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Drug Policy – what is it in Poland and UE

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Abstract

Demographic situation – growth population of people advanced in years, greater detestability of illnesses connected with better diagnostic methods and partial covering of the costs of medicines from the public funds what causes the growth of financial expenditure for the protection of health. Considering the payment possibility of the public payer, which is obligated to finance health care services, decisions to be taken in this field must be based on clear specific requirements and defined and verified information. A proper state body which is authorized to create the structured and conscious drug policy should take planned operations aiming at rationalization of budgetary expenditure and furthermore the supply of safe, effective and cheap drugs to patients.

Keywords: drugs, drug policy, health policy, pharmacoeconomics, financing health care services, refund

Each country reaching a basic level of society's civilization, especially nowadays, deals with the problem of appropriate planning and the balancing of public expenses. A very significant part in every state budget is allocated for public health expenditure. Moreover, constant public debates, proper for the state and global economies, implying legislative changes are held. Meanwhile, apart from the used systemic solutions, the dynamic growth of health spending is observed in nearly every country in the world. 9% of GDP on average is spent on this area in Europe. Poland is ranked one of the last countries in the EU with the expenditure, depending on the assumed calculation method, ca 4.5% of GDP including private spending for this aim – up to 6.5% of GDP [2, 8].

It is worth reminding the important relevant value of GDP per capita, which ranks Poland 23rd in the European Union, which shows the efforts in creating a government policy to ensure citizens' health security. Expectations and health needs of the society are significantly higher than the national budget, which is the an unavoidable consequence of the argument that spending on health care budget will consistently grow.

It is estimated that by 2020 the European Union countries will have spent approximately 16% of GDP on health care. This value seems to be a natural consequence of health changes that occur in an aging society and moreover the indicated level of 30-35% of GDP, which will have to be spent before 2050, raises serious concerns because it is difficult to achieve a well-balanced budget, even in a wealthy society where such a huge part of it will be spent only in one area of the economy. Such an increase in the expenditure is, as I previously mentioned, determined above all by the growing health needs of an aging population. It is worth remembering that the average age reached in populations of developed societies, over the last century, increased by more than a third in analogy to the nineteenth century. However the growing cost of health care system is equally important but the biggest dynamics of spending is observed in the drug economy [1].

From 1997 to 2007, the worldwide sales of drugs increased by 150%. In Poland from 2004 to 2009, the spending for the reimbursement increased from the 6 billion 118 million PLN to 8 billion 213 million PLN. Considering that the statistically consumption of drugs grows rapidly among the people after 56 years of age, it has become a clear need for a rational drug policy. What is the rational management of drugs defined as a drug policy? The drug policy is comprehensive, organizational and it constitutes legal measures by which one of the main tasks of the Minister of Health is executed. The Ministry of Health is constitutionally responsible for the whole public health in the majority of European countries among others for guaranteeing the safe and effective access to drugs to citizens while implementing systemic process of reducing the patient's copayment in the share of the medical treatment [7].

This is a multidisciplinary operation by the Government and its shape is influenced not only by both the Ministry of Finance and the Ministry of Treasury, but it is also a key health department and whole orientations of socio-political, which it has government and parliament performance in the period of the state power.

There are some mechanisms and instruments which allow for rational development of drug policy. At the central level, the main role of the policies of the Minister of Health and central units subordinated to him is to market medicinal products and to make decisions regarding the rate of prices and subsidies for reimbursement. Even if there is no change in the reimbursement system, the increase of expenditure on drugs will still be observed, because of the dominant factors in this area and demographic as well as pharmacoeconomic indicators. The phenomenon of drug spending growth is thus not the main and the only factor determining the dynamics of health spending [6, 10].

Pharmaceuticals is a sector of the economy where, as in no other, due to the progress of sciences and engineering, introducing new molecules of medicinal products, the latest engineering technologies, the most effective ways of treating diseases that have recently been a death sentence or a long-term illness. The number of introduced innovative drugs is huge. Thanks to innovation in the pharmaceutical industry there is the progress and more effective option to treat complex diseases. However considering what this "innovation" is how to measure or rate it in the sense of public expenditure [6, 9]. At the conference of Health Ministers of European countries titled Innovation and Solidarity on Pharmaceuticals, which took place in early September 2010, the Director General of EMA, Thomas Lönngren, tried to define innovation in the pharmaceutical sector. He pointed out that the medicinal product may be considered as innovative if it meets the following criteria:

1. represents a real therapeutic value for the individual or to society,

2. shows the actual therapeutic value,

3. presents an economic value,

4. is relatively more effective than existing drugs in terms of effectiveness, efficiency and safety. He pointed out that "new and approved is not necessarily a new and improved".

