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REGULATING OF REIMBURSEMENT PRICES OF DRUGS IN THE SLOVAK REPUBLIC

Abstract:

Systems of reimbursements within the European Union have relatively similar principle in most cases of the inclusion or case of non-inclusion the medicine into the positive list on the basis of the decision of the regulator or its authorized institution.

Effectiveness in sharing of the costs increases by reducing of the excessive demand and the total drug expenses are regulated. Therefore, the existence of mechanisms for the protection before the high costs is a very important.

One of the problems of Slovak public health were high public expenses on drugs and their considerable consumption and since joining into the OECD in 2000 Slovakia has regularly occupied the front position together with Hungary.

Keywords:

Reimbursements, public expenses on drugs, Regulation and participation

JEL Classification: H51, I18

Introduction

Drug policy is an integrated part of the national health policy, which has the main objective to provide for the public availability of quality, safe and effective medicines at a reasonable price. It can be expressed by the procedure that to the correct diagnosis must add the correct drug at the right dose, at the right time, in the right dosage form and at an affordable price.

State is the responsible body for decision-making in pricing and reimbursement of pharmaceutical products.

Thanks to analyzing of the documents we determined the positives and benefits of the introduction of co-payments for reimbursement of medicinal products which are part of all payment systems in developed countries, which was introduced in an attempt to control pharmaceutical expenses and in an effort to check and influence the demand for prescription drugs. We distinguish four different forms of cost-sharing – a percentage participation, fixed participation, deductible item, participation as part of the reference system of reimbursements.

Regulation and participation

The character of each regulation is given by the decision (of who will, what institutions, governments ...) and by whether the decision was political or public, through structure and by management control, by form, but mainly through of its culture (regulation, agreement, compliance and exaction ...).

We can say that the factors increasing the cost of drugs are demographic changes (13 %), changes in pathological nature (30 %) and the offer of new drugs (55 %). New medicines are used increasingly in the shorter period, and they are abandoned due to the newer preparations. All regulatory measures have to before their introduction to undergo a thorough discussion and analysis and support by scientific and verifiable criteria.

Participation systems have been created especially to address the "moral hazard" – i.e. over-exploitation, which occurs when the services are free or very inexpensive considering their value. Many contemporary studies proving that increased payments from the patient's pocket lead to lower compliance with taking medicines and also to more frequent interruption of medication, as patients are also "consumers."

Such behavior may lead to worse health results and can contribute to the fact that others people will delay necessary medical care so that the overall effect of increasing the proportion of patients on costs is unclear since the short-time reduction of consumption of "medicaments" may be outweighed by an increasing of medical costs in the future.

It is accepted that a completely free market for medicinal products as a tool for resource allocation should fail. Patients do not have the necessary knowledge (education) for the selection of treatment, and they do not bear (directly) the total cost of their purchase (option). Physician acting as a representative of the patient also does not bear the cost of purchasing the medicine (option), and he can be influenced through the advertising activities of the producer. In fact, the major players in this market are the payer (a regulatory body) and the pharmaceutical company (producer). The main objective of categorization, beyond question, is minimizing of the expenses

to easily identifiable part of medical costs (medicaments), but taxpayers are aware that payment mechanisms have an impact on research and development as well as the choice of treatment to individual patients.

Systems of payments within the European Union have relatively similar principle in the most cases of the inclusion or non-inclusion of the medicine to the positive list on the basis of the decision of the regulatory body or its authorized institution. However, in the practice, there are significant differences across countries in what should and should not be covered and also different criteria for the assessment of medicines. On the basis of this fact, it is unlikely that sometimes it comes to centralizing sale of drugs, like assessment at EU level in the case of the approval of the entry of drugs into the EU market.

Part of all payments systems in developed countries is sharing of the cost of medicines in the form of co-payments with patient, which was introduced in an attempt to control both pharmaceutical expenditure and also affect the demand for prescription drugs.

Effectiveness in sharing of the cost is increasing by reducing the excessive demand, and the total expenditure on medicines is regulated. The patient sensitively reacts to prices and therefore tries in order to the cost of treatment were as low as possible. In the case of choice an alternative therapy, the sensitivity towards prices for some individuals may lead to lower prices. Because patients prefer treatment and interventions that present for them high value, the introduction of co-payment may help in preventing the use of unnecessary and often for the patient also harmful medicaments. Many countries have introduced exemptions for vulnerable groups divided by age, income and clinical status, or rescue mechanisms such as the maximum limit for participation per year. However supplementary voluntary health insurance that is covering most of the population in some countries, for example in Slovenia, Croatia, France removes price stimuli determined for demand reduction.

