SLOVENIA

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JAZMP (Agency for medicinal products and medical devices of the Republic of Slovenia)

Slovenia
Total population: 2.084.301
GDP per capita: 22.083 EUR
Organisation of HC sector: social health insurance system
Health expenditure per capita: 1.689 EUR
Health expenditure in % of the GDP: 8,2 %
Pharmaceutical expenditure: 600 million EUR

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

PRICING

Responsible institution	JAZMP - Agency for Medicinal Products and Medical Devices
Legal basis	Medicinal Products Act, Rules on price setting for medicinal products for human use
General information	**Every MP financed/intended for financing from public revenues should have list price determined prior to market launch** Price structure: ex-factory element of price + wholesale margin + pharmacy fee + VAT

Medicinal products for human use:

MAP (maximum allowed price)	EHAP (exceptional higher allowed price)
Re-determined twice yearly for every MP on the market (N = cca. 4700) **External Reference Pricing model (RCs: AT, DE, FR)** MAPs are determined and regulated by calculation of administratively determined ex-factory element of price (PEC) which may not exceed maximal allowed value of PEC, to which regulated wholesale margin is added. Three approaches for calculation of MAP: - Original (innovative) MP - Biosimilars - Generic MP	EHAP possible in cases when MAP does not enable the authorization holders to supply the market (e.g. due to small market size) (N = cca. 900) Committee for the determination of EHAP. Determined for a period of up to 1 year, several times consecutively or intermittently HTA-elements (pharmacoeconomic analysis and relative therapeutic evaluation) are taken into account; no pharmacoeconomic analysis and relative therapeutic evaluation is needed when annual sales (for all presentations on the market) are below 50.000 € or if the medicinal product has a temporary MA and complies to an item on the national Essential or Indispensable Medicines lists

REIMBURSEMENT

Responsible institution	HIIS - Health Insurance Institute of Slovenia
Legal basis	Health Care and Health Insurance Act, Rules of classification of medicinal products for human use on the list
Reimbursement criteria	Public health priorities, Clinical criteria, Therapeutic value, Relative effectiveness, Economic criteria, Pharmacoeconomic analysis, Budget impact analysis, Ethical criteria (orphans), Data and evaluations from reference sources

Measures for all drugs
- Internal reference pricing system for interchangeable drugs (ATC 5) since 2003
- Reference pricing for therapeutic drug groups (clusters, ATC 4 or 3) since 2013
- Pricing and managed entry agreements: discounts (reduction of price), rebates (material discount), price-volume agreements, payback agreements, performance-based (outcome-based) agreements
- Prescribing restrictions

Prescription drugs
Positive list: 100 % or 70 % covered by compulsory HI, the rest is paid by voluntary co-insurance or by patient, 1.799 MPs (458 INN)
Intermediate list: 10 % covered by compulsory HI, the rest is paid by voluntary co-insurance or by patient, 933 medicines (198 INN)
Exceptions: vulnerable groups (children, young people in education, and patients with certain diseases): 100 % reimbursement for positive list; for socially vulnerable people the voluntary co-insurance is paid by the government.

Hospital/Ampulated drugs
List B (91 expensive medicines separately paid to hospitals for treatment for in-patients, most of them ATC B or L)
List A (30 medicines separately paid to all providers for out-patients including home treatment)