Meanwhile, it is estimated that in fact innovation, according to the abovementioned definition is less than 5% of recently developed drugs. The other 95% of medicinal products has a slightly higher clinical efficacy of existing drugs, slightly greater safety, different dosage forms or do not show an advantage over existing ones, except for a consistent difference in price [4,6].

Interesting information was presented by Professor Garattini. The professor used the example of the breast cancer therapy. The median 5-year survival rate in the seventies was 68%, in recent years (2000-2007) this grew to 81%. Accordingly, in the case of colorectal cancer there was an increase from 58% to 69%. The median monthly cost of therapy in the seventies was $ 64, in 2007 it reached $ 6559. So 13% and 11% increase in the effectiveness of therapy represented more than 1000% increase in its costs [6, 5]. The task for each country becomes on the one hand, encouraging innovation, implementing the latest technology in the production and use, on the other hand, which is essential to the drug policy of any State rationalizing expenditure. The above data show how difficult this task is and that it does not generate only positive results in every case.

In the context of limited funds, especially when we deal with such precious common wealth as health every zloty a dollar or euro should be spent in a rational and purposeful way in order the positive effect to cover as much of society as possible with the smallest allocation of national income. The instrument that allows the operation of this type is pharmacoeconomics, the field that came into being relatively recently and which is defined as a scientific discipline, dedicated to comparing the value of medicinal products and medicinal therapy. It is a subdiscipline of the "Health Economics" with its meaning interepreted as the economics of health. Pharmacoeconomics evaluates the cost and effectiveness of a drug technology, which consists of price, performance and Quality-Adjusted Life Year (QALY), which corresponds to the improved quality of life. The beginning of pharmacoeconomics was the formation in 1996 of the English agency called NICE which is accountable for the issue of recommendations that helped to rationalize the financing of selected therapies. The activity was also noticed by other countries which began to create their own agencies.

In Poland, by order of the Minster of Health as of 1 September 2005 on the establishment of the Agency for Health Technology Assessment (AHTA), the agency was founded whose purpose was to help the Ministry of Health in the rationalization of public spending on drug technologies. Its position was not clearly defined. It functioned as a budgetary unit and recommendations issued by it were not binding. As a result of reforms introduced by the new government, the Agency was empowered by the act as of 25 June 2009 amending the act on healthcare services financed from public funds and the act on Prices (Journal of Laws of 2009 no. 118, item 989) and became an important element of the reimbursement system . The aim of the Agency is to perform tasks related to the assessment of health care benefits in the scope of:

a) making recommendations on: the qualifications to provide health care as a guarantee benefit, specifying or changing the level or method of financing as a guaranteed benefit, removing the provision of health care from the list of guaranteed benefits,

b) preparing reports on the evaluation of health care services excluding however reports on the evaluation of a drug or medical device,

c) development of the assessment reports on the evaluation of health care services,

d) development, verification, collection, sharing and dissemination of information on the methodology of evaluation of medical technologies and medical technologies developed in the Republic of Poland and other countries,

e) issuing opinions on health programs.

Currently, most clinical trials and analyses of medicinal products are based on comparing a drug to a placebo. However globally calls for comparative testing of drugs i.e. head-to-head research, which provides best information on their effectiveness and allows to answer the question which drug is better. In such studies the rules under which they are carried out are most important At the Selling Sickness conference held in Amsterdam from 8 - 10 October 2010 was attended by the representatives of the pharmaceutical industry and governmental agencies responsible for regulatory and legislative rationalizing the government expenditure on drugs. They pointed out that the medicinal product should be compared with the best available drug in its group and only if this analysis falls in its favor entering the product into the list of reimbursed drugs should be considered. All stakeholders in the pharmaceutical market acknowledge the need for such a solution. Only after complementing the system with this type of study, one can speak of the effective evidence-based medicine. In Italy, the mechanism created by Professor Garattini successfully works it is called the Garattini tax. Pharmaceutical companies have been charged with 5% of tax on marketing expenditure This money is spent on independent head-to-head research. The introduction of similar solutions is envisaged in Poland.

