

Pricing and reimbursement (as of 1. 1. 2018)

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 health insurance fund who can apply for price or reimbursement. Companies (marketing authorization holders - MAH) are obliged to pay the fee for their applications.

Application for the determination of the maximum price or the amount and terms of reimbursement:

- new active substances, new combination of substances, new indications, new pharmaceutical form for new indications – CZK 20 000,-
- new pharmaceutical forms without assignment for a new indications, new strength – CZK 10 000,-
- generic product or new size of packaging – CZK 8 000,-
- food for special medical purposes – CZK 10 000,-
- in other cases – CZK 10 000,-
- medicinal products included in the registry of orphan medicinal products – CZK 0,-.

Application for the change of a decision on the established maximum price or the amount and terms of reimbursement:

- extended indications, restriction of existing terms of reimbursement or increased reimbursement – CZK 20 000,-
- 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 40 % lower than the price and reimbursement of the originator. In case of biological products

the price and reimbursement has to be at least 30 % lower. Price and reimbursement of the second originator is cut down by 15 % against the first originator.

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 HOM whose prices were not regulated at all. Since June 2009, also HOM 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 10 % for most pharmaceuticals (or 15 % for some foods for special medical purposes and special medical goods not classified as medical devices) as of 2015. The ex-factory price of a certain medicinal product is set as the average of 3 lowest ex-factory prices of this medicine found in the reference basket (reference basket states – All EU countries except for Austria, Bulgaria, Cyprus, Czech Republic, Estonia, Germany, Greece, Luxembourg, Malta and Romania). If the reference basket lowest price is extremely low (more than 20 % lower than the average of 2 other lowest prices of the same product) then price is set as the average of 2 other lowest prices of the reference product. If the medicine (with the exception of highly innovative drugs) is not on the market in at least three reference basket states, agreed price of the medicine 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 medicine 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 two thirds 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 MAH. 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 co-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 for the usual daily therapeutic dose. 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 medicinal product. The Ministry of Health issues a Decree on the list of reference groups. The Decree determines about 200 groups of pharmaceuticals based on therapeutic indications. Reimbursement price is set according to the EU lowest price of a medicinal product 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 by patients: sickness funds only reimburse up to the price of the product, i.e. the reference price. It is also possible to set increased reimbursement for a specific group of patients or a specific indication which is not covered by reimbursement of the reference product.

Other

Prescription only medicines and some OTC drugs can be dispensed only by pharmacies or drug dispensaries. Some OTC drugs can also be sold outside pharmacies (drug stores, gas stations etc.). There is also small group of medicines with restricted dispensing containing pharmaceuticals with pseudoephedrine. Dispensing per single patient is monitored. Wholesalers and pharmacies 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 price. Annual co-payment ceilings are set at 1000 CZK for patients under 18 years and above 65 years old, 500 CZK for patient above 70 years and 5000 CZK for other patients.