

New medicine

**European Medicines Agency (EMA) or
State Medicine Control Agency under MoH of Lithuania (SMCA)**

Task: Decision on authorization and registration. Decision on dispensing requirements (prescription only, OTC, hospital)
Criteria: Quality, safety, efficacy (Directive 2001/83/EC as amended) and Law on Pharmacy; order of MoH

SMCA is also in charge of **pharmacovigilance**

AUTHORISATION/
CLASSIFICATION

VIGILANCE

Ministry of Health

Reimbursed medicines

with opinion

MoH Reimbursement Commission

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

Non reimbursed medicines

Price notification for non reimbursed medicines with price changes in the out-patient sector

"free pricing"

Pharmaceutical companies

PRICING
at ex-factory level

Medicines distributed via

Wholesaler

Maximum regressive wholesale mark-ups scheme for **non reimbursed** medicines set by the Government Decree.

Pharmacies

Maximum regressive wholesale mark-ups scheme for **reimbursed** set by the Order of MoH



Hospital pharmacy and/or Pharmaceutical and Therapeutic Committee per hospital

PRICING
at wholesale and
pharmacy level

Hospital purchasing body (general purchasing)

in cons. with

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

Pharmaceutical formulary per hospital

National health Insurance Fund under MoH (expensive medicines)

in cons. with

Commission for centrally purchased medicines

Task: every year assessment and inclusion of medicines into the List of centrally purchased medicines
Criteria: criteria of therapeutic, pharmacoeconomic and social value
▪ medicine for in-patient treatment which is very expensive but does not exceed 37650,6 EUR per year or per treatment course

Adviser body

MoH Reimbursement Commission

Task: Decision on the reimbursement status
Criteria: Therapeutic, pharmacoeconomic value, EU average price

Adviser body

National Health Insurance Board

REIMBURSEMENT

Reimbursable medicines

Positive list (price list set by Oder of MoH)

Reference price shall not exceed 95 %of the average price in 8 EU countries.

Medicines for treatment of rare diseases
Reimbursement according individual application

No general reimbursement

Waiting list

Medicines with essential added therapeutic value, but positive impact to Compulsory Health Insurance Fond budget will be included in Positive list if additional finances are foreseen.
No reimbursement
Price notification

Not listed

Non reimbursable medicines and medicines not applied for inclusion in the Reimbursement list
No reimbursement
Price notification

OUT- IN -
PATIENT