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Mechanisms determining prices of products on the pharmaceutical market

Introduction

A characteristic of the pharmaceutical market is the existence of state regulations which restrict the freedom of the market. The lack of free market character, we can also talk given the fact that in this case the consumer does not always decide alone about purchasing goods. Thus when he buys a drug is dictated by doctor's recommendation. Thus this market is specific in any way compared with other industry markets [Michalik, Pilarczyk and Mruk 2008, p. 11].

It deserves a special attention the fact that the pharmaceutical industry is one of the fastest growing sectors of the economy around the world. For certain contribute to this phenomenon factors increasing the demand for drugs, such as: the aging population, increased incidence of chronic disease, the formation of new medical technologies and also increased awareness of patients and their expectations connected with health care [Łanda, 2009, p. 12]. Accordingly, global expenses of medication rise. Yet by 2005 their dynamics was disproportionately fast compared to increase general expenses for health, but also to the growth of GDP. The current average datas for OECD countries speak about the average expenses on drugs (public and private) amounting to approximately 17% of the expenditure allocated for the functioning of health care. Between individual countries you can see a vital correlation: the country is poorer, the bigger the percentage of the health system budget is spent on drugs [OECD 2011]. Independently of this, all countries strive for rationalize expenses on drugs simultaneously assurance as much as possible wide access to health care for their citizens. In this context, fair distribution also given disproportionately increase demand for drugs (demand) compared to financial expenditure allocated for the health care sector should be based on the efficient allocation of resources. The pharmaceutical market is a regulated market, there are a number of administrative and legal tools which can be used to limit spending on drugs.

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These mechanisms may directly or indirectly affect the pharmaceutical sector cause essential changes on both the supply and demand.

Review of selected factors determining price on pharmaceutical market

There are many reports talking about what should be taken into account in the process of valuation of the medicinal product. Nacinovich MR. JR mentions, among other things: expenditure incurred during discovery of the substance, the cost of its implementation, marketing and distribution of drugs and the existence of similar drugs, competitive. It is also important to define the target group of the drug and characterize disease entity, which applies to the product.

Accordingly that the pharmaceutical market will never take place free market game, most of the tools of economic analysis and determining the price (constructed with a view to free markets) will not apply here [Lis, Skrzekowska-Baran and Wendykowska 2009, p. 126–129]. Factors which in this case have a real impact on determining prices of drugs can be grouped into three categories:

- medical factors;
- economic factors;
- political and environmental factors.

In the group of medical factors can be distinguished among other things patent protection. In this case, it does not differ from patents obtained for other products are not medicines. Thus, the drug treated the same as other inventions can be covered by patent protection lasted about 20 years. Accordingly of the fact that manufacturers must apply for a patent already in early testing, the actual duration fluctuates within 7–8 years. The ultimate goal of obtaining this type of protection is to recover incurred total expenses on the drug from the manufacturer. Natural seems to be that the funder of clinical trials of a drug, not only does not want to incur losses, but also wants get financial benefits from expenditures. Patent protection provides the producer a monopoly – no one else for the duration of the patent can not use the knowledge gained during the research. Membership in the European Union makes it possible to extend the patent for another five years. In practice, this period is much longer, as manufacturers to protect their medication many patents those obtained not only in the basic substance in the drug, but also to new uses and its various pharmaceutical forms. Such situations make impossible the consumer access to generic medicines that contain the same active ingredients, and their cost is much lower due to the elimination in the process of implementation on the market, the need for clinical trials.

Another medical factor influencing prices of medicinal products is so-called the cost of producing the drug. It consists of expenses: research laboratory the

molecules, preclinical researches, clinical researches I, II and III phase, manufacturing, registration, marketing, administration and distribution. As in the case of patent protection this factor is an indicator of profitability. Producing the drug should guarantee return on expenditure (Return on investment, ROI).

