

HUNGARY

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

Pricing

Pricing regulations apply for only reimbursed drugs in the in- and out-patient sectors. Free pricing prevails outside the reimbursement system. VAT: 5% for all medicines

Pricing in the out-patient sector

Pricing at ex-factory level

- *External reference pricing:* EU 28 + Switzerland + Norway + Iceland
- *Internal reference pricing* - therapeutic groups and active substance groups with fixed prices

This applies for generic drugs and drugs with similar efficacy.

Maximum amount of reimbursement for each drug in the group is based on the lowest priced medicine (with a minimum required DOT turnover).

Required cut down prices for generic drugs:

- 1st generic drug – 40%,
- 2nd generic drug – 20%,
- 3rd generic drug – 10%,
- 4-6th generic drugs – 5%,
- afterwards 0,3 Euro Cent.

Biosimilar drugs: yearly tendering process, the cheapest medicine is required to prescribe for the new patients. Required cut down prices for biosimilar drugs: 1st – 30%; 2nd – 10%; 3rd – 10%

- *Sales representative registration fee* ~ 3100 EUR/capita/year
- *Cost-effectiveness requirement for innovative medicines* (ICER ≤ 2-3 x GDP per capita)

Pricing at wholesale level

- *Strictly regulated regressive margins*
8% - 6,5% - 5% - 4,4%, depends on the ex-factory price
- *Statutory pricing* according to Decree of the Ministry of Health 5/2007

Pricing at pharmacy level

- *Strictly regulated regressive margins*
27% - 23% - 20% - 18%, depends on the wholesale price
- *Co-payment* - Patients should pay 1 EUR for 100% reimbursed drugs
- *OTC products have free pricing*
- *Statutory pricing* according to Decree of the Ministry of Health 5/2007

Pricing in the in-patient sector

- *Centralised or hospital tendering* is required for some medicines
High-cost oncology and biological drugs (item-based reimbursement)
Separate budget for haemophilia and HCV infection
Tenders are valid for 1-3 year.
- *Pharmaceutical companies* may offer discounts to hospitals or to NHIFA (National Health Insurance Fund Administration).

Main acts

- Decree of the Ministry of Health 32/2004 (IV.26.) Legal framework for price setting
- Decree of the Ministry of Health 5/2007 (I.24.) wholesale and pharmacy mark-up, price margins
- Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Therapeutic Medical Devices

Links

- <http://www.oep.hu/pupha>
- <http://www.oep.hu/iframes/gyogyszerkereso>
- http://www.oep.hu/felso_menu/szakmai_oldalak/publikus_forgalmi_adatok/gyogyszer_forgalmi_adatok

Reimbursement

Reimbursement in the out-patient sector

Positive list

Positive list publicly available for reimbursed drugs.

Reimbursement categories

- *Without restrictions* – normative reimbursement
25%, 55% and 80% reimbursement provided to patients
- *With restrictions* – binded to therapeutic indication and specialization
50%, 70%, 90%, 100% reimbursement provided to patients
- *Special medicines* for haemophilia and HCV infection
100% reimbursement provided to patient
- *Vulnerable groups*

Named patient program:

Fairness reimbursement for seriously ill persons without reimbursed therapy or in off-label indications. Decision is based on individual cases.

Patients with Prescription Exemption Certificate:

Fairness reimbursement for socially indigent persons. Decision is based on individual cases.

Special requirements

- *Generic drugs and drugs with similar efficacy are labelled to therapeutic or active substance groups*
- *Price volume agreements on medicines*
~ This provides a secure cap for budget overspending for certain drugs or indications.
~ Simple payback on every unit sold
~ Outcome contract which stipulates that the Marketing Authorization Holder (MAH) pays back a pre-determined amount, if the real-life effectiveness of the product falls behind the clinical efficacy on which its reimbursement dossier has been based.
- *Reimbursement payback for all pharmaceutical companies*
~ overspending-based payback in case of defined budget deficit
- *Reimbursement payback for all wholesale companies*
2,5% payback
- *Statutory 20% payback* on sales revenue
- *Statutory 10% additional payback* on sales revenue for drugs being reimbursed for 6 years without competitors

Reimbursement in the in-patient sector

- *high-cost oncology and biological drugs (item-based reimbursement)* 100% reimbursement category for expensive medicines that are used in hospitals. Reimbursements of these drugs are binded to therapeutic indication and paid directly by the Health Insurance Fund Administration.
- There is no *co-payment* for hospital medicines.
- *The diagnoses-related group (DRG) system* covers all the costs of acute hospital care, including pharmaceuticals.