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ANALYSIS OF THE REIMBURSEMENT POLICY IN CENTRAL AND EASTERN EUROPEAN COUNTRIES - THE POLICY OF POLAND, ROMANIA, HUNGARY AND THE CZECH REPUBLIC, PART II

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SUMMARY

In light of the above, the purpose of this study is a comparative analysis between national models of reimbursement of medicines in selected Central and Eastern European countries - the policy of Poland, Romania, Hungary and the Czech Republic. For conducting comparative analysis of specific legislation and mechanisms of reimbursement of medicines in those eastern European countries was examined in the literature databases, legislative bases and national health reports. Individual European countries were affected to varying degrees by the global financial crisis, but as a result all had to take austerity measures in many policy areas, including on health services and medicines. Since 2008, the cost reduction measures have been taken in Europe, especially but not only in the CEEC. It is important to note that although at a slower pace, the countries of Central and Eastern Europe implement policies that increasingly bring them close in terms of reimbursement and to some extent in terms of access to medicines to the old member states.

KEYWORDS: Financing, reimbursement, drug positive list, sharing schemes risk, health technologies assessment.

INTRODUCTION

Every healthcare activity requires a certain amount and quality of resources - labor medical professionals /physicians, nurses, technicians, support staff, medicines, administrative services, overhead costs, etc. For all these resources are needed funds.

With purpose to brought into line the health policy objectives of sustainability, equity and quality of care with ongoing incentives for innovation in the pharmaceutical sector, the governments tend to use pricing and reimbursement, which are adapted to three different categories of medicines[1]

-patent-protected medicnes, primarily those with high financial volumes- The pricing is based on added therapeutic value, discounts and / or price volume agreements;
- medicines with lower sales financial volume, including patented drugs and those with expired patents as medicines for rare diseases, and target therapies – Pricing is based on price volume arrangements that promote innovation, with the possibility of (confidential) discounts for extra price;
-generic (off patented) medicines – pricing is based on competition, offering quotes from different companies. However, this principle can not apply to all generics (eg. Biosimilars).

Successful dissemination of original medicines is crucial for pharmaceutical companies such as manufacturers and for the patients[2]. This distribution, in particular financing and reimbursement is influenced by several characteristics
- Micro level: socio-demographic and professional characteristics of medical specialists;
- Meso level: prescribing by doctors, the marketing efforts of pharmaceutical companies, interpersonal communication between doctors and patients, the quality and effectiveness of medicines, and patient characteristics - national, cultures and personality;
- Macro level: government policies.

They can be referred three cost-containment measures that mainly apply
1. control the price of the product;
2. reference pricing;
3. Control of profit

When we talking about the Central and East European Countries (CEEC), in this case, we need to consider several factors that distinguish them from the economically developed west European countries[3]
- Global economic recession initiatives to reduce public spending;
- International organisations (e.g. European Commission, International Monetary Fund), that put pressure on CEE governments to reduce public health care spending, with special focus on pharmaceutical expenditure;

- Severe cost-containment measures for pharmaceuticals, including pressure by payers on pharma companies to justify prices of their medicines

Patient access in CEE countries is further restricted by volume limits on prescribing. According to Kaló, there are implicit volume restrictions such as price volume agreement and explicit ones such as central tendering and volume limits for healthcare practitioners. The latter are frequently used in CEE markets. "It is difficult to find a doctor who will prescribe the drug," according to Kaló.

And therein lies the additional risk to patient access in CEE markets. There are hidden barriers to access - which it should be noted - precede the austerity measures: quota systems that limit how many specialist referrals GPs can issue per month or how many prescriptions can be written out mean that patients in CEE markets end up paying out of pocket to procure prescription medicines they are denied access to under the public healthcare system. And these are generally patients who can ill afford to spend much on medicines. Should we be surprised then that standardised death rates in CEE countries remain significantly higher than in Western Europe?[4]

In light of the above, the purpose of this study is a comparative analysis between national models of reimbursement of medicines in selected Central and Eastern European countries - the policy of Poland, Romania, Hungary and the Czech Republic.

MATERIALS AND METHODS

For conducting comparative analysis of specific legislation and mechanisms of reimbursement of medicines in those CEEC was examined in the literature databases, legislative bases and national health reports. The analysis focused on market size and cost-containment measures applied by the health insurance funds towards the reimbursement of the medicines.

RESULTS AND DISCUSSION

Poland (table 1): According to the Law in force since early 2012, reimbursement for medicines covers the following prices

1. official price list - ex-manufacturer price (MSP) + tax (VAT 8%). The official prices of medicines are published in the reimbursement list, which is updated by the Minister of Health every two months and have a fixed nature.

2. wholesale price - the official pricelist wholesale + margin (level of 6% in 2013 and 5% from 2014)
3. Retail price selling price = price wholesale + retail margin, which is calculated from the wholesale price of the product to a certain limit ("w") within a certain therapeutic class, given the number of DDD.

Patients are required to pay part of their drug costs, which varies depending on the category of reimbursement, but not to pay medication with proven efficacy in the treatment of malignant cancer, mental disorders, as well as a number of other conditions and medicines reimbursed special programs.

There is a flat fee that patients pay for drugs for chronic diseases, which do not pose a significant financial burden for the patient. Prepared for import versions of such drugs, the fixed sum equivalent to 0.5% of the monthly minimum wage.
- 30% extra charge: For drugs that must be taken for more than 30 days (DDD), but which do not meet the criteria to be without extra charge or a flat fee.
- 50% extra charge: For drugs that must be taken for 30 days or less (in DDD), but which do not meet the criteria to be without extra charge or a flat fee.

Patients must also pay the difference between the price of the drug purchase and the reference price of the same. Ministry of Health published updated reimbursement list on its website every two months, in accordance with the requirements of the reimbursement.

Entered into force by 2012 amendments to the reimbursement of medicines, food for specific nutritional purposes and medical devices (Official Gazette No. 122, item 696), are aimed mainly at
1) improving access to and availability of medicines, food for specific nutritional purposes and medical products for patients;
2) effective monitoring of the presence of drugs, food products for special nutritional purposes and medical devices and limits the possibility of exporting them, if their presence on the market is limited;
3) limit the scope of information required to provide in order to reduce the official selling price and shorten the length of the decision to recover;
4) introducing the possibility of making changes to reimbursement on request of a particular participant;

5) facilitate the participation of new drugs in the PDL;
6) elimination of interpretative doubts regarding the Act for reimbursement, such as removal of interpretative differences in the calculation of value added tax (VAT) during the pricing on the chain of distribution channel

Introduces an obligation for periodic evaluations of the HTA analysis by the Agency for Health Technology Assessment, hereinafter called "the Agency", every five years in the case of medicines, without equivalent for a given indication, this principle will not apply to active substances authorized for marketing for the first time for a given indication before 1 January 2002. In case of a negative opinion from the Agency, with regard to submitted to the analysis, the Minister of Health may revoke the decision for valid reimbursement or refuse reissue the decision.

Introduces a simplified regime for access to medicines containing active substances which are not authorized for marketing in the Republic of Poland, but is used for chemotherapy. Furthermore, it can be financed equivalents of chemotherapy drugs on the lists of recovery in case of their temporary shortage. Minister of Health decided for reimbursement of such drugs.

Romania (table 1)

Historically Romanian health system During the transition years passed through several stages. Pharmacists were the first health professionals who were admitted to private business.[5,6,7]

According to the Medicines Act, the Ministry of Health sets maximum retail charges. Drugs that are not financed with public funds are sold freely on the market, the Ministry of Health does not control them, but the producers / owners of OCs are required to notify their prices to MofH on a quarterly basis. Determine the lowest price in reference countries. Determine the gross profit margin of 7.5 percent for manufacturers and importers, as the importer can only add an additional margin of 8.5%, due to costs associated with imports. The total allowance for imported drugs is 30% until 2003. Since then, it gradually reduced.

Price adjustments applied on an annual basis by applying a formula linked to the change in exchange rates. Prices are published in the PDL, which is updated every quarter (www.msf-

dgf.ro). Aggregation margin of wholesalers and retailers varies around 12% for prices above € 2,14 and 24% for prices below € 0.5.

Measures used for monitoring and analysis of pharmaceutical consumption is implemented by the Romanian Ministry of Health and the Social Fund, which fund collects data on drug consumption by regions, pharmacies and doctors, there is no clear correlation between consumption and pricing or reimbursement. Proposals for the introduction of generic substitution continues to maintain a long debate between doctors and their professional associations and the Ministry of Health. Introduction of generic substitution is postponed several times, as the pharmacist at the pharmacy must inform the patient for the potential substitute of prescriber drugs. Initially are introduced indicative budgets for prescribers, but later this nostrum is abandoned in favor of budgetary ceilings for expenditure incurred in pharmacies, which are determined by the Public Fund (NHIF). According to Law 95/2006, patients have access to drugs, partly or fully covered by the NHIF. Each year the Ministry of Health and NHIF up a positive list of medicines that list includes prescription drugs and reimbursed by the Public Fund, whether using them insured patients. This list is drawn up on the recommendations of the Transparency Committee, which includes representatives of the College of Pharmacists, the Ministry of Health and NHIF. Law 95/2006 defines details on the criteria for establishing this list, the Ministry of Health issued an order, which regulates the activities of the Commission on transparency.