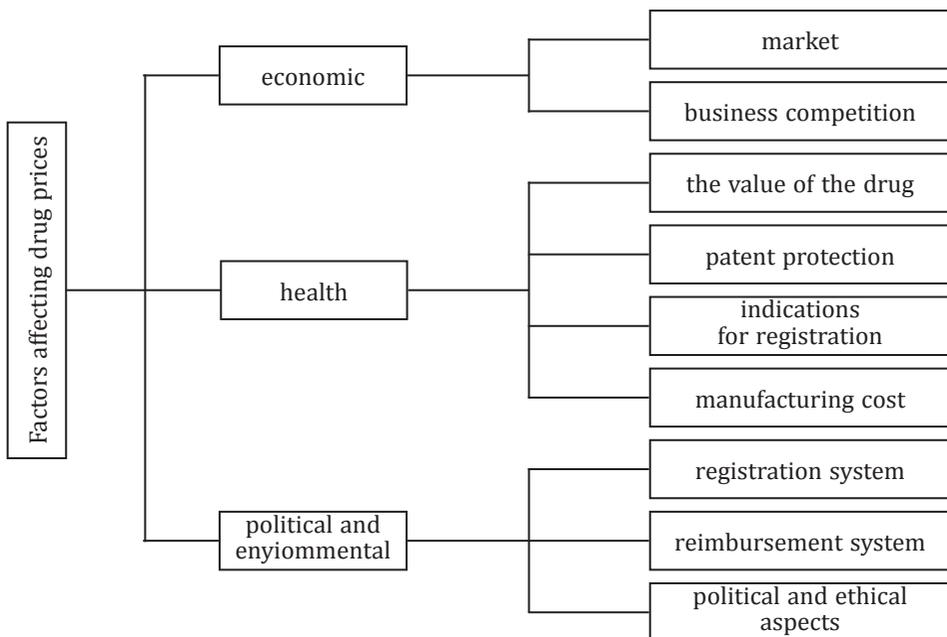
Within the framework of the medical factors can be distinguished also the value of the drug, or evaluate the efficacy and safety of the therapy conducted with it. The greater efficacy and safety, this one can expect higher its price. This factor was further described by the authors in the next chapter.

Another big group of factors are so-called economic factors – taking into account the aspect of market competitiveness of enterprises. These can include:

- size of the manufacturer;
- nature of the company – whether it is a research unit of the pharmaceutical company;
- return on investment – effectiveness of use of expenditure in order to achieve a profit (return on investment, ROI);
- profitability of the company.

The remaining group of factors (environmental, and political) refer mainly to national regulations. They are connecting to, among others, the registration system of marketing authorization, but also with reimbursement system that determines whether and how drugs are financed from public funds. Reimbursement has an indirect impact on the price of medicines covered by it. In addition, this group also can include political and economic aspects.

Chart 1. Factors affecting drug prices



Tools for valuation the medicine on the manufacturer's side

Determination the price of the drug on the basis of the value

One of the most important tools for determining the price for the manufacturer's side is the so-called valuation based on the value of the product (value based pricing, VBP). This method defines the clinical and therapeutic value of the drug by comparing its effects and costs with efficiency and valuables current therapeutic programs. Constituent evaluation value of the drug are: economic analysis and analysis of clinical effectiveness. The most commonly used economic analysis in this case is the so-called analysis of the impact on the budget of the payer (BIA). BIA is the financial analysis carried out form perspective of the payer. It informs whether the implementation of a new drug therapy affects the current consumption of the health care system budget. BIA starting point is to determine:

- how much the current therapy costs;
- whether the introduction of new therapy will affect the number of medical visits, hospitalization and the purchase of medicines;
- which group of patients and at what stage of the disease a new therapy is to be proposed;
- and what is the size of the population, to which to be addressed new technology?

Clinical effectiveness analysis is however a review of reports from scientific research to keep compare the effectiveness of new drugs with similar therapeutic options in mind.

