

# Current Activities and Trends in the Pharmaceutical Pricing and Reimbursement Policy in the Republic of Slovenia

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Pharmaceuticals represent a key element of a national health policy. The expenditures for pharmaceuticals have in Slovenia in 2007 amounted to 15.5% of the total health funds (13.4% of the public funds). Increasing pressures for the improving access to existing and expected new pharmaceuticals make it necessary to further develop policies in the area. Considering that its per capita GDP is at the level of 83% of the EU-27 average, Slovenia must allocate funds for pharmaceuticals in a rational way. While maintaining the national competence in the pricing and reimbursement decision making, it is of great importance to take account of the EU-level activities and initiatives.

## 1. Upgrades of Pricing and Reimbursement Regulations

The primary purpose of the ongoing upgrade of sections of the act on pharmaceuticals is to harmonise the regulations governing the field of pricing of medicinal products and their inclusion into the health insurance system with the Directive 89/105/EEC. An additional purpose is to introduce new mechanisms in the pricing and reimbursement regulations which will sustain the financial stability of public health funds while maintaining competition in the national pharmaceutical market. The obligation of the system regulator is to give and implement proposals to maintain a high level of health care in this area before it comes to serious financial difficulties or disturbances in the access to medicines that are financed or co-financed by public funds.

### 1.1 Pricing Regulations: Upgrade of the Medicinal Products Act

Publication of the Act Amending the Medicinal Product Act (Official Gazette of the Republic of Slovenia, No. 45/2008, dated 09.05.2008) has brought about changes in the system regulation of medicinal product prices in Slovenia. The Act came to power on May 24th 2008 and has brought transitional provisions for the Minister of Health to issue an Implementation Regulation in the coming two months which will in turn regulate the matter to the level of technical details. Hereby, the main content of the part of the Act dealing with regulation of pricing is presented.

With the law we are acceding to the most necessary amendments to the Medicinal Products Act (Official Gazette of the Republic of Slovenia, No 31/06; hereinafter, ZZdr-1) mostly due to a more precise harmonization of procedural provisions on pricing of medicinal products with the Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. At the same time this is also a conceptual upgrade of the field of pricing of medicinal products. The law shall implement and regulate the maximum prices of medicinal

products paid from public funds and at the same time the possibility of an agreement between authorized persons and the payers for attaining lower prices.

According to the provisions of the Act, the subject of price regulation at a national level are only the maximum prices, the pricing mechanism of which on a technical level is given by the provisions of the implementing regulation. Applicable price of medicinal products financed from public funds is therefore the maximum price formed in accordance with the criteria of the implementing regulation, as well as the lower price than the maximum price agreed between the health insurance provider or legal entities or natural persons, who perform the health care activity financed from public funds, and the authorized persons for the pricing of medicinal products. Moreover, the legal foundation for setting the extraordinary higher maximum price in exceptional cases, which is higher than the maximum price if so determined by the competent agency for medicinal products, is also provided. A standing committee is foreseen to provide opinions for the decision making on such extraordinary higher price

The prices of medicinal products, which are used on the market, could be equal to the maximum allowed price after implementation of stated amendments (if there is no business interest of the authorised persons or in cases without negotiations for lower prices or agreed lower prices in the public procurement procedures), or they could be lower than their maximum allowed price based on the business interest of the authorised persons or based on negotiations and lowering of prices in the public procurement procedures. Both types of prices of medicinal products, the maximum allowed price that are regulated as well as the lower ones that are agreed, are valid (applicable) prices of medicinal products and used in accordance with provisions of the regulations governing the prices of medicinal products.

## **1.2 Reimbursement Regulations: Upgrade of the Health Care and Health Insurance Act**

The field of medicinal products is one of the most developed within the health care system and that the rights in the field of medicinal products are extremely broad. That is why we would like to maintain them at the current level. This is possible only if we introduce the mechanisms in due time, which shall enable expenditure management. According to the pharmaceutical industry's forecasts, many new and extremely expensive medicinal products are entering the market, especially in the field of oncology, which means that the expenditure shall begin to increase, or that the classification criteria shall have to become stricter if we want to maintain financial sustainability.

The currently applicable law does not contain the definition of lists, therefore it was necessary to appropriately fill this legal gap. Two general definitions of lists are offered in the proposal. Due to international comparability and greater understanding it is necessary to emphasize that the medicinal products and foodstuffs intended for particular health care purposes are classified according to the positive list principle, or that the intermediate list is in fact positive, but with a smaller share of coverage under the compulsory health insurance.

The secondary purpose of the upgrade of the Act is to enable the holder of compulsory health insurance a more efficient management of expenditure for medicinal products from public funds, which is also the purpose of the above-mentioned Directive. The objectives that we want to achieve are:

- to enable the formation of lower price from its maximum prices which is within the competence of the competent agency responsible for medicinal products, in accordance with the regulations governing the field of pricing of medicinal products;
- to introduce negotiations between the authorised persons (manufacturers of medicinal products or their representatives, and holders of authorisations for import or introduction of medicinal products) and the compulsory health insurance provider, on the basis of which can be established lower prices form its maximum allowed price;
- to enable the formation of lower from its maximum allowed price - of medicinal product on the basis of the business interest of the authorised persons.

The act legally regulates the field of the highest acceptable cost-value of medicinal products. So far this area was regulated by the Institute's acts, whereby the decision was based on definitions in the act, which gives the Health Insurance Institute the competence to determine standards and norms of services and rights from the compulsory health insurance. The highest acceptable cost-value is the price standard. In accordance with the criteria that include also international comparisons and cost analyses, the highest acceptable cost-value for the groups of mutually interchangeable medicinal products, which have the same medicinal substance, pharmaceutical form, strength and comparable packaging, shall be defined.

The highest acceptable cost-value that is created with the arrival of generics in the frame of their mutual interchange ability after proposed provisions shall become the price standard.

The proposed upgrade of the Act defines the framework criteria for classification of medicinal products into the list. Among other, a legal basis is provided for pharmacoeconomic criteria, which are becoming more and more important, because more expensive medicinal products are entering the market. The pharmacoeconomic analyses enable an equal treatment of different groups of medicinal products and medical treatments, which is important from the viewpoint of ensuring equal or comparable rights in different areas of health care. In cases of severe and rare diseases, like for example some forms of cancer, multiple sclerosis etc, ethical criteria are especially emphasized.

The Act also provides the legal basis to limit the authorisations for prescribing or issuing of certain medicinal products. Prescribing limitations may refer to indicator areas, target groups, as well as to the circle of medicinal products' prescribes. Such regulation contributes to the optimum use of medicinal products, with which larger conditions for greater totality of availability of medicinal products are created that is in accordance with the national priorities in the field of health.

The legal basis for negotiations or the agreement for valid prices of medicinal products is also defined, which was not appropriately legally regulated so far. These areas were otherwise regulated by the Institute in its internal acts. With regard to the required transparency of classification of medicinal products into the lists and determining the highest acceptable cost-

value for mutually interchangeable medicinal products, it is necessary to regulate these issues by law.

The new upgrade of the Act determines a more detailed procedure for proposing the classification of medicinal products and foodstuffs intended for particular health care purposes (e.g. phenylketonuria) into the lists, consideration of applications before the Institute's authorities, and information of applicant of their decisions. It also determines possible appeal procedures in case that the applicant not satisfied with the decision by the Institute's authorities and court protection of the applicant. This upgrade of the Act summarises key requirements of the "transparent" Council of the European Communities Directive 89/105/EEC, which besides the stated also determine the deadlines, in which the decisions on prices and reimbursement of medicinal products have to be made. The draft law also contains the provision, under which a decision has to be made within 180 days and came in to the force, reduced by the days that the competent agency responsible for medicinal products used to determine the maximum price, and the application for classification is not possible until the maximum allowed price is determined.

## **2. Slovenian EU Presidency Activities and Achievements in the Area of Pharmaceuticals**

Slovenian EU Presidency has brought about substantial contributions to the EU health agenda also in the area of pharmaceuticals. This is the result of considering the importance of health agenda in the current social policies as well as to the good coordination among the German-Portuguese and Slovenian joint presidency Programmes. This, also in the area of pharmaceuticals, produced a strategically and operationally strong programme. Five regular meetings of the National Competent Authorities have taken place and six informal meetings of the scientific committees of the EMEA took place in the first part of the 2008. This has contributed to the continuity of the work of those bodies.

EPSCO Council has on its meeting on June 10th, 2008, accepted the Council Conclusions on information to patients. The aim of the conclusions is to express the common position of Member States regarding the provision on information to patients with regard to the Commission Communication and announced legal proposal. The Council in this view expressed the importance of ensuring that patients have access to good-quality, objective, reliable, complete, comprehensible, and non-promotional information on medicinal products, as well as the need for reducing the differences in access to information for patients in different Member States. In the ensuing political debate, the ministers agreed that the ban on advertising of prescription medicinal products be maintained, and they also stressed the necessity to develop appropriate models to monitor and control the dissemination of such information. Progress has also been made in the co-decision procedure with regards to the legal proposal regulation the variations to the marketing authorizations of medicinal products.

On the basis of the Slovenian Presidency Initiative, and in a project co-organized with the European Commission, the Competent Authorities for Pricing and Reimbursement of Pharmaceuticals of EU/EEA Member States have met at Brdo, Slovenia, and established a strategic and high-level network. The aim of the network is relevant for the implementation of G10 recommendations and the deliverables of the Pharmaceutical Forum. The network should be able to contribute to the achievement of principal goals of those initiatives: to enable the access to medicines, to optimize

the managing of public funds allocated for pharmaceuticals, to provide for the reward for pharmaceutical innovation, and improve the accessibility of medicines in the national markets of EU Member States. Activity of the network includes regular meetings addressing current issues in pricing and reimbursement of pharmaceuticals.