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) as well as evaluation of the current system from the literature and reports provided by the State Institute for Drug Control (SUKL).

Results
Changes in the Pricing and Reimbursement system
Until 31 December 2007 the pricing system (setting maximum prices of medicines) was under the responsibility of the Ministry of Finance. The Ministry of Health (Moi) was responsible for the reimbursement procedure for medicines. A so-called Categorisation Committee with representatives from MoH, health insurances, academics, patent groups, professional organisation of pharmacists and pharmaceutical industry was set under the responsibility of the MoI. Decisions of this committee were not based on transparent criteria and to decisions were unapproachable.

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 Directive1 and by the ruling2 of the Constitutional Court of the Czech Republic which cancelled current regulations. In new principles there should be reflected transparency, law enforceability and judging in separate cases. Therefore since 1 January 2008 the pricing and reimbursement system moved from jurisdiction of Ministry of Health and Finance to State Institute of Drug Control (SUKL). SUKL is drug regulatory agency responsible for marketing authorisation, pharmacovigilance, clinical trials regulation and pharmacy and wholesaler supervision. The Categorisation Committee was cancelled.

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 MoI). 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 equivalent 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 procedure1.

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.

Administrative Procedures
Process of administrative procedure of determination of maximum prices and the reimbursement level defined by the Act on Administrative Procedures3 and the timeline is stated in the Act on Public Health Insurance1. The administrative procedures are individual and assure the participants the possibility of revocation of the decision to the Ministry of Health in certain time limits. Deadlines of the pricing and reimbursement procedures (75 days) and the joint procedure (165 days) are described in the figure.

The transparency is assured by the possibility of access to the administrative materials under specific conditions (possess of the electronic signature). The administrative procedure can be started on request of the possible participant in the procedure or ex officio by SUKL. The law states that the whole reimbursement system should be reviewed on annual basis which is clearly a big challenge.

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 via 2008, currently there are only 20% revised (April 2010)2.

References
2 State Institute of Drug Control (SUKL), www.sukl.cz, accessed 30.10.2010
4 Rule of the Constitutional Court of the Czech Republic (FS 30/2004, 15/2000).