With the clinical effectiveness it is related the clinical value of the substance contained in the medicine. This evaluation is carried out according to the criteria of evidence-based medicine (EBM), and its endpoint is the determination of the height of indicator QALY for a given technology. It is a widely known measure specifying the health benefits included in life years corrected by quality.

Carrying out these analysis is the starting point for the VBP, the purpose of which is, as mentioned earlier, a comparison of the effect and the cost of new technology with existing. Therefore, for value based pricing is important to specify with what the new drug to be compared, or to define the comparators. VBP therefore can be used, in the case when it is known at least one therapy for the definite indication, that is, when it is possible to determine the comparator. The assumption VBP does not apply to drugs generic, because they are included in the same active substance, it is difficult for them to specify such a comparator, which would have a different effect. Another situation is when for a given drug proposes entering its new pharmaceutical form. In this case, the VBP applies.

Within the framework the value based pricing the determining prices is based on the dependence of the price of the level of innovation of the proposed

technology. Innovative materials, whereby is obtained greater benefit to the patient may be higher valued than their comparators. This phenomenon is called a premium price and refers to “the bonus of additional health benefits”.

VBP may be impractical tool for the process of valuation of drugs, in situations where the substance is characterized by the different effectiveness of various groups of patients or to different disease entities. Then, for each population and each indication, the drug is a completely different technology, for which should be applied other prices. This situation is frequent phenomenon, and manufacturers and national law regulators, manage with it in different ways. The most commonly used is to register the substance under different names for different indications.

The return on investment

Another essential tool is the ROI (return on investment, ROI). It helps to determine the optimum percentage or in cash, for which the investment is profitable. This decision is usually taken after clinical researches for the drug, which absorb the greatest part of defence. According to EFPIA (European Federation of Pharmaceutical Industries and Associations) in 2013, the cost of all researches in the pharmaceutical industry for the European area amounted to 30 630 million euros. However total defence on researches on one drug consume an average of 1,172 million euros (according to data from 2012). Before the drug get into the market passed average of 12–13 years since the first synthesis (EFPIA 2014, s. 7–8).

In the settlement of whether the investment is profitable, the key is to compare the expected extreme income and extreme cost of capital. If the extreme income is equal to or greater than final cost of capital, then the investment is favorable and the manufacturer can proceed to estimate the price of the final product.

At the height of the ROI is affected by many indirect external factors of which the most important are demographic change and an increase in the demand for drugs. Its variability is also conditioned by phenomena occurred within the market, such as: parallel import and reducing defences on drugs by the payer.

Parallel import is a subject to the EU law rules. It is favorable for consumers because it provides access to the same drugs, but with fundamentally lower prices. [Chomont, Grzebieluch, 2012 p. 53]. It also contributes to a unification European pharmaceutical market [Zaprutko and others, 2012, p. 136–144].

Reducing of payer’s expense and the related with it increase in indicator the return on investment (at the same time assurance for beneficiaries of the system wide access to modern therapies) is the cause of signing a so-called risk-sharing schemes (risk sharing schemes, RSS) between the producer and the payer. Generalizing the risk occurring on the producer’s side involves

primarily to the lack obtain a reimbursement and on the payer's side the most frequently associated with making the wrong decision reimbursement.

Competitiveness and pricing strategy on the pharmaceutical market

The existence of competition affects the fixing of prices within a given market. Irrespective of the sector of economy, manufacturers in the first collect data about the prices of the same or similar goods of competitors.

There are different determining prices strategies on non-monopolistic markets. For the pharmaceutical market can be enumerated:

- ❑ penetration strategy consisting in the initial valuation of price of the drug below the price level of competition – the aim is to take market share and reduce the risk of emergence of new competitors;
- ❑ parity strategy, according to which a new drug should cost the same how much it costs the same drug in the competition;
- ❑ strategy of Skimming pricing used when no anticipated strong competition on the market; in this case, the manufacturer determines initially higher price.