Owing to information asymmetry, transposed demand and diversity of the pharmaceutical market and its distortions, shortcomings of the regulatory function of participation are arising. To a great extent, the demand for health care is determined by the prescribing physician, and from these reasons, regulations that are aimed to the consumer demand may not be as effective in influencing of consumption as these were focused at an offer or an influence of the demand through the prescribing physician. Participation at the costs also causes a change in solidarity in the distribution of health benefits, because for low-income groups the height may present a barrier of access to health care, thus its limiting. Therefore, an existence of mechanisms for the protection against to the high expenses is a very important.

Regulation in the Slovak Republic

In the Slovak Republic currently the cost of medicines and to other medical material make up more than 30% of the budget. There are several options to reduce costs for medicines. Slovakia decided to go by the way of categorization.

Reimbursement of the medicine and contingent patient´s participation is one of the key regulatory factors of consumption and expenses it is an economic regulatory element. Reimbursement is determined in the process of categorization, which is the evaluation process, which aims to eliminate obsolete and inefficient processes, to implement procedures with proven effectiveness, prevent of the introduction of drugs

with not proven clinical and cost-effectiveness, to coordinate possibilities of the budget for medicines and medical instruments about their actual consumption and effectiveness, to optimize possibilities of the budget for medicines and medical aids in respect of their actual consumption and to determine what proportion of the price of the medicine is paid by the insurance company and how much pays the patient. The assessment is based essentially on the epidemiology of the disease, medical evidences and pharmaceutical-economic parameters.

Categorization is a partition of medicines and medical supplies into categories (in our country 3) according to the level of reimbursement by insurance company or according to the degree of contribution from patient´s side. During the process of categorization result from the opinions of experts of individual medical fields, taken into account the economic possibilities disregarding the possible social consequences. Into the first group belongs in our country the medicines, for which full price is paid by the health insurance company. The second group includes drugs for which part of the cost is paid by the patient, and the part is paid by the health insurance company. The third group consists of those drugs, whose full price is paid by the patient. The part, which is paid by patient, is highly variable. Within the context of the categorization is important the introduction of a daily defined dosage (DDD - dose of a drug required for one day for an adult patient for the treatment of the disorder for which the drug is determined in the main indication). The active substances are classified according to the ATC groups (Anatomical Therapeutic Chemical Classification). After conversion to the amount of DDD per package of a particular preparation, it is determined reimbursement for the preparation in relation to the fact whether the price is above or below of the calculated reimbursement and also is determined the level of reimbursement so called full or partial reimbursement. Reimbursement for DDP is converted in accordance with legal rules for individual preparations.

High public expenses on medicines were one of the problems Slovak health service together with considerable consumption of medicines and since joining the Slovak Republic to OECD in 2000 Slovakia has regular front position, together with Hungary, in both, to the amount of total expenses on medicines measured as a share of total spending on health service and well as a share of GDP.

Price of medicines in years 2009 and 2010 according to the data of Ministry of Finance of the Slovak Republic spared public expenses on medicines in the amount of 165 million Eur, during three years. Consistent application of referencing pricing of medicines and negotiations with pharmaceutical firms resulted in the fact that expenses on medicines in 2009 didn't grow in such way as in previous years and in recent years also lagged behind the growth of total expenses on health service. For comparison, expenses on medicines increased year-on-year in Slovakia by 1.1 %, while in the Czech Republic by 10.3 % and 10.2 % in Poland. Slovakia belonged according with this indicator in 2009 among the most successful EU countries. [1]

The result is that our consumption of medicines has significantly impacted to the pharmaceutical market and gross domestic product and of course we have a dominant role in the tax system and the private health insurance because it affects the pharmaceutical market. As well as with any insurance, there is a moral hazard and also with stimuli for consumers to excessive consumption and/or using of unnecessarily expensive medicines. Beside this, insurance creates stimuli for pharmaceutical firms to charge higher prices than they would have in the absence of

insurance. In reaction to these distortions caused by insurance, the governments created complicated regulatory systems to control expenses of medicines mainly through regulation of producer's prices, total expenses of medicines or gains of industry.

In Slovakia, there is a maximum limit for co-paying of the rest of medicines – it is **limit of participation** that was provided by law and it concerns only to the underprivileged population. It represents the maximum amount of patient co-payments for prescription of medicines, which are partly reimbursed from the public health insurance. This limit is calculated for each calendar quarter. In practice, there are two maximal limits of supplements. One for old-age pensioners (€ 45 per quarter) and second (€ 30 per quarter) for handicapped people and disabled pensioners.

