AUSTRIA

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

New medicine

AUTHORISATION/ CLASSIFICATION

European Medicines Agency (EMA) OR Austrian Federal Office for Safety in Health Care (BASG) / Austrian Medicines and Medical Devices Agency (AGES MEA Medizinmarktaufsicht)

Task: Decision on authorization and authorisation
Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Austrian Medicines Act

Austrian Medicines and Medical Devices Agency — in consultation with — BMG: **Prescription Committee**, **Restriction Committee**

Task: Decision on prescription, dispensing requirements and if a medicine fulfills the criteria of medicines
Criteria: Directive 92/56/EEC, Austrian Medicines Act, Prescription Act, Prescription Ordinance

The Austrian Medicines and Medical Devices Agency is also in charge of **pharmacovigilance**

VIGILANCE

PRICING at ex-factory price level

Federal Ministry of Health (BMG) — in consultation with — **Pricing Committee** — supported by — Pharma Price Information (PPI) service at the Austrian Public Health Institute (GÖG) – checking pharmaceutical prices on request

Medicines applying for out-patient reimbursement — Statutory pricing

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

Medicines not in out-patient reimbursement — Free pricing

Price notification to BMG for medicines with price changes or outside the Reimbursement Code (EKO) in the out-patient sector

PRICING at wholesale and pharmacy price level

Medicines distributed via

OUT- PATIENT

Wholesalers — Statutory pricing
Maximum regressive wholesale mark-up scheme set by **BMG** (2 different schemes, one for Green + Yellow box products, one for the remaining)

Pharmacies — Statutory pricing
Maximum regressive pharmacy mark-up scheme set by **BMG** (2 different schemes: one for 'privileged' customers (e.g. sickness funds) and one for private customers)

VAT: 10%
Co-payment (prescription fee of €5.55) for reimbursed medicines

IN - PATIENT

Price negotiations — Tendering

Statutory wholesale or pharmacy margins are not relevant, unless products are bought from wholesalers or community pharmacies.

Hospital purchasing body (individual hospital pharmacist or joint purchasing body) — in cons. with — Hospital pharmacy and/or pharmaceutical depot

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

REIMBURSEMENT

Main Association of Austrian Social Insurance Institutions (HVB) — in cons. with — **Pharmaceutical Evaluation Board (HEK)**

Task: Decision on the reimbursement status
Criteria: Eligibility for reimbursement; pharmacological, medical therapeutic, pharmacoeconomic criteria

Reimbursable POM

National Reimbursement Code "EKO" (100% reimb.)

Green Box	Light Yellow Box	Dark Yellow Box
For prescription of medicines no approval necessary Price < EU average price	Medicines for defined indications Ex-post check of prescription behavior Max. EU average price	Medicines with essential added therapeutic value Ex-ante approval of head physician necessary Max. EU average price

Red Box

Ex-ante approval of head physician necessary
Max. EU average price or price indicated by industry, as long as there is no EU average price fixed by the Pricing Committee
- contains new medicines available in the Austrian market that have applied for inclusion in the national reimbursement code.
- decision on inclusion in Green or Yellow Boxes (as decision also includes and depends on the price, period is 180 days); if negative decision – delisting of the product from the Red Box

Non reimbursable medicines

Reimbursement on individual application possible
(Non reimbursable medicines and medicines not applied for inclusion in the Reimbursement Code)

Only price notification

Medicines Commission

Task: Development of joint provision models for the in-patient and out-patient sector for high priced and specialized medicines. It is charged with establishing the eventual 'best point of service' reflecting medical-therapeutical, health economic and health care considerations.

Public hospitals which receive public funds

Federal Ministry of Health (BMG) — in cons. with — Federal Commission of regional decision makers / payers (BGK)

Task: Definition and assessment of DRG groups (LKF) and medical services (MEL) and inclusion of medicines
Criteria: Pharmacological, medical therapeutic, pharmacoeconomic criteria

Medicines are integrated in the lump sums (with some exceptions) which can be generated for reimbursement of the procedure and diagnosis-orientated case groups (DRG) in hospitals.

Use in hospitals

Hospital/ Hospital owner association — in cons. with — Pharmaceutical and Therapeutic Committee in hospital (association)

Task: Decision on use of medicines

Pharmaceutical formulary per hospital (owner)

The financing of the medicines does not depend on the inclusion in a pharmaceutical formulary. Once included price negotiations/tendering start.

No co-payments for patients

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