The process of reimbursement is based on the reference price system, which is based on the lowest price of the product within a group of drugs. In addition, patients themselves have to pay 10% or 50% of the reference price (ie the lowest priced products in the cluster). These clusters are formed on the basis of the generic substance, pharmaceutical form and content. There are two lists A and B.

A list containing generic mass while List B includes expensive generics and innovative new medicines. Medicines paid 100% by public funds, the reference price is not in effect until May 2005, when the system of reference pricing is added and the list C, including drugs that are partially reimbursed. There are some restrictions to control the cost of drugs, public funding: for chronic disease patients receive no more than one recipe per month with no more than four drugs belonging to list A or B.

If the prescribed drug belongs to the B list, a maximum of three drugs is allowed to be administered to a recipe and the total cost should not exceed 300 lei (approximately € 85). The exceptions are subject to special approvals.

Currently, the existing system of reference prices adjusted to the level of ATC 5 (active ingredient and dosage form). At the end of July 2014, Nicolae Banicioiu, Romanian Minister of Health approved new criteria for updating the Positive drug list, which was released in the last months of last year. The criteria are in line with EU requirements and similar provisions in countries like the UK, Germany and France. The new way of assessing of drugs for reimbursement will allow the periodic updating of the list. Before the medicines to get reimbursed, "applying" drugs must receive at least 80 out of 145 points and has already received reimbursement drugs can be excluded from the PDL, if you receive less than 50 points.[5,6.7]

New drugs will receive 25% of the maximum score if they are already more than 50% recovered more than half of European countries. In addition, new therapies may attract an additional 30% of the maximum score, if more than 5% cheaper than equivalent current treatments. As to those already included in the PDL drugs that will be reviewed can be removed if evaluated in a negative light by institutions in the United Kingdom, France and Germany.

In May 2014. The Health Ministry added 17 new molecules to treat diseases that have no therapeutic alternatives in the PDL. This is the first case in the last six years, during which new drugs are included in the PDL.[6]

Hungary (table 1)

Medicinal products are reimbursed by the Public Health Fund. Through Budget Law determines the annual financial and economic plan of the Republic of Hungary, in particular, the maximum amount that may be spent for reimbursement of pharmaceutical products for a year.

The administration of the HIF (OEP) makes decisions which drugs to be reimbursed. Under the relevant statutory provisions, pharmaceutical products may be included in the list to restore only at the request of the holder of OCs or his representative, and only if:

- The competent authority has verified its safety and efficacy and authorized its marketing;

- There are therapeutic and economic evidence for its use;
- Cost effectiveness of its use is proven;
- The necessary public funding is available or can not be guaranteed;

The holder of the authorization or his representative shall undertake to disseminate and store the product in storagewhich is subject to reimbursement.

As a general rule, 90 days is the period, the competent authority shall submit its decision from the date of receipt of the request for inclusion. However, this time is reduced to 60 days in some cases (prescribed by the relevant laws), if the request for inclusion in the PLD applies for a new generic product whose active ingredient has already reimbursed.

Drugs prescribed in hospital are free for the patient. National Health Insurance Fund covers part or all costs when the prescribed medicine is included in the list of social assistance scheme. In 2012 the allocation of the overall budget of the Health Fund of Hungary for medicines is 315 129.5 HUF. The rules relating to approval of drugs is determined by ministerial decree defining standard care. And increasing the maximum amount of aid depends on the decision of the National Health Insurance Fund (Országos Egészségbiztosítási Pénztár).[8,9]

Hungary applied externally and internally referencing the prices of medicinal products, and for some new molecules and HTA. This group includes all novel drug molecules.

First reference pricing was introduced in 1999. And in 2003 supplemented by a model of therapeutic comparison. From 2007 Hungarian government puts more and more emphasis on stimulating competition and exclusion of the most expensive products from reimbursement list of competing groups of substances. In Hungary are applied systems for risk-sharing in the form of quantitative pricing agreements for selected drugs since 2003. Partial payments from manufacturers based on the agreed limit of annual sales, while the share of repayment is changing gradually, depending on the level overrun.

In case of reimbursement of pharmaceutical products, the relevant legal provisions provide maximum margins of wholesale and retail, which is determined based on the price of the product. In the course of the procedure for inclusion in the PLD, the maximum allowable wholesale and retail price, added to the production cost.

The amount of reimbursement and the price paid by the patient are calculated by applying the recovery determined by OEP. Therefore, the amount of the refund is equal to the maximum percentage of the price serving as a basis for recovery to be applied in the category of recovery.

Czech Republic (Table 1)

Authorization of medicinal products, pricing and reimbursement shall be made by the Ministry of Health in consultation with the Ministry of Finance and GHIF. Chamber of Pharmacists, as well as representatives of the health associations play a role in this process. In the case of outpatient care, pharmaceutical products are classified into three categories. The first category contains fully reimbursed medicines and includes the cheapest effective products (often locally produced) of all essential drugs.

The second and the third category contained drugs, partially or fully paid by patients, insurers only reimburse the generic equivalent.

Medicines and medical devices are authorized for use by the Institute for control of medicines and medical devices (SUKL), which is directly managed by the Ministry of Health. The system of pricing and reimbursement in the Czech Republic is characterized by

1. introduction of therapeutic groups in 1994
2. introduction of generic substitution in 2007
3. The application of international reference pricing, using the lowest price for a product in three countries of reference of the EU and the introduction of a temporary reimbursement in 2008
4. The introduction of electronic auctions and regulation of drug prices in 2012.[8]

Procedures and types of pharmaceutical products reimbursed by the National Health Service (NHS) are foreseen in the Health Insurance Law (Law № 48/1997 on Health Insurance, as amended Insurance Act).[10,11]

Drugs intended for use in outpatient care, reimbursed from the NHS and are listed as active substance in Annex 2 of the Health Insurance Act, the decisions about whether to be reimbursed and what percentage is determined by the Control Institute of drugs and medical products (SUKL) in accordance with applicable regulations.[12]

Medicines for hospital care, pharmaceuticals and products used in blood transfusion, which not having a major impact on the budget, are fully reimbursed by the NHS, ie, patients do not participate in schemes for an extra charge.[11]

In determining the amount and conditions of reimbursement of pharmaceutical products, the Institute includes drug in a reference group (a group of pharmaceutical products that are therapeutically interchangeable, generally similar in efficacy and safety with similar clinical use). The list of reference groups is determined by the Ministry of Health to set regulation. Main "loop" of reimbursement of pharmaceutical product equals on

A) the output level of recovery for the reference group in which the drug is incorporated., Ie a daily therapeutic dose of the active substance contained in the pharmaceutical products and is the same for the reference group. In case the product must be "available" in the market, ie sales should amount to at least 3% of total sales of interchangeable pharmaceutical products with an active substance in the previous calendar quarter;

B) output level of reimbursement of a given pharmaceutical product is determined by the daily cost of other therapies, if it is comparable to the efficiency and cost effectiveness in the use of the pharmaceutical product under the above conditions, taking into account the time needed of treatment for a drug and necessary time the comparable therapy;
In) the final cost to consumers as a result of price competition, if that price is lower than identified in accordance with subparagraphs (A) or (B);

D) the highest final consumer price determined in agreements in the interest of public health between health insurance companies and the holder of the marketing authorization of the manufacturer or importer, if that price is lower than that referred to in points (A) (B) or (B).

Under applicable laws, direct price control is carried out by the Institute for control of medicines and medical devices (SUKL), but is limited to pharmaceutical products, whose value is recovered from the NHS.[11]

Reimbursement by public funds of pharmaceutical products is complete and partial recovery with varying degrees of charge. Cost control use agreements between the NHS and the producers or owners of authorizations for the base value of the product and arrangements for risk sharing, but they are not yet common practice.

Do not apply a policy to promote the use of generics, ie as faster approval, registration fees are the same as in the case of innovative products.

According to existing regulations, the price of the first generic product is set at 25% lower than the maximum selling price of innovation, unless the price of the manufacturer / marketing authorization for use is lower. The maximum price of second generation generics is further reduced by 10%.[11]

Table 1. Medicines reimbursement policy in Poland, Romania, Czech Republic and Hungary

State	PLD	NLD	HTA	sharing schemes of risk	Copayment from patient	reference pricing
Poland	yes	no	Да	no	yes	yes
Romania	yes	no	Да	no	yes	yes
Czech Republic	yes	no	type of pharmacoeconomic evaluation	yes	yes	yes
Hungary	yes	yes	yes	yes	yes	yes

DISCUSSION AND CONCLUSION

The economic value of pharmaceutical products for patients and society as a whole is not well studied based on drug costs. When considering the price of pharmaceutical products must take into account the value they add and also the problems that can arise from pharmacological treatment (with or without prescription, medication errors and other kinds of interaction, incomplete treatment side effects pharmaceutical and bacterial resistance).

When we talk about reimbursement, ie an expense of public funds inevitably comes agenda with the issue of limiting of these costs. It should be noted that the processes of pricing and reimbursement measures to limit the costs of drugs are closely related.[13]

Individual European countries were affected to varying degrees by the global financial crisis, but as a result all had to take austerity measures in many policy areas, including on health services and medicines. Since 2008, the cost reduction measures have been taken in Europe, especially but not only in the CEEC. It is important to note that although at a slower pace, the countries of Central and Eastern Europe implement policies that increasingly bring them close in terms of reimbursement and to some extent in terms of access to medicines to the old member states.

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