National mechanisms regulating the prices of medicines

In most European countries in the process of making decisions of prices and reimbursements pharmacoeconomic analyzes are used and the results of health technology assessment (HTA, health technology assessment). It is usually a required element of the national law.

HTA is a interdisciplinary process. During this type of analysis takes into account the reports not only in the fields of medical science, but also economic, ethical, legal, and social. Health technology assessment aims to deliver information about a change in health status of the person subject to the exposure of a given technology. The term medical technology is meant here: the use of a given drug in a specified indication of health, surgeries and operations, but also therapeutic and health programs. Health's change is however so-called the end-point. Comparison of the incidence of specified endpoints in patients subjected different therapies about the same indication, allows indices technology with the highest efficiency. In the HTA report makes a breakdown of figures specifying positive and negative effects of a given technology. It is important to bear in mind in preparing the evidence of their quality and the principles of evidence-based medicine (EBM). For decision-makers, HTA analysis is a tool for making a choice involve the reimbursement of given medicine, where there are many alternatives. Through to the existing health technology assessment agencies in openly way can be realise social solidarity rule and secure equal access to medical services, at the same time controlling the budget.

In the case of an positive opinion occupying HTA agencies in the given country, a specific drug can be placed on the reimbursement list. Previously, the price is fixed official and the principles on which will be based co-payment for the drug by the payer and the patient. In this case, the given drug is gaining privileged market position. The drug covered by the reimbursement is much more available for the patient, and therefore its expected higher sales compared with drugs not reimbursement. The process of granting reimbursement is for the manufacturer an opportunity to negotiate the price (in a situation where pricing agreements are legal), or the making a deal about the division of risk. For the manufacturer, it is important that the drug was listed as reimbursement at the possible highest price and the highest limit. In the Polish law distinguished group of medicines covered by the common drug limit. General criteria for qualifying for the group defines the Minister of Health in the relevant regulation. General rules for the allocation to the group is to have by the medicine the same indication, comparable effectiveness, similar side effects and way of ministratation. If the price of the drug's packaging from given group exceeds a set limit a patient must pay the difference. Therefore, according to Polish legal regulations limit of price is a part paid by the payer, while in most European countries this is possibly the largest part of the fee for the drug, which may be payable by the patient.

According to the World Health Organization participated in funding drugs by the patient should not exceed 40%. In Poland, there is no unequivocal data that would determine what is the proportion of patients in co-paying for drugs. The disproportion between the data from the National Health Fund and independent research is huge and fluctuates from 33,23% (according to data from the National Health Fund) to 68,78% (according to data from the report Expert Pharma) (report 2008).

Reimbursement systems in individual countries provide for additional tools regulating the pharmaceutical market. One of them is the price freeze mechanism aimed at maintaining the hitherto level of prices, which in special circumstances affects positive on maintaining the balance of the pharmaceutical market.

Pharmaceutical market in Poland

Polish pharmacy market in 2009 in producer's prices was worth 19,4 billion zł, including pharmacy market – 16,7 billion zł [Golinowska, 2008, p. 104]. According to the current data it is the largest of this type market in Central and Eastern Europe and the sixth market in Europe [PAIZ, 2013, p. 1–3].

Membership in the European Union enforces on all Member States to make reimbursement decisions by the so-called transparency directive. It is related to the obligation to justify and calling upon objective premises. In Poland

that process is occupying by the state organizational unit: Agency for Health Technology Assessment (AOTM). Recommendations issued by the AOTM for the inclusion of a particular drug on the reimbursement list are not binding for the Ministry of Health. According to available data, only 60% positive or negative recommendation of the Consultative Council AOTM was consistent with the presence or absence of a drug on the reimbursement list [Czech Republic, 2010, p. 124]. Medical Technology Assessment Agency formulating recommendations take into account factors such as:

- therapeutic benefits
- benefit for the patient,
- profitability,
- impact on the budget.

Comparison of aspects taken into account within the framework the assessment of medical technology in various European countries shown in table 1.

