

CZECH REPUBLIC



State Institute for Drug Control

Regulation and reimbursement of pharmaceuticals in the in- and out-patient sector

State Institute for Drug Control (SUKL, Czech medicines agency) or **European Commission (European Medicines Agency)**

AUTHORISATION CLASSIFICATION

ex-factory level

Wholesale/Pharmacy level

PRICING

If a product meets criteria for pharmaceuticals, a decision on marketing authorization is issued. This decision includes information on classification for supply and dispensing requirements

Quality, safety, efficacy (Directive 2004/27/EC) and Czech Act on Pharmaceuticals

SUKL is also in charge of pharmacovigilance activities and GMP/GDP inspections

SUKL is also in charge of price

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Task: Calculation of price for

medicines if reimbursement has been applied for (IN/OUT-PATIENT)

Criteria: External price referencing

Ministerial Decision on deregulated ATC

Price notification for medicines with deregulated price (IN/OUT-PATIENT)

"Free pricing"

Wholesalers

Wholesale mark up of reimbursed products is limited by Ministerial Decision (1 scheme, see pharmacies) IN/OUT-PATIENT

Pharmacies

Maximum regressive mark up scheme set by Ministry of Health (Ministerial Decision). 1 scheme: combines wholesale and pharmacy mark-ups for reimbursed products. IN/OUT-PATIENT

controls

Individual hospital purchase (hospital pharmacy)

Task: Bid pricing. Obligatory tenders (Act on Public Procurement) for non-private

Criteria: Depending on the product or on the

Pharmaceutical formulary per hospital (owner)

Definition and assessment of DRG groups. DRG reimbursement of acute bed care since 2008

market situation of the medicine

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Decision on the level and conditions of Task: reimbursement

Criteria: External price referencing, internal price referencing, comparison of therapeutic

effectiveness, safety, compliance and cost effectiveness and other relevant factors

Administrative procedure

pharm. companies (MAH)

Parties:

insurance funds

Consultation:

medical associations

Insurance funds Task:

Ministry of Health

Task:

hospitals.

Decision (agreements with hospitals) on use of specific medicines

> Act on Public Health Insurance

Hospital only medicines (reimbursed)

List of items with reimbursement

REIMBURESMENT