

Pricing and reimbursement

Introduction

Till the end of 2007, setting the maximum ex-factory prices fell under the remit of the Ministry of Finance. The Ministry of Health was responsible for decisions on reimbursement of pharmaceuticals. Reimbursement price and conditions of reimbursement were issued by a ministerial decree and were revised four times a year by a Categorization committee. There were no statutory guidelines for assessing pharmaceuticals during the decision-making process about reimbursement. Since January 2008, SUKL (the State Institute for Drug Control) has been responsible both for setting the maximum ex-factory price and for decisions on reimbursement. This responsibility is based on Act No. 48/1997 Coll. SUKL is only responsible for reimbursement of out-patient drugs (not hospital only products) and it is responsible for pricing of both out-patient and hospital only drugs.

Act No. 48/1997 Coll. sets the legal framework for calculation of maximum ex-factory drugs prices and also establishes the methods for reimbursing pharmaceuticals. Generally only prices of reimbursed pharmaceuticals are regulated (maximum ex-factory price and/or regressive mark-up scheme).

Requirements for acceptance of the application for setting the maximum price and/or reimbursement (meaning both reimbursement price and conditions of reimbursement) differ for the applicant of generic and original medicinal products. Requirements on application are specified by Act No. 48/1997 Coll.. The application for reimbursement of a generic or biosimilar product is simpler than the application for reimbursement of the originator. Among others, it is necessary to submit data from clinical trials as well as cost effectiveness analyses and budget impact analyses in case of an originator product or in case of a new indication. The application for price is the same for all pharmaceuticals.

It is the marketing authorization holder or insurance fund who can apply for price or reimbursement. Companies (marketing authorization holders) are obliged to pay the fee for their applications (application for new active substances, new combination of substances, new indications, new pharmaceutical form for new indications – CZK 20 000, application for a new pharmaceutical form without assignment for a new indication, new strength – CZK 10 000, generic product or new size of packaging – CZK 8 000, in other cases – CZK 10 000). Pricing and reimbursement procedure runs as individual administrative proceedings with fixed terms and conditions. The company (both originator and generic) has to apply (fill the form) and the decision is made within 75 days in case of application only for price or only for reimbursement (165 respectively for joint application for price and reimbursement). Since 2012, a special type of short 30-days procedure is available for generic and biosimilar products. The appeal authority against decisions made by SUKL is the Ministry of Health. There is no space for negotiating between the competent authority and the companies independently on the nature of the company, nature of the product and the market conditions.

Price and reimbursement of the first generic product has to be at least 32 % lower than the price and reimbursement of the originator. In case of biological products the price and reimbursement has to be at least 15 % lower.

Pricing

There is no special rule for HOM (Hospital-only Medicines) or original/generic or any other pharmaceutical types. The only criterion is whether it is reimbursable or not. For generic products there is also one additional short procedure available to choose from.

Until the beginning of June 2008 there were only 2 groups of pharmaceuticals from the aspect of price regulation. Reimbursable pharmaceuticals were regulated by the maximum ex-factory price and regressive mark-up scheme. Prices of non-reimbursable pharmaceuticals were not regulated. Since the beginning of June 2008, a new ministerial regulation has been in force which introduces the category of pharmaceuticals regulated only by the mark-up scheme and hospital-only pharmaceuticals whose prices were not regulated at all. Since June 2009, also hospital-only medicines are price regulated (by fixed maximum ex-factory price and a degressive mark-up scheme).

Thus, in the Czech Republic there is statutory pricing for all reimbursable pharmaceuticals. Prices of non-reimbursable pharmaceuticals are not regulated.

Prices of pharmaceuticals are set at ex-factory level or are regulated by statutory prices (these are prepared medicinal products or prepared parenteral nourishment, prepared radiopharmaceuticals and transfusion products made in the facilities of the transfusion service). The maximum pharmacy retail price can be defined based on fixed wholesale and pharmacy mark-ups and VAT which is currently 15% (as of 2013).

The ex-factory price of a certain pharmaceutical is set as the average of 3 lowest ex-factory prices of this pharmaceutical found in the reference basket (reference basket states – All EU countries except for Austria, Bulgaria, Cyprus, Czech Republic, Estonia, Germany, Luxembourg, Malta and Romania). If the pharmaceutical (with the exception of highly innovative drugs) is not on the market in at least three reference basket states, agreed price of the pharmaceutical can be used in the evaluation. If none of the above mentioned procedures is applicable, the price is set as the maximum ex-factory price of the closest therapeutically comparable pharmaceutical available in the Czech Republic or in the reference basket countries. For highly innovative drugs it is possible to set the ex-factory price as the average manufacturer's price found in at least 2 reference basket states.

About half of the medicinal products reimbursed from public health insurance are regulated by the maximum price. Manufacturers can decide to supply pharmaceuticals for lower prices than the stipulated maximum ex-factory price, in order to reduce or fully eliminate the difference between the price and the reimbursement paid by the patient and thus increase the sale of its product.

When the medicinal product is not regulated by a maximum price, it relies on the price policy of the holder. Medicinal products which are not regulated that way undermine the market competition (there are at least four holders of marketing authorization); we can expect a higher effort to compete on the market by charging the minimum or no additional payments to patients.

Reimbursement

In the Czech Republic the system of **reference groups** is in place. The reference group is a group of pharmaceuticals which have similar effectiveness, safety profile and clinical use, and are considered to be therapeutically interchangeable. Mostly it associates drugs on ATC5 level but it is not always the case. All pharmaceuticals within the same reference group have the same reimbursement price. It is also possible to give a premium reimbursement price in case that a drug has better effectiveness, better safety profile or better compliance rate than the reference product. The Ministry of Health issues a Decree on the list of reference groups. The Decree determines about 300 groups of pharmaceuticals based on therapeutic indications.

Reimbursement price is set according to the EU lowest price of a pharmaceutical within a reference group (reference product). If the EU lowest price is extremely low (more than 20% lower than the average of 2 other lowest EU prices of the same product) then reimbursement price is set as the average of 2 other lowest EU prices of the reference product.

Act. No. 48/1997 Coll., also specifies 195 **pharmacotherapeutic groups** of pharmaceuticals within which at least one product should be fully reimbursed. In this case reimbursement price is not set according to the lowest EU price but according to the lowest Czech price. These pharmacotherapeutic groups are not always identical with the reference groups. Usually pharmacotherapeutic groups associate a wider variety of different medicines.

In general, the cheapest out of a defined group of pharmaceuticals (in most cases a generic, often a locally manufactured one) is fully reimbursed. All other pharmaceuticals are partly or fully paid for by patients: sickness funds only reimburse up to the price of the product, i.e. the reference price.

It is also possible to set a second reimbursement price for a specific group of patients or a specific indication which is not covered by reimbursement of the reference product.

Other

POM and some OTC drugs can be dispensed only by pharmacies or drug dispensaries. There is a small group of drugs called restricted pharmaceuticals which can also be dispensed outside pharmacies (drug stores, gas stations etc.). All restricted pharmaceuticals belong among OTC drugs.

Wholesalers and pharmacists are remunerated by a regressive mark-up scheme. This scheme is issued by the Ministry of Health in a ministerial regulation and is valid for all reimbursable pharmaceuticals. The margins are common for both wholesaler and pharmacy. It means that the lesser margin is kept by the wholesaler, and the greater margin can be applied by the pharmacy. The estimated share of wholesaler margin is 5-7% for the cheapest products. Discounts are possible both for wholesalers and for pharmacies. Maximum mark-ups are not always applied and thus prices of pharmaceuticals can vary throughout the country.

In general, the maximum mark-up is not fully used, which leads to different prices for the same pharmaceuticals (especially in the OTC segment) in pharmacies. Therefore patients have the possibility to shop around for the cheapest pharmaceutical.

Patients pay a co-payment which is the difference between the actual price of a drug and the reimbursement. In addition to the co-payment there is a fixed regulatory fee of CZK 30 (1,2 €) for the prescription (only two items are allowed on one prescription form).

Conclusion

As the procedural rules concerning reimbursement of pharmaceuticals were not published in the past (decision was made by the Ministry of Health), the reimbursement process was - compared to other EU Member States - rather non-transparent. The change of legal rules as of 1 January 2008 therefore seems to be crucial, because since then this issue has been dealt with by SUKL on the grounds of conditions stipulated by the Administrative Procedure Code. This increased the transparency of the entire procedure and improved competition on the market. The prices of pharmaceuticals are regulated by the state only if subsidized from the system of public health insurance, no matter if the pharmaceuticals are original or generic. Pharmaceuticals (both original and generic), which are not even partly reimbursed from the public health insurance, are subject to free price competition. The generics and biosimilars are treated differently when the maximum amount of price or reimbursement is being set. First of all, their maximum price and reimbursement is always set up to 85 % (in case of biosimilars) or 68% (in case of generics) of the maximum price or reimbursement of the original drug. The price of generics is thus always lower than the price of original pharmaceuticals, i.e. generics are a cheaper alternative for consumers. The lower reimbursement should motivate doctors to prescribe cheaper generics. Also the rules for submission of applications on price and reimbursement should be beneficial for producers of generics under the condition they only apply for the same conditions of reimbursement as the original product. Additionally, a special short-time procedure for generics is available. After the expiration of the patent protection of an original pharmaceutical and the entry of its generics substitute on the market, the generics are in fact prioritized as a result of the reimbursement policy. In case that reimbursement is set as the lowest Czech price, usually the cheapest generic in each pharmacotherapeutic group is fully reimbursed from the public health insurance (only in the case the group does not cover any generic, the original is fully reimbursed). This could again lead to more frequent prescription of cheaper generics. On the other hand the principle of joint margin of pharmacists and distributors and rules for drug prescription does not give any economic preference to originals or generics.