Table 1. Criteria taken into account in the assessment of medical technology in European countries

Criterion	Austria	Belgium	Switzerland	Germany	Finland	France	Netherlands	Norway	Poland	Great Britain
therapeutic benefit	X	X	X	X	X	X	X	X	X	X
the benefit for the patient	X	X	X	X	X	X	X	X	X	X
profitability	X	X	-		X		X	X	X	X
impact on budget		X			X	X	X	X	X	X
innovation	X	X				X	X			X
the existence of alternative methods of treatment	X						X			X
availability								X		X
impact on public health						X				

Source: Sorenson, Kanavos, Drummond, 2007.

Reimbursement lists and therapeutic programs are the main drug reimbursement regulations. Behind shape reimbursement lists responsibility of the Ministry of Health. However, therapeutic programs, covering mainly cancer therapies are regulated by the National Health Fund.

Medicines from the list of reimbursed medicines are divided into therapeutic groups, within the framework is effective a one limit price, determined by the drug on lowest price. Reimbursement is divided into three levels: 100%, 70% and 50%. In the case of one hundred percent refund, the patient is obliged to pay a fee flat rate which is currently 3,20 zł.

In contrast to countries such as Hungary, Estonia or Latvia, in Poland for non-reimbursed medicines there is no legal regulations related to their price. However, in the case of products from the reimbursement list has laws specifying the maximum amount of wholesale margin (8,91%) and pharmacy margin (7% VAT). The regulated in that way prices of products covered by reimbursement from public funds is aimed at assurance the stability and control of the budget of the National Health Fund.

A huge problem of Polish legal regulations related to the reimbursement of medications is non-compliance with EU law. Although there is a state unit dedicated to the research of the merits of reimbursement of a medicine, but the process of considering applications reimbursement and determining prices takes longer than specified in the Directive (max. 180 days) [Czech, 2010, p. 87–157].

Ending

There are many mechanisms having direct or indirect impact on the prices of medicinal products. The ability to regulate them has positive and negative sides, which depend on the circumstances of their implementation. Factors that affect the final result of used mechanisms include: financing, and expenditure on pharmacotherapies, the type of health care system, the existence of the state of health technology assessment or stage of development of the pharmaceutical market.

The most important, from the point of view of price formation on the pharmaceutical market, is the fact that its primary regulator is the state. Its activities are centered mainly on reducing prices, with the aim of relieving the budget of the payer. In many countries, prices are also regulated of non-reimbursed medicines. This behavior, to some degree limits the development of the pharmaceutical sector, which is one of the most important and largest industries in the world. The great difficulty and challenge for national regulators is to strike a balance between supporting the pharmaceutical industry as an important sector of the economy and providing its citizens the widest possible access to the best medicinal products, in a situation of financial constraints.

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Summary

The pharmaceutical market is characterized by the existence of state regulations restricting his freedom to market and is one of the fastest growing sectors of the economy all over the world. Factors that have a real impact on determining the price of drugs can be grouped into three categories: medical factors, economic factors, political and environmental factors. In the group of medical factors can be distinguished patent protection, the cost of producing the drug and the value of the drug. To economic factors, taking into account the aspect of market competitiveness of companies, include: the size of the producer, nature of the company – whether it is a research unit of the pharmaceutical company, return on investment – effectiveness of use of expenditure with the aim of achieving a profit (return on investment, ROI), profitability entity. The remaining group of factors (environmental, and political) relate mainly to national regulations. They are connected with among others the registration system of marketing authorization, whether a reimbursement system that determines whether and how drugs are financed from public funds. Membership in the European Union forces on all Member States to make reimbursement decisions by the so-called Transparency Directive. It is connected with the obligation to justify decisions, and calling upon objective reasons. Medical Technol-

ogy Assessment Agency formulating recommendations take into account factors i.e. a therapeutic, benefits for the patients, cost-effectiveness, impact on the budget.

