Ministerstvo zdravotníctva SR

PPRI
Pharmaceutical Pricing and Reimbursement Information

SLOVAKIA

High-cost medicines

- Specific funding / reimbursement schemes for high-cost / innovative medicines (since December 2011) :

  1.Reimbursement only at level max 20% of retail price if that medicine has not officially determined price at least in 5 countries within EU

  2.“Conditional categorization”(CC)- for period 2 years, at least 180 days before expiring of this period MAH is required to submit a pharmaco-economic analysis and evidence of drug efficacy in clinical practice. Based on this data Ministry of health decides on further listing or about the change in reimbursement of this medicine.

  MAH is obliged to submit proposal of maximum amount of reimbursements for period of duration CC.

  After the end of CC Ministry of health assess the real amount of reimbursements and if that sum is higher than the proposed final sum, MAH is obliged to refund the difference to Health Insurance Companies.

- No specific committees (Categorisation committee asseses high-cost medicines as well as other medicines, it has an advisory function), no specific procedures and specific requirements

- Pricing of innovative medicines:

  normal pricing rules, the second lowest price within EU as others medicines

- Price of high-cost medicines– proposal by the marketing authorization holder (MAH) and approval by Ministry of health

- Key challenges of innovative medicines and approaches for solutions

Generic policies

- INN prescribing (positive list - contains about 300 active substances of 900 with “per os” route of administration), mandatory since December 2011
- Generic substitution is allowed (since 2005)
- Generic price link in place: the generic must be 30% lower than the originator
- No tendering-like practices in the out-patient sector
- Reference price system in place: according The Announcement in place since December 2011

  clustering of reference groups, mostly at ATC 5, in some cases at ATC 4 level, with the same route of administration, pharmaceutical form but different amount of active substance in dose, or with different pharmaceutical form, or with different route of administration - methodology of calculation “reference price” (reimbursement amount) is determined by Announcement for each group by the coefficient of reimbursement level

- Some information activities to patients and prescribers about generics (leaflets, press releases, guide for physicians) due to introduction of INN prescribing

- Web application on the website of Ministry of health compares prices between generics and originator so patients can choose the cheapest one
- Generics share:

  share of generics is 44% in volume (packages) and 26 % in value (costs) in 2010 in out-patient reimbursement market

Changes in the pharmaceutical system – end 2011/2012

- New legislation (Act Nr.363/2011) in place since December 2011
- Change in external price referencing: Slovak maximal ex-factory price is set on the second lowest price within prices in EU
- Changes of publishing reimbursement lists - since January 2012 is published monthly instead of quarterly
- Introduction reference price system for some groups of medicines according The Announcement Nr. 435/2011 since December 2011 includes changes in methodology of clustering the reference price groups and the calculation of the reference price
- Reimbursement reviews - 4 times a year
- Introducing the list of medicines which were delisted from reimbursement list classified as treatment for not serious diseases (as a supportive and complementary therapy)
- Changes of generic policies - INN prescribing is mandatory since December 2011
- Introducing reimbursemnt list of special medical supplies with officially determined prices

Measures under discussion or planned

- *Any*

Evaluations and studies on pharmaceutical policies

Peter Pažitný : ***Evaluation of health policy 2009***

- published by HPI (Health policy institute) in January 2010
- Key results: Most beneficial measure of health policy was external price referencing
- Conclusions and implications: expenditure on medicines were managed to maintain at approximately the same level as in 2008

A. Szalayová : ***Generic prescription***

- published by HPI (Health policy institute) in April 2011

- Conclusions and implications: benefits and risks of generic prescription, summary of the implementation of generic prescribing in different EU countries