POLAND

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

AUTHORISATION/ CLASSIFICATION

New medicine

European Medicines Agency (EMA) OR
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Prod-

Task: Decision on authorization and registration, qualification to prescription
Criteria: Quality, safety, efficacy, pharmacovigilance

PRICING / REIMBURSEMENT

OUT- PATIENT

IN - PATIENT

Ministry of Health
The drug has to be available in Poland before the reimbursement application is submitted

Medicines/Medical devices/FSMP applying for out-patient reimbursement

Medicines applying for out-patient reimbursement (chemotherapy or therapeutic program)

new clinical indication (do not reimbursed yet)
the same procedure for original/generic/hybrid/biosimilar product

reimbursed clinical indications (generic)

formal evaluation

HTA evaluation (clinical and economical)

Price negotiations (Economic Commission)
product price in EU countries + EFTA countries are supporting information

decision of the Minister of Health

Medicines distributed via

Wholesalers	Wholesale mark-up – 5% Pharmacies regressive mark-up medicines, medical devices VAT – 8 % FSMP VAT – 5% or 8% or 23%
Pharmacies	

Tendering (involving wholesalers and manufacture's wholesalers)

Maximum mark-up (5% + 8% VAT)

100% → medicines for specific indications (treatment of malignant tumors, psychotic disorders, mental retardation or developmental disorders, infectious diseases epidemic of the specific hazard for the population), war veterans, medicines and FSMP used in pharmaceutical programmes, oncology chemotherapy; in-patient sector are free of charge)

Fixed rate (app. EUR 0.75), 70%, 50% → rate depends on the disease duration (up to 30 days or more than 30 days) with correlation to the cost of treatment and the minimum wage

The Act of Reimbursement does not define the originator drug. The law defines the reimbursement INN in specific clinical indication. In case the next drug with the same INN (the next application form) in the same specific clinical indication is applying, its manufacturer is obliged to propose a price decrease of at least 25% in comparison to the first drug.
After the expiry of the period of market exclusivity, the official price must be reduced by at least 25%.

The pricing procedures is only for reimbursement products.

Medicine do not available in Poland, and without authorization and registration

Application for individual access made by doctor/regional/national consultant – decision during 30 days
Application for individual reimbursement made by patients – decision during 30 days

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