Key word: medicine, medicinal product, the price, the pharmaceutical market, parallel imports, HTA, patent protection, the reimbursement, health economics, pharmacoeconomics

Mechanizmy ustalania cen produktów na rynku farmaceutycznym

Streszczenie

Rynek farmaceutyczny cechuje się istnieniem regulacji państwowych ograniczających jego swobodę rynkową i jest jednym z najszybciej rozwijających się sektorów gospodarki na całym świecie.

Czynniki, które mają realny wpływ na ustalanie cen leków można pogrupować na trzy kategorie: czynniki medyczne, czynniki ekonomiczne, czynniki polityczne i środowiskowe. W grupie czynników medycznych wyróżnić można ochronę patentową, koszt wytworzenia leku oraz wartość leku. Do czynników ekonomicznych, biorących pod uwagę aspekt konkurencyjności rynkowej firm, zalicza się: wielkość producenta, charakter firmy – czy jest to jednostka badawcza czy firma farmaceutyczna, zwrot z inwestycji – efektywność wykorzystania nakładów w celu osiągnięcia zysków (return on investment, ROI), rentowność podmiotu. Pozostała grupa czynników (środowiskowe oraz polityczne) odnoszą się głównie do krajowych regulacji prawnych. Związane są m.in. z systemem rejestracji dopuszczenia do obrotu, czy systemem refundacyjnym, który określa czy i w jaki sposób leki są finansowane ze środków publicznych.

Przynależność do Unii Europejskiej wymusza na wszystkich państwach członkowskich, podejmowanie decyzji refundacyjnych według tak zwanej dyrektywy przejrzystości. Związana jest ona z obowiązkiem uzasadniania podjętych decyzji oraz powoływaniu się na obiektywne przesłanki. Agencja Oceny Technologii Medycznej formułując rekomendacje bierze pod uwagę czynniki tj. korzyści terapeutyczne, korzyści dla pacjenta, opłacalność, wpływ na budżet.

Słowa kluczowe: lek, produkt leczniczy, cena, rynek farmaceutyczny, import równoległy, HTA, ochrona patentowa, refundacja, ekonomika zdrowia, farmakoeconomika

Механизмы определения цен продуктов на фармацевтическом рынке

Краткое содержание

Фармацевтический рынок характеризуется существованием государственных регулирований, ограничивающих его рыночную свободу, и является одним из очень быстро развивающихся секторов экономики во всём мире.

Факторы, которые имеют реальное влияние на установление цен лекарств, можно разделить на три категории: медицинские, экономические, политические и социальные. В группе медицинских факторов можно выделить патентную охрану, расходы, связанные с созданием лекарства, а также стоимость лекарства. К экономическим факторам, принимая во внимание аспект рыночной конкурентности

фирм, относятся: уровень производителя, характер фирмы – является ли она исследовательской или фармацевтической фирмой, покрытие инвестиции – эффективность использования затрат для достижения прибыли (return on investment, ROI), рентабельность субъекта. Остальная группа факторов (социальные, а также политические) относятся, главным образом, к отечественным законодательным регулированием. Они связаны, кроме всего прочего, с системой регистрации допущения к обороту, или системой возмещения затрат, которая определяет, как и каким образом лекарства будут финансированы из публичных средств.

Принадлежность к Европейскому Союзу требует от всех членских государств, принимать решения по софинансированию согласно, так называемой директиве прозрачности. Связана она с обязанностью обоснования принимаемых решений, а также указания объективных предпосылок. Агентство Оценки Медицинской Технологии, формулируя рекомендации, принимает во внимание следующие факторы, а конкретно, терапевтическую пользу, пользу для пациента, окупаемость, влияние на бюджет.

Ключевые слова: лекарство, лечебный продукт, цена, фармацевтический рынок, параллельный импорт, ХТА, патентная охрана, возмещение затрат, экономика здоровья, фармацевтическая экономика

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