REVIEW

Pharmaceutical market in the Republic of Croatia

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ABSTRACT

Most European health systems are currently undergoing reforms. According to the World Health Organization, the aim of the health system reforms are health gains, and one of the issues brought to the foreground with respect to this is cost-containment. Available indicators show that there is an irrational over-consumption of medicines. The paper aims to make a contribution towards rationalizing the use of medicines through the application of a more rational pharmacotherapy, i.e. using the most recent achievements of pharmacoeconomics.

Rational pharmacotherapy implies using the right medicine in the right dosage, over a necessary time period, and at the lowest cost for both an individual and the community. The decrease of excessive consumption would result in a better operation of the medicine market, as the Croatian Health Insurance Institute would be able to make more regular and more timely payments to pharmaceutical wholesalers, which would improve business results of pharmaceutical wholesalers, pharmacies, and factories (Belupo, Pliva-Barr).

It is a well-known fact that the demand for drugs (and other goods) is always higher than the actual payment ability. In most countries in the world the expenses for drugs grow faster than GDP and make up 10-20% of total health care costs, i.e. 1-2% of GDP.

The analyses conducted in the developed countries indicate that the increase in drug expenses is influenced mostly by the changes of the population's demographic structure (aging of the population), chronic non-infectious diseases, and the dynamics of continuous introduction of new and increasingly more expensive drugs.

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INTRODUCTION

The use of drugs in the Republic of Croatia is too high and it is not rational, increasing the pressure of health care costs on the depleted state budget. In searching for the model of rationalization of drugs use, it is possible to apply a more rational pharmacotherapy and the recent findings of pharmacoeconomics. Rational pharmacotherapy presupposes the use of the right drug in the right dose, at the right time, and at the lowest cost for the individual and the community. These are the principles based on which the Republic of Croatia prepares the measures for reducing the use of medicines. A decrease in unnecessary drug consumption would contribute to better functioning of pharmaceutical market, and the Croatian Institute for Health Insurance (HZZO) could make payments to pharmaceutical wholesalers in a safer and a timelier manner.

The paper aims to make a contribution towards rationalizing the use of medicines through the application of a more rational pharmacotherapy, i.e. using the most recent achievements of pharmacoeconomics.

PHARMACEUTICAL MARKET

The Republic of Croatia has been facing extensive health care expenses since the early 90ies, which pose a constant threat of the health care system crash. This has lead to the need of a thorough reorganization or re-engineering of the entire health care system. The characteristics of the new system, which is still in the process of reorganization and re-engineering, are a more thorough application of health care economics, defining and application of health care standards, determination of ownership rights for each health care institution (town, county...), privatization of parts of the health care system, introduction of users' participation in health care costs, additional health care insurance, and acceptance of the principles and a more dynamic application of pharmacoeconomics.

The reform of the health care system in the Republic of Croatia started with the centralization of health care funds, introduction of financial discipline in collecting contributions, obligatory use of tenders that determine prices and/or suppliers for the largest part of health care expenses. The procurement of medical equipment has also been centralized and standardized, resulting in savings in procurement, and the same standard of equipment in health care institutions in the entire country.

Pliva (Zagreb) and Belupo (Koprivnica) are two largest Croatian pharmaceutical companies. Galenski Laboratory (Rijeka), Imunoloski Zavod (Zagreb) /Immunology Institute/, and Zavod za transfuziju krvi (Zagreb) /Blood Transfusion Institute/ have smaller production of pharmaceuticals. In the Croatian pharmaceutical market, the largest share is taken by Pliva d.d. (46%) and Belupo (18%), with sales of almost $20 million USD. The share of 20% taken by Slovenian producers Lek and Krka is a result of tradition and habit rather than better quality and price of their products. Over fifty more pharmaceutical companies that have their local branches or agencies in Croatia are also part of the Croatian pharmaceutical market.

The trading process in pharmaceutics is strictly regulated. The process of drug and other medical products registration is especially strict, time-consuming and expensive. The Croatian Ministry of Health issues a special permit for importing drugs, without which it is not possible to clear the customs for imported drugs. Each series of imported drugs cannot be put on the Croatian market before they are issued a positive opinion by the Croatian Agency for Medicines and Medical Products. Local producers are allowed to control their products in their own quality control labs.

The main subjects in the pharmaceutical whole sale business are large drugs wholesalers. Drugs wholesalers are trading companies that supply health care institutions with medical supplies, drugs, and expendable medical supplies (1). Drugs wholesalers are registered and work

in line with the Law on Trading Companies. Drugs wholesalers are free to set their margins, prices and other sales conditions for their products. As not only the price, but also the supplier for each product are determined using tenders according to the Croatian Law on Healthcare, the Ministry of Health with HZZO have the negotiating position, often dictating the conditions for doing business with drugs wholesalers.

Although drugs wholesalers make only 0.5% of all Croatian wholesalers, very high shares of whole sale drugs trade in the total income and total profit in whole sale business in the Republic of Croatia confirm that there are relatively few well positioned and funded companies.

Organizational positioning in drug trading in the Republic of Croatia makes it possible to distinguish between three types of drugs wholesalers: national drugs wholesalers, drugs wholesalers - focusers, and drugs wholesalers - differentiators. National drugs wholesalers (Medika, Medical Intertrade, Octal Pharma, Phenix) are the biggest and work in the entire Croatia. They offer all sorts of products and provide for all 'classes' of buyers. Drugs wholesalers - focusers (Medifarm, Jadranfarma, AdriaPharma, Uniform) are active in certain regions of Croatia (Slavonia, Dalmatia), have a relatively wide product range, and focus only on particular buyers (pharmacies or community health centers), whereas drugs wholesalers differentiators {Hospitalija, Medias, Medicom) have only a clearly differentiated product range.

Market criteria in the field of drug prices initiate prompt solutions for big price differences within EU member states on one side, and countries that will or have just become members of the EU. Since average prices of drugs in the Republic of Croatia are at 30% of prices in EU member states, the screening process calls for a fast and efficient solution.

Market regulation through pharmacoeconomics

Recent findings in the field of science and practice of investigating, creating, producing, selling, distributing, marketing and using drugs in pharmacy and medicine indicate that the funds used in both rich and poor countries are still insufficient to satisfy the population health care needs.

The well known slogan 'health is priceless' is in current market conditions challenged with the question 'under which conditions?' This gives rise to a new scientific discipline - pharmacoeconomics.

Pharmacoeconomics is a young, interdisciplinary scientific discipline seeking to give answers on how to best use drug funds at our disposal.

When the new drug was being registered ten years ago, efficiency, safety and acceptable quality had priority. They were taken as crucial in deciding whether the drug should be used at all and what was its position in relation to other drugs in the market that were used for same indications.

The development of pharmacoeconomics, i.e. the application of certain techniques of pharmacoeconomics analysis calls for the introduction of the 'value for money' criterion. Pharmacoeconomic analyses of drug efficiency vs. price are part of the necessary standard specifications in most highly developed countries for the registration of new drugs. The EU members are working on the system of drug registration mirroring those of Canada and Australia. These systems should be compatible and mutually transparent.

The essence of pharmacoeconomics is not only in saving, but also in redistribution of limited funds, aiming for maximum efficiency for the invested funding.

Seeking to find the answer to the question 'what do I give up in favor of something else?' (2) (e.g. investments in heart transplants or inoculation of newborns, prevention of osteoporosis or cardiovascular diseases, the use of drug A or drug B for treatment of schizophrenia, etc.). Understandably, the increase of cost for one intervention or drug necessarily reflects on the reduction of funds for another intervention (opportunity cost).

The use of pharmacoeconomics is now a reality in health care systems and pharmaceutical industry.

Examples

Australian Pharmaceutical Benefits Advisory Committee (3) is in charge of estimating economic legitimacy of proposed drug prices, thus making a pharmacoeconomic study an obligatory part of a registration file in case of: introducing a new drug to the drug list, registration of a drug for new indications, considerable increase of prices for listed drugs.

In Canada, Drug Quality and Therapeutics (3) proposes drugs to be listed to the Minister of Health, and need to attach a study that confirms economic legitimacy of a certain drug to the registration file.

POSSIBILITIES OF PHARMACOECONOMIC STUDIES

Today there is a wide range of models and applications of pharmacoeconomic studies. The most popular are 'piggyback' studies, and studies of cost efficiency.

The most frequent method of pharmacoeconomic studies is conducted together with clinical tests, piggyback studies, i.e. a questionnaire about necessary pharmacoeconomic data in the clinical studies protocol (4). The advantages of this method are in the timely collection of data on cost efficiency. There are additional data on quality of life (QoL) and preferred health conditions. They are conducted in strictly controlled conditions, not characteristic of routine medical practice.

Cost efficiency studies (5) are an alternative to piggyback studies. Such studies are specially planned for the analysis of cost efficiency. As opposed to clinical studies, patients for the sample are selected using statistical tools, and are analyzed regardless of behavior (co-operation or withdrawal). The aim of a cost efficiency study is to continuously compare the examined therapy with the regular practice over a certain time period. The advantages of this method are the analysis of everyday medical practice in conditions typical of the environment in which the costs are incurred. The disadvantages are the long duration and variations in medical practice, and the impossibility of simple comparisons of different national settings.

The model (3) obligatory elements of pharmacoeconomic studies in economic analysis are: types of cost analysis - analysis of cost efficiency, benefit analysis, cost-effectiveness analysis (cost-benefit analysis), and cost minimization analysis perspectives of analysis - society, patient, buyer, supplier of service cost types - direct medical costs, indirect costs, immeasurable costs.

The models most frequently used in pharmacoeconomic studies can be classified as: clinical models for decision analysis and epidemiological models

Clinical models for decision analysis are based on medical practice. Clinical decisions are connected to interventions and are suitable for the analysis of cost efficiency studies. Epidemiological models monitor factors and the development of a disease, giving transitional estimates of clinical procedure outcomes (3).

Results and example of using pharmacoeconomics hypercholesterolemia

The link between the increased level of cholesterol and the development of coronary diseases is well known. High cholesterol levels contribute to the development of coronary diseases. The increase of the level of cholesterol may be controlled by changing habits and using drugs. The pharmacoeconomic principle is applied in treating hypercholesterolemia. PROC AM Study (6) used in the Republic of Croatia indicates that out of 4,800,000 people, 1,500 die in the most productive age from coronary disease complications, and further 3,000 suffer from acute heart disease. Due to coronary diseases in the most

productive age, over 22,000 years of life, and about 9,000 years of active work are lost.

The analysis of clinical tests has shown that the treatment of hypercholesterolemia in patients who had a stroke can reduce the incidence of non-fatal stroke by 25%, fatal stroke by 15%, and total death rate by 10% (1). In other words, out of 1,000 patients treated for stroke, 25 can be prevented with appropriate treatment. The success is unfortunately 75% lower in primary prevention (1). The analysis of results obtained indicates that the cholesterol level can be decreased by 15% with dieting, and by 30% with regular use of medicines, thus preventing the incidence of 600 strokes in the active population, and about 200 coronary deaths a year (1).

The computer model programmed according to the data of the Framingham Heart Study by Goldman et al (6) calculated the cost of a year of saved life if certain classes of hyperlypidemics are prescribed the drug Lovastatin at 20 mg.

The cost of a yearly treatment with drugs (simvastatin or lovastatin) is estimated at about 3,300,00 HRK. Results indicate that an annual prevention of a cardiovascular incident in secondary prevention costs about 85,000 HRK. A range of variants has to be taken into consideration (7).

The application of the Framingham Hear Study model indicates that the cost of a year of saved life is lower for men than women. As the cardiovascular disease (CVD) risk increases, the cost decreases, so for certain high risk groups it turns from cost to savings. Savings do not refer only to money; the prevention is cheaper than treatment, but also to saved lives that could not have been saved using available treatment. The therapy should therefore be individualized. The higher the risk, the secondary prevention, i.e. therapy with hypolipidemics becomes not only ethically justified, but also pharmacoencomically cost-effective.

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