Recommendations for improving the medicinal product pricing process

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Contents

Introduction

The pricing of medicinal products for human use and issuing decisions on their inclusion in the national health insurance system represent measures that generally aim to ensure better availability of medicinal products for patients, with optimal utilization of resources intended for funding healthcare and fostering research and development of new medicinal products.

Like other European Union Member States, Croatia must ensure that its national measures for the pricing of medicinal products for human use and the inclusion of medicinal products in the basic and the supplementary reimbursement list of the Croatian Health Insurance Fund (hereinafter: "the Fund") are harmonized with the requirements of the *Council Directive 89/105/EEC 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*[1] (hereinafter: "the Transparency Directive").

The *Draft proposal of the Legislative activity plan of the Ministry of Health of the Republic of Croatia for 2018*[2] foresees amendments to the *Medicinal Products Act*[3] in order to establish a new medicinal product pricing system pursuant to which the Agency for Medicinal Products and Medical Devices, HALMED (hereinafter: "the Agency"), would establish the highest permitted price of a medicinal product at which a marketing authorization holder could sell the medicinal product on the Croatian market, while the Fund could stipulate a price that would be lower than the established highest permitted price of a medicinal product based on a contract with the marketing authorization holder or wholesaler in further proceedings.

In this position paper, AmCham provides recommendations for improving the current medicinal product pricing process, taking into account the information available in the aforementioned document.

[1] *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* (OJ L 40, 11.2.1989)

[2] Republic of Croatia, Ministry of Health: *Draft proposal of the legislative activity plan of the Ministry of Health of the Republic of Croatia for 2018*, available at: https://zdravstvo.gov.hr/pristup-informacijama/savjetovanje-sa-zainteresiranom-javnoscu-1475/otvorena-savjetovanja/nacrt-prijedloga-plana-zakonodavnih-aktivnosti-ministarstva-zdravstva-za-2018-godinu/3005

[3] *The Medicinal Products Act* (Official Gazette 76/13 and 90/14)

The Current Situation in the Republic of Croatia

Issuing decisions on medicinal product pricing and including medicinal products in the basic and the supplementary reimbursement list of the Fund is implemented in accordance with the provisions of the *Medicinal Products Act*, *the Ordinance establishing the criteria and the method for wholesale pricing of medicinal products and the method for reporting wholesale prices*[4], and *the Ordinance establishing the criteria for the inclusion of medicinal products in the basic and the supplementary reimbursement list of the Croatian Health Insurance Fund*[5] (hereinafter: "the Act" and "ordinances") currently in force.

Based on the application submitted by the marketing authorization holder, the Fund issues a decision on the price of a medicinal product that is included in the basic or the supplementary reimbursement list of the Fund, or the price of a new medicinal product proposed for inclusion into the basic or the supplementary reimbursement list of the Fund. By entering into a financing agreement with the marketing authorization holder, the Fund is able to negotiate paying a price for the medicinal product that will be lower than the established highest permitted price, thereby reducing the risks of uncertain clinical efficacy, cost-efficiency and budgetary impact.

Time Frames for Issuing Decisions

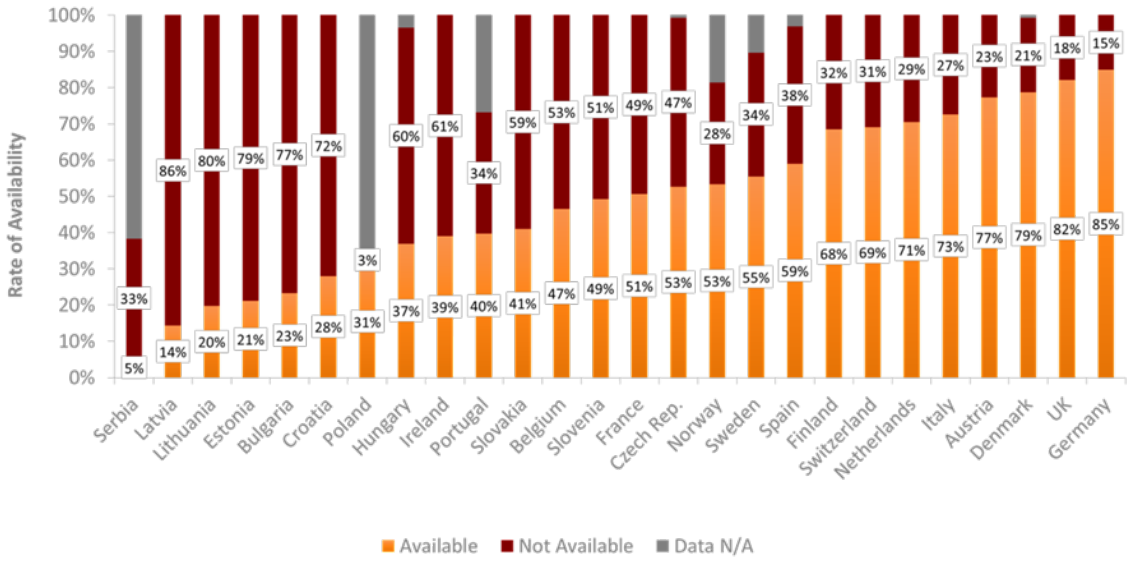
The deadlines for issuing decisions on medicinal product pricing and the inclusion of medicinal products in the basic or the supplementary reimbursement list of the Fund that are laid down by the Act and the ordinances currently in force are in line with the provisions of the Transparency Directive and amount to 90 days from the day of receipt of a valid application for each individual procedure, or 180 days for both procedures. However, according to the experience of AmCham member companies, the deadlines within which such decisions are issued in day-to-day practice substantially deviate from what is stipulated.

According to data from the *European Federation of Pharmaceutical Industry and Associations* (EFPIA), the Republic of Croatia has one of the lowest rates of availability of new medicinal products (i.e. medicinal products with a new International Nonproprietary Name [INN]) in Europe, measured by the share of new medicinal products that were granted marketing authorization in European

[4] *Ordinance establishing the criteria and the method for wholesale pricing of medicinal products and the method for reporting wholesale prices* (Official Gazette 83/13 and 69/14)
[5] *Ordinance establishing the criteria for the inclusion of medicinal products in the basic and the supplementary reimbursement list of the Croatian Health Insurance Fund* (Official Gazette 83/13 and 12/14)

countries in the 2014–2016 period and that are available to patients in 2017 – the Croatian rate being 28%.

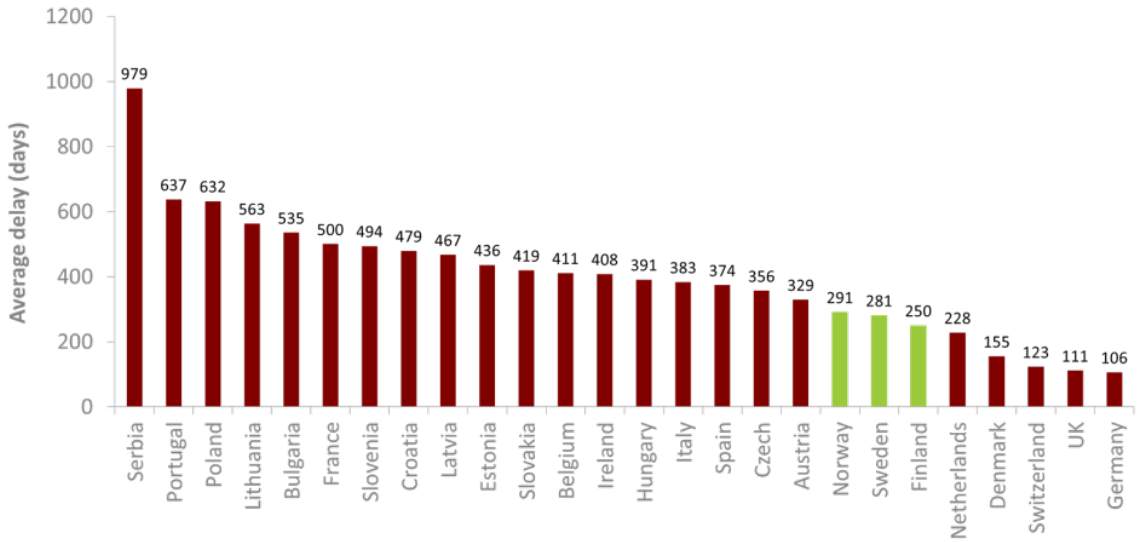
Table 1: Rate of availability of new medicinal products



Source: EFPIA, 2018

Moreover, the Patients W.A.I.T. Indicator, measured by the average time from when a medicinal product is granted marketing authorization to when it actually becomes available to patients by being included in the basic or the supplementary reimbursement list of the Fund, is among the highest in Europe as it amounts to nearly 500 days.

Table 2: The average time from when a medicinal product is granted marketing authorization to when it actually becomes available to patients (Patients W.A.I.T. Indicator)



For most countries patient access equates to granting of access to the reimbursement list, except for hospital products in FI, NO, SE where some products are not covered by the general reimbursement scheme and so the zero-delay is artificially declining the median and average. In France, some innovative products without

competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average for France is higher than in reality.

Source: EFPIA, 2018

The Patients W.A.I.T. Indicator points to the delay in the availability of new medicinal products as a consequence of the time required by the competent authorities to issue a decision on including a new medicinal product in reimbursement lists pursuant to the Transparency Directive, but also of the time required by marketing authorization holders to prepare the comprehensive documentation of the application for the inclusion of a new medicinal product in reimbursement lists.

Transparency in Issuing Decisions

Pricing proposal for a new medicinal product to be included in the Fund's reimbursement lists

Pursuant to Article 12 of the *Ordinance establishing the criteria and the method for wholesale pricing of medicinal products and the method for reporting wholesale prices* currently in force, when the basic or the supplementary reimbursement list includes comparable medicinal products with the same or similar pharmacotherapeutic properties, the wholesale price of a prescription medicinal product that contains a new active substance must not be higher than 100% of the average reference price of the medicinal product, and the price payable by the Fund must not be higher than 90% of the price of the cheapest comparable medicinal product payable by the Fund. Furthermore, when the basic or the supplementary reimbursement list includes comparable medicinal products with the same or similar pharmacotherapeutic properties, the wholesale price of a medicinal product that is dispensed in hospitals and contains a new active substance must not be higher than 100% of the price of the cheapest comparable medicinal product.

Defining a comparable medicinal product as a "medicinal product with the same or similar pharmacotherapeutic properties" enables new medicinal products to be priced by taking into account the prices of medicinal products at different levels of comparison in line with the Anatomical Therapeutic Chemical Classification (ATC classification levels 3–5) that are already included in the basic or the supplementary reimbursement list of the Fund.

Consequently, the assessment of medicinal product price comparison levels is subjective and may result in the inability of a marketing authorization holder to market a medicinal product in the Republic of Croatia due to a potentially extremely low price.

Therapeutic reference pricing

Pursuant to Article 20 of the *Ordinance establishing the criteria and the method for wholesale pricing of medicinal products and the method for reporting wholesale prices* currently in force, reference groups with reference prices of medicinal products within each reference group are laid down by a decision of the Governing Board of the Fund, and generic medicinal products or medicinal products of equal effect and safety are included in reference groups by taking into account ATC classification levels 3–5.

Transparent criteria for determining the groups of medicinal products for which reference pricing will be implemented have not been established. Furthermore, therapeutic reference pricing can be implemented at various Anatomical Therapeutic Chemical Classification levels (ATC classification levels 3–5), without transparent and uniform criteria for determining the level at which the referencing is to be implemented.

Consequently, the assessment of the ATC level at which reference pricing for individual therapeutic groups will be implemented is subjective and may result in high levels of additional payments and unequal availability of new medicinal products for patients.

Fostering Production, Research and Development of New Medicinal Products

Pursuant to Article 12 of the *Ordinance establishing the criteria and the method for wholesale pricing of medicinal products and the method for reporting wholesale prices* currently in force, when the basic or the supplementary reimbursement list includes comparable medicinal products with the same or similar pharmacotherapeutic properties, the wholesale price of a prescription medicinal product that contains a new active substance must not be higher than 100% of the average reference price of the medicinal product, and the price payable by the Fund must not be higher than 90% of the price of the cheapest comparable medicinal product payable by the Fund. Furthermore, when the basic or the supplementary reimbursement list includes comparable medicinal products with the same or similar pharmacotherapeutic properties, the wholesale price of a medicinal product that is dispensed in hospitals and contains a new active substance must not be higher than 100% of the price of the cheapest comparable medicinal product.

The amount payable by the Fund for a new medicinal product for which comparable medicinal products have been included in the basic or the supplementary reimbursement list is lower than or equal to what the Fund pays for the cheapest medicinal product with the same or similar pharmacotherapeutic properties (ATC classification levels 3–5). This completely disregards the added therapeutic value a new medicinal product can have when compared to medicinal products of similar pharmacotherapeutic properties that are already included in the Fund's

reimbursement lists, in the sense of the new medicinal product having a more favorable effect on clinical outcomes and the quality of life, a better safety profile or a method of administration better suited to the patient.

Neglecting the value of innovation for the advance of medical treatment indirectly prevents fostering production, research and development of new medicinal products on which the maintenance of a high level of public health within the community ultimately depends.

European Union Law

The Transparency Directive lays down the obligation of European Union Member States to issue decisions on the pricing of medicinal products and on the inclusion of medicinal products in the scope of national health insurance systems within defined time frames and in a transparent manner, and to have in place medicinal product price control measures with the objective of improving the efficiency of medicinal product production and fostering research and development of new medicinal products.

Time Frames for Issuing Decisions

Member States must ensure that medicinal product pricing decisions are issued within 90 days from the receipt of an application submitted by a marketing authorization holder; they must ensure that decisions on applications for the inclusion of medicinal products in reimbursement lists within the scope of national health insurance systems are issued within 90 days from the receipt of an application submitted by an authorization holder; i.e. they must ensure that the overall period of time taken by the two procedures does not exceed 180 days.

Transparency in Issuing Decisions

The decisions issued by Member States on medicinal product pricing and on applications for the inclusion of medicinal products in reimbursement lists within the scope of national health insurance systems must be based on transparent, objective, and verifiable criteria.

Fostering Production, Research and Development of New Medicinal Products

According to European Commission recommendations[6], Member States should limit their direct control over medicinal product prices to those medicinal products that are financed with national insurance resources, while free market competition among key stakeholders in the medicinal product supply system (including manufacturers, wholesalers, and pharmacies) should be allowed for other medicinal products in order to ensure a broader selection at lower prices.

The objectives of indirect and direct medicinal product price control measures must be to improve the efficiency of medicinal product production and to foster research and development of new medicinal products on which the maintenance of a high level of public health within the European Union ultimately depends.

[6] Pharmaceutical forum – Working Group on Pricing and Reimbursement, *Guiding principles for good practices implementing a pricing and reimbursement policy* (Ares(2014)3849191), available at: ttps://ec.europa.eu/docsroom/documents/7584/attachments/1/translations/en/renditions/pdf

Recommendations

Time Frames for Issuing Decisions

The amendments to the *Medicinal Products Act* should be implemented as part of a comprehensive reform of the policy on medicinal product pricing and the inclusion of medicinal products in the basic or the supplementary reimbursement list of the Fund. The reform should also comprise the amendments to the implementing regulations, i.e. the *Ordinance establishing the criteria and the method for wholesale pricing of medicinal products and the method for reporting wholesale prices* and the *Ordinance establishing the criteria for the inclusion of medicinal products in the basic and the supplementary reimbursement list of the Croatian Health Insurance Fund.*

The change in jurisdiction for determining the highest permitted price of a medicinal product must not in any way prolong the duration of the procedure of issuing a decision on medicinal product pricing, or the overall duration of the procedure of issuing a decision on medicinal product pricing and issuing a decision on the inclusion of a medicinal product in the basic or the supplementary reimbursement list of the Fund.

The methodology for calculating the highest permitted price of a medicinal product should be described in detail, and the authorization holder should be allowed to propose a price for the medicinal product if the price of that medicinal product was not published in official data sources of reference countries at the time of submission of the application for the inclusion in the basic or the supplementary reimbursement list of the Fund.

Transparency in Issuing Decisions

Pricing proposal for a new medicinal product to be included in the Fund's reimbursement lists

It must be ensured that all new medicinal products for which an application for the inclusion in the basic or the supplementary reimbursement list of the Fund has been submitted have equal treatment with regard to the highest permitted price as the medicinal products that are already included in reimbursement lists. This means that, when the basic or the supplementary reimbursement list includes medicinal products with similar pharmacotherapeutic properties, the wholesale price of a new medicinal product that contains a new active substance must not be higher than 100% of the average reference price of the medicinal product in reference countries.

The Fund and the authorization holder should have the option of contractually stipulating additional conditions for medicinal product financing or risk-sharing.

Therapeutic reference pricing

The implementation of therapeutic reference pricing is justifiable solely for mutually interchangeable medicinal products, and it should be done by including medicinal products with the same international nonproprietary name, the same pharmaceutical form and strength in therapeutic groups.

Fostering Production, Research and Development of New Medicinal Products

It is justifiable to implement direct or indirect control over medicinal product prices for those medicinal products that are financed with mandatory health insurance resources, while the regulation of prices of those medicinal products that are not within the scope of national health insurance systems should be left to free market competition.

When issuing a decision on pricing and the inclusion of a new medicinal product in the national insurance system, the added therapeutic value of the new medicinal product should be taken into account in comparison to medicinal products with similar pharmacochemical properties (ATC classification level 4) that are already included in the Fund's reimbursement lists, in the sense of the new medicinal product having a more favorable effect on clinical outcomes and the quality of life, a better safety profile or a method of administration better suited to the patient.

Conclusion

AmCham hereby wishes to support the intentions of the Ministry of Health in the process of establishing a new medicinal product pricing system, under the assumption that the purpose of the aforementioned changes is to improve the efficiency of the system for everyone involved, and by taking account of the welfare of patients as end users of medicinal products.

Adopting AmCham's recommendations would enable better harmonization of procedures implemented at national level in Croatia with the legal framework of the European Union and practices of other Member States, and it would be an important step towards improved efficiency.

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