Limit of the participation in height of € 45

If the patient is old-age pensioner, he'll pay € 45 for drugs per calendar quarter.

Other returns health insurance company. **However, on the first day of the calendar quarter, the patient must meet the following conditions:**

- he must be a receiver of a retirement pension, pension for policemen and soldiers from retirement security under the regulations on social security for policemen and soldiers at the age of entitlement to old-age pension, he must receive a pension from abroad or pension from another Member State of the European Union, if the patient has not health insurance in that Member State of the European Union, he has a duty to achieve the retirement age while not entitled to a retirement pension.

This limit doesn't apply to the patient, when at the same time with the above mentioned:

□□ he has an income that is subject of income tax under the Tax Act Income excluding income from agreements performed outside employment contract. Therefore, it doesn't concern to employees or self-employed persons (SZCO),

he has a sum of the pension over 50 % of the average monthly salary in the economy of the Slovak Republic ascertained through the Statistical Office of the Slovak Republic in the calendar year which going before two years the calendar year for which the limit of participation was determined. For 2014 is set limit € 402.50“.[2]

Limit of the participation in height of € 30

This limit can be applied by every insured person, whose is on the first day of the quarter:

- He holds a card of a physical entity i.e. person with a severe disability, or he is the holder of the card of a physical person with severe disabilities with escort, and he is a receiver of an invalidity pension, invalidity service rent under the legislation on social security for police officers and soldiers, or disability and he shall not be entitled to an invalidity pension.

This limit shall not apply to the patients if they at the same time:

- If the patient is an employee or self-employed person – thus not be the subject of the income tax under the Income Tax Act, excluding income from agreements

performed outside employment, a pension is 50 % higher than the average monthly salary in the national economy according to the Statistical Office Slovakia ascertained two years ago. For 2014 is set limit € 402.50“.[3]

If the patient meets the conditions of the two groups, in this case he'll apply the higher limit, so € 45.

To the limit of participation are not counted all the medicines that can be bought at the drugstore.

Include only those:

- are issued on prescription – i.e. here does not include those medicines and supplements that can be bought by patient himself at the drugstore so called "OTC - over-the-counter medicines," are the cheapest for the relevant disease.

It means that if a doctor prescribes a medicine for a patient and he choose the drug from drugstore that has a cheaper alternative, into limit of the patient is counted price of the cheapest drug. So it is not the price of the drug that the patient has actually choses in the drugstore. This is called recalculated supplement. Therefore, insurance company Dôvera recommends to patients in order to doctor and pharmacist asked about the most cost-effective medicines for their disease.

For disabled and elderly people to date (August 2013) were reimbursed medicines for almost four million Eur. Over one thousand euros were returned for client of Všeobecná zdravotná poisťovňa (General Health Insurance Company) back, from the amount which was spent on medicines in the drugstore. The amount represents the highest amount that was reimbursed understatement of the Office for supervision of Healthcare, for insured persons under the Act.[4]

Limits on payments for drugs were introduced in 2011. Beginning this year, health insurance companies together have issued more than 3.8 million Eur.

The upper limit for payments according to analyst of INEKO is the solidarity element that protects patients to pay unacceptable payments for medicines and treatment. However, he notes that they also exist socially deprived other groups of people such as seniors and the disabled.

Ministry of Health itself doesn't want in the future to expand the range of people those are related with above mentioned limits. Our task is to guide so medicament's policy that in order to for each chronic disorder there is at least one medicament free of charge or with socially acceptable additional charge up to one euro. According to this strategy medicines will accessible to everyone and not just for selected groups.

Conclusion

Additional charges of patients grow in recent years in Slovakia by a higher rate than the total expenses of medicines from public sources. So-called unnecessary additional charges represent from these supplements up to 30 %, i.e. charges that patients shouldn't have to pay if they always would obtain medical products for the lowest additional charge.

This ratio remained constant over recent years, nor even the introduction of generic substitution and nor its simplification has not improved this ratio.[5]

Thanks to analysis and investigation, we concluded that the introduction of generic prescription prevents the reduction of patient co-payments, reduce drug prices, simplify the prescriptions and increase confidence in generics.

In conclusion, we would like to emphasize that the support of positive effects for achieving the correct adjustment of regulation of generic prescription, and support of such activities as are educational campaigns and motivation mechanisms aimed at doctors, pharmacists and also at patients themselves.

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