DESCRIPTION OF THE PRICING AND REIMBURSEMENT SYSTEM IN THE CZECH REPUBLIC

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Objective

To investigate changes realized in the Czech pricing and reimbursement system since January 2008 and to describe the current development of this system.

Methods

We described the legal framework defining the Czech system (Act No. 48/1997 Coll. as amended by the Act No. 261/2007 Coll. on Public Health Insurance[1]) as well as evaluation of the current system from the literature and reports provided by the State Institute for Drug Control (SUKL)[2].

Results

Changes in the Pricing and Reimbursement system

Until 31st December 2007 the pricing system (setting maximum prices of medicines) was under the responsibility of the Ministry of Finances. The Ministry of Health (MoH) was responsible for the reimbursement procedure of medicines. A co-called Categorisation Committee with representatives from MoH, health insurances, academics, patient groups, professional organisations, pharmaceutical industry was set under the responsibility of the MoH. Decisions of this committee were not based on transparent criteria and its decisions were unappealable.
Since January 2008 new legislation is in force for pricing and reimbursement in Czech Republic. The law modification was partly forced by European Commission request for adherence to EU Transparency Directive[3] and by the ruling[4] of the Constitutional Court of the Czech Republic which cancelled current regulation. In new principles there should be reflected transparency, law enforceability and judging in separate cases. Therefore since 1st January 2008 the pricing and reimbursement system moved from jurisdiction of Ministry of Health and Finance to State Institute of Drug Control (SÚKL). SÚKL is drug regulatory agency responsible for marketing authorisation, pharmacovigilance, clinical trials regulation and pharmacy and wholesaler supervision. The Categorisation Committee was cancelled.

Pricing system

The pricing rules were fully changed. The responsibility for setting the maximum market prices before the law change has had Ministry of Finance. The prices were not negotiated and were without reference to international price levels. Nowadays the maximum price is set based as the mean value of all available ex-factory prices in the reference price basket (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain). The price is calculated as mean value of these countries.

Participants in the maximum price proceeding are[1]:

- SUKL
- Marketing authorization holder or the Importer or inland manufacturer if it considering non-authorized medicine which is used in the approved specific treatment programs (not registered medicines).
- Health Insurance Companies

Reimbursement system

The Czech reimbursement system in based on internal and external references. The reference reimbursement system contains 251 reference groups of therapeutically interchangeable products with similar clinical efficacy and safety (should be updated annually by MoH). The reference groups represent the internal reference system.

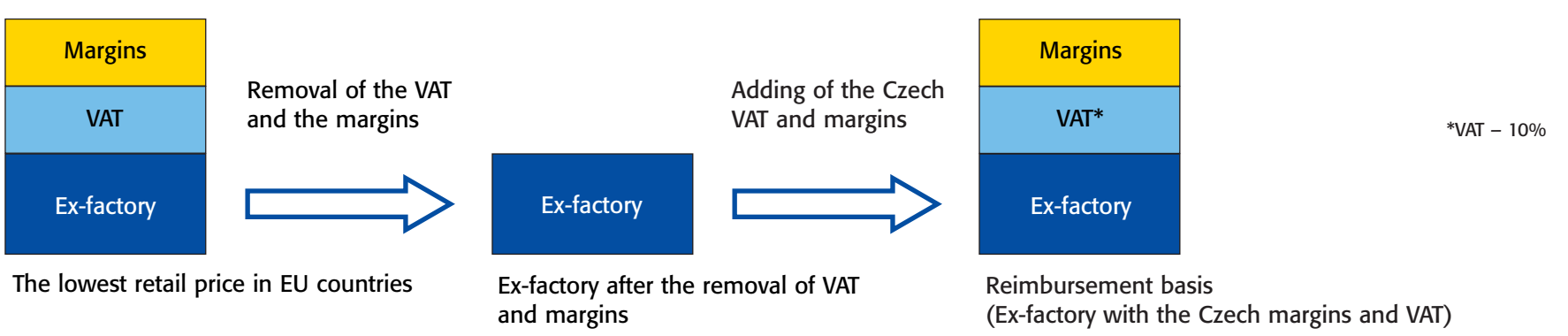
Medicinal products included in one reference group have the main common therapeutic indication in the same reimbursement level which is calculated on the basis of cheapest retail prices in all EU countries. Such system represents the external reference system. The cheapest price for equipotent dose is chosen and re-counted according to local pharmacy and wholesaler margins and value added taxes (see Figure 1).

In compliance with new legislation the pharmacoeconomic criteria (cost-effectiveness evaluation and budget impact analysis) should be taken into account. There is possibility of extra bonus of basic reimbursement for better efficacy, safety, dosing schedule, compliance, etc.

The main participants in the process of reimbursement are the same as in the pricing procedure[1].

There is also the option for provisional reimbursement in highly innovative products without availability of effectiveness and efficiency data at the time of application. The one year reimbursement is granted and the level and conditions are reappraised after this period.

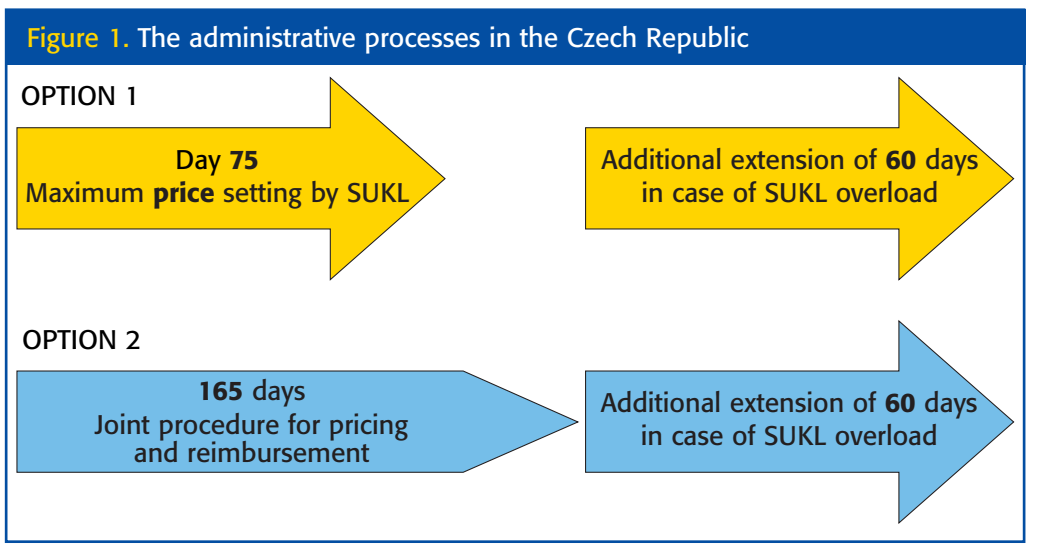
Figure 1.



Administrative Procedures

Process of administrative procedure of determination of maximum prices and the reimbursement level is defined by the Act on Administrative Procedures5 and the timeline is stated in the Act on Public Health Insurance[1]. The administrative procedures are individual and assure the participants the possibility of revocation of the decision to the Ministry of Health in constant time limits. Deadlines of the pricing and reimbursement procedures (75 days) and the joint procedure (165 days) are described in the figure 1.
The transparency is assured by the possibility of access to the administrative materials under specific conditions (possession of the electronic signature).
The Administrative procedure can be started on request of the possible participant in the procedure or ex offo by SUKL. The law states that the whole reimbursement system should be reviewed on annual basis which is clearly a big challenge.

Figure 1. The administrative processes in the Czech Republic



Conclusion

The system has gone through dramatic changes in last two years and some aspects are still facing challenges. Although the new system should reassessed all medicines covered in the country till 2008, currently there are only 20% revised (April 2010)[2].

References

1 Act No. 48/1997 Coll. On Public Health Insurance, http://portal.gov.cz/wps/portal/_s.155/701?kam=zakon&c=48/1997 , accessed 1/10/2010
2 State Institute of Drug Control (SUKL), www.sukl.cz, accessed on 21.10.2010
3 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 within the scope of national health insurance systems (Official Journal L 40, 11/2/1989 p. 8-11; Finnish special edition: Chapter 15 Volume 9 p. 45; Swedish special edition: Chapter 15 Volume 9 p. 45)
4 Ruling of the Constitutional Court of the Czech Republic (PL ÚS 36/05 16.1.2007)
5 Act No. 500/2004 Coll. On Administrative Rule, http://portal.gov.cz/wps/portal/_s.155/701?kam=zakon&c=500/2004, accessed 1/10/2010

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