The Minister of Health with the information provided by the Agency for Health Technology Assessment decides which of society health needs are the priority and which drugs will be covered the reimbursement system, and which are excluded from it. After the completion of price negotiations with pharmaceutical companies, the Minister of Health announces the drug to be entered into the list of reimbursed drugs by reimbursement regulations.

Establishing the price of the reimbursed medicinal product is another important issue requiring careful analysis of the market in comparison to actual needs of the society. It was mentioned that the increase in spending on drugs is the most important factor determining the dynamics of growth of expenditure on the health care. Professor Erik Shokkaert from the University of Leuven shows that spending on innovative medicines accounts for half the growth of health spending in the general government budget regarding the amounts allocated for this purpose. At the same time he draws attention to the unique mechanism of pricing these products. Because, the price is created during bilateral negotiations between a responsible entity and the government, it is extremely important to this process that it is not governed by any economic mechanisms, but primarly by the health needs of citizens. Moreover, the authorities of the State, as a rule, are not able to refer to costs and prices submitted by a company in the form imposed by the company's internal standards of pricing policies.

It is therefore extremely important who and how negotiates. Depending on the negotiating skills of its officials the State may lose or gain hundreds of millions. We are proud of the achievements in this area, as drug prices in Poland are among the lowest in Europe, which has been the result of the activities of the Ministry of Health in recent years.

Of course, the important factor is that our country is almost a market of 40 million people what is taken into account by any pharmaceutical company.

Undertaking reasoned decisions and appropriate establishing of reimbursement prices creates budgetary expenditure on reimbursed drugs. However, this does not cover the subject of reducing the patient's copayment. In Poland, the reimbursement of more than 3700 medicinal products, which are grouped in 417 active ingredients, until the introduction of the Reimbursement Act with its 310 limited groups. Thus doctors had and still have quite a substantial flexibility in deciding which drugs with the same indication to prescribe. The great majority of reimbursed drugs are generic, which are much cheaper than original drugs. System of subsidies for drugs is based on the structures of limited groups, which include drugs with similar therapeutic effect. The level of subsidy of the drugs is determined by the level of payment specified in the relevant list of the Minister of Health and the level of the cheapest drug in the group. So if a patient chooses a more expensive drug he or she pays the portion which is not subject to the reimbursement from the budget of the public payer, i.e. the National Health Fund, increased by the difference in price between the purchased and the cheapest drug. Article 38 paragraph 4 of the Act of 27 August 2004 on health services financed from public funds (Journal of Laws no. 164 item 1027 as amended imposes the an obligation on pharmacy to inform the patients about the possibility of replacement of the prescribed drug with a cheaper substitute. In practice, patients are not informed of this possibility and the law is not observed due to the system of retail margins, which discourages pharmacists and retailer owners from "pro-patient". Behavior the value of retail margin is a fixed percentage, the difference between the wholesale price and retail price, thus the higher a retail price the higher a margin.

The value of the pharmacy market in 2009 amounted to almost 26 billion PLN (according to IMS PharmaExpert and IMS Poland), including the market of reimbursed products which accounts for slightly more than 11 billion PLN. The value of generic medicines market according to the Polish Association of Pharmaceutical Industry Employers accounted for about 65% with its highest rate in Europe. According to these estimates, the public payer saves approximately 7 billion PLN each year due to such a high consumption of generic medicines. At the European Union level, at the aforementioned conference on Innovation and Solidarity on Pharmaceuticals this need was acknowledged, stating that a change in market structure will bring huge savings, which will help to fund more valuable innovative medicines.

Poland, with regard to sales of innovative medicines, has one of the worst positions in Europe, only with Bulgaria, Lithuania and Latvia ahead, which was presented at the conference by Bruno Flamiona from EMA. The Ministry of Health proposes to introduce a fixed margin calculated on the basis of the price of the drug, which is the basis of the limit in the group limited. The aims of the procedure is to stop a pharmacist from offering more expensive medicines, at least in comparison to the reimbursed drugs. This should further increase the share of generics in the market and result in savings for the payer. This approach is beneficial to all stakeholders in the pharmaceutical market, because if the National Health Fund makes savings the reimbursement of medicinal products, this money may be spent on innovative products and introduction of new therapies, which will increase therapeutic possibilities for patients.

It is also important how the dialogue with pharmaceutical companies is conducted. Before 2007, the dialogue with responsible entities was conducted by the department of health in a chaotic, if not incidental, manner, On 19 February 2008, the procedure for cooperation with companies was established for the first time. This procedure requires the subject of the meeting to be defined and the right representation of the company. The time of appointment is scheduled in advance, provided that the subject of the meeting must be presented no later than 5 days before the meeting. Meetings are recorded and minuted. Each meeting is attended by at least three representatives of the Ministry. Employees of the Ministry may not accept any documents and items and all correspondence is addressed via official channels, ie.., with the participation of the Central Registry of the Ministry. The adopted solutions structure the dialogue between the private and public sectors and introduce clear rules of conduct. The above mentioned procedure is positively evaluated in Europe by many countries e.g. France trying to develop similar solutions. It should be noted that the discussed procedure corresponds with the 89/105/EEC Direc-

tive of 21 December 1988 regarding the transparency of measures regulating the pricing of medicinal products for human use and extend the scope of national health insurance systems (Journal of Laws 1989 L 40, p.8), hereinafter referred as the Directive of transparency. The described situation, entered into on 01.01.2012 i.e. the date of entry into force of the Act of reimbursement, which radically changed the Polish pharmaceutical market, while preserving and clarifying of the existing solutions.

To conclude, the main objectives presented above, and state drug policies are intended to reduce drug prices and rationalize expenditure allocated for health care. Conducting a planned, rational drug policy in the management of the state budget is a relatively new concept. The planned effort to achieve the objective should be pursued in a systematic way, in an open dialogue with all stakeholders in the pharmaceutical market. The origins of the creation of the conscious, organized drug policy are the effects of work of recent years, exemplified by the harmonization of medicinal products, the establishment of the Agency for Health Technology Assessment and undertaking specific actions by the Minister of Health. Calculating costs of reimbursement shall not be understood as an attempt to limit the availability of medicines to patients. The drug policy is to transform the money spent into the best possible therapeutic effect for the patient. The rationalization of expenditure is to increase the availability of different therapies to patients resulting in the announced amendments to the list of the reimbursed drugs which introduces more new products owing to the savings brought by the activity of the Ministry of Health.

The aim of the policy is also to reduce a patient's copayment, which in October 2010 fell to the level of 31.1%. The creation of the coherent system of drug policy creates huge opportunities for the overall health of the society, the state budget and the health safety of an individual patient. Conducting independent comparative testing of drugs that will result in reasonable recommendations is the first step and the basis on which the system should operate. The next step is to conduct effective price negotiations with the entities responsible and take rational reimbursement decisions based on evidence of cost-effectiveness, which is possible if the decision maker has appropriate actual data. At this stage, there is a necessity to organize and define the relationship of administration and responsible entity more precisely. After the completion of that process a need for the efficient functioning of the mechanism for encouraging greater consumption of cheaper drugs with the same therapeutic effect remains.

The above mentioned activities involve the implementation of Art 68 of the Polish Constitution, which formulates the general principle of state policy by which everyone, regardless of their financial situation, has the right to healthcare. However, to perform the task while respecting the expectations of patients, demanding the application of modern, often the most expensive treatment which assures high performance and high safety applied at the same time of therapy, there was a need for a rational drug policy, based on the efficient management of expenses and costs. The crowning achievement of the State's activity in this area is the enforcement , of the Act on reimbursement of medicines foodstuffs for particular nutritional and medical devices, commonly known as Reimbursement Act on 1 January2012, which clearly regulates the market, while maintaining appropriate balance between the manufacturer, distributors and the State tax payer, while maintaining compliance with the applicable procedures of the EU Transparency Directive and the Polish patient's constitutional right to access to the latest drug technology in the healthcare system.

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