## REPUBLIC OF NORTH MACEDONIA Health Insurance Fund of RNM

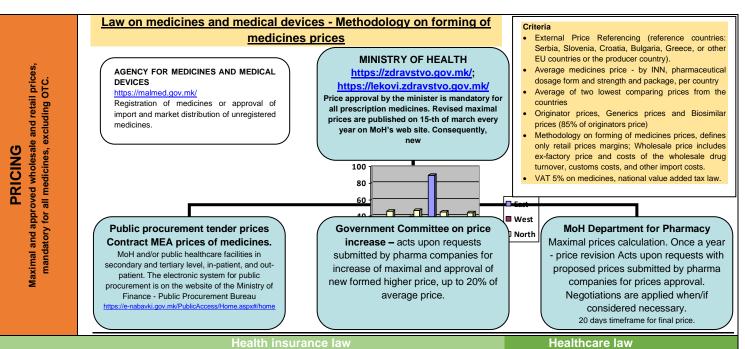
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## PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES (In-patient and out-patient sector)



### Positive list of medicines

2023 MoH rulebook on Positive list of medicines – ongoing implementation process.

- MoH is the administrative centre for PLD procedure.
- MoH Committee on PLD proposal.
- Pharmacoeconomic analyses
- · HIF opinion on submitted PhEA's
- Decision of HIF Management board on PLD is final when published in the Official gazette after minister's consent.

<u>Criteria:</u> Reimbursement status in reference countries, offered price/pharmacoeconomic analyses, disposable HIF budget for List A – primary healthcare list and List B – hospital list, optional MEA, etc.

• MoH special committee for Managed entry agreements (MEAs) – TBI

## Consent on public procurement of medicines for hospitals.

- Consents are mandatory prior to public procurement procedure of medicines for hospitals/university clinics, for all medicines that are not included in the Positive list.
- Procedure starts with submission of a request by public hospital/clinic.
- MoH consent
- HIF consent (with financial limits, number of patients, indications/diagnoses per medicine, other limitations).
- HIF Conditional budget used also for expensive medicines with consent.
- In- and Out-patients

HIF Department of Pharmacy

Data colection on medicines

prices in reference countries (Slovenia, Serbia, Croatia and Bulgaria) and RNM

Revision of RPM - once a year, after the MoH sets new prices

and/or upon request from pharmaceutical company

### **Government Programmes**

- Rare diseases programme / Orphan drugs
- Insulins/ Anti-diabetics/ Anti-obesity medicines
- Transplantation
- HIV/AIDS
- Prevention of illnesses / Vaccines
- Tuberculosis
- MoH prepares Programmes
- MoH special committee for Managed entry agreements (MEAs) TBI
- In- and Out-patients

### Out-patient sector

INN-based RPM System (no or with co-payment medicines, patient choice possible)

In-patient sector

DRG / Packages - Tender/Contract prices up to RPM or MoH approved Price.

# HEALTH INSURANCE BY-LAW - Rulebook on the method and methodology for determining reference prices of drugs from positive list

### Criteria

DECISION MAKING PROCESSES (registered, unregistered, OTC drugs)

REIMBURSEMENT

REIMBURSEMENT PRICES

- External Price Referencing (reference countries: Serbia, Slovenia, Croatia, Bulgaria)
- Internal Price referencing MoH prices, public procurement prices, offered prices by pharma producers/MAHs, invoiced, and import prices for OTC drugs, consumption data, etc.
- Average of two lowest comparing prices from the countries, per unit
- GDP PPP coefficients used in calculations
- Pharmaceutical sub-group RP (up to ATC level 3)
- RPs are set at the level of Wholesale price
- VAT 5% on medicines, national value added tax law.

https://fzo.org.mk

### RPM Commission

### (one member from the MoH)

Calculations for reference prices (ERP and IRP)

Proposal for the new RPