effects of referent pricing and their negative impact over the competition in pricing for the drugs [11]. In order this concept to be successful key assumption is reference price for certain drug to be set to enable the availability of the drug at all pharmacies. The patients who do not have the ability to pay higher co-payment to purchase the drug of particular producer, would at least be able to have the same generic product at the referent price

selected by the Ministry of health and paid by the Health Insurance Fund. In contrary, if the drugs are not available for purchase by the referent prices in pharmacies, but just drugs available with higher copayment, then instead to increase the access and affordability, it is to assume that this government policy actually forces the patients to pay higher out of pocket expenses what directly increases inequities as shown internationally [12, 13]. More affected by such changes would be the poorer parts of the population. Available international experience has demonstrated the negative effect of increased user charges particularly among the poor, what is to be expected to take place in Macedonia as well [14].

## Conclusions

This paper discusses the implementation of two government policies designed to reduce health inequities. This first policy (the adoption of new Law on Patient Rights) was aimed to improve the patient's access to information and to protect their rights while accessing services in health facilities. The second policy is introduction of the reference price system for pharmaceuticals in order to reduce the out of pocket expenditure and to improve the availability. The difficulties in implementation of these interventions showed that reduction of health inequities can be very challenging and sometimes-elusive task. While the first intervention went under complicated and timely procedure of adoption of the law, the key challenge remained in the actual implementation of the law. Moreover communication of the key principles' of the law with less educated, vulnerable and disadvantaged groups will be important and crucial in order for the law to be effective in practice. The second intervention shows that instead of achieving objectives of better access and availability of pharmaceuticals, the initial effects were quite opposite and they have resulted in increase in the out of pocket expenditure for the citizens. The international experience points out that this would disproportional affect more vulnerable, disadvantage and unemployed population thus additionally jeopardizing their health status. More specific studies needs to be designed to assess the impact of these policies on the equity in the health care system in Macedonia.

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