

# SLOVAKIA, 4st PHIS Network Meeting, Rome, September 27-28, 2009

## New medicine

AUTHORISATION/  
CLASSIFICATION

**European Medicines Agency (EMA) or  
State Institute for Drug Control**

Task: Decision on authorization and registration  
Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Slovak medicines Act

Task: Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the criteria of pharmaceuticals  
Criteria: Directive 92/56/EEC, ASlovak Medicines Act, law on prescription requirement, etc.

SIDC and IforPH (vaccines) is also in charge of **pharmacovigilance**.

VIGILANCE

PRICING  
at ex-factory level

**Ministry of Health (MoH)**

in consultation

**Ministry of Finance**

Task: Calculation of EU average price for medicines applying for inclusion in Reimbursement list in the outpatient sector  
Criteria: External price referencing

External reference pricing for all 27 MSs, published in Degree of MoH for all pharmaceuticals (outpatient and inpatient) including setting of maximal mark-ups for wholesalers and pharmacies

**Pharmaceutical companies**

**Medicines distributed via**

PRICING  
at wholesale and  
pharmacy level

**Wholesaler**

Maximum regressive whole sale mark up scheme set by the **Ministry of Health** (2 different schemes: fixed mark up for hospitals and regressive for outpatient customers)

**Pharmacies**

Maximum regressive pharmacy mark up scheme set by the **Ministry of Health** (mark up regulation only for retail pharmacies)

**Hospital purchasing body (individual hospital pharmacist or joint purchasing body)**

Task: Price negotiations or tendering of medicines  
Criteria: Depending on the product or on the market situation of the medicine

Hospital pharmacy and/or pharmaceutical depot

**Ministry of Health**

**Categorisation Committee**

in consultation with

Task: Decision on the reimbursement status  
Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria, proof of EU average price



**Public hospitals which receive public funds**

**Ministry of Health and sick funds**

based on

Task: Definition and assessment of cost for bed-days per treatment and medical services inclusion of medicines  
Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria

Evaluation of costs and treatment per treatment procedure and case incl pharmaceuticals

Reimbursable medicines

List of Reimbursable pharmaceuticals

Internal reference pricing ATC 5 level, differentiated by pharmaceutical form, possibly also strength and package.

Prescription limitation and indication limitation in the case of reimbursement is for limited cases of licensed diagnosis.

5 000 pharmaceuticals in positive list,

**Hospital / Hospital owner association**

in cons. with

Task: Decision on use of medicines in specific hospitals

Pharmaceutical and Therapeutic Committee per hospital (owner)

Pharmaceutical formulary per hospital

REIMBURSEMENT

OUT- IN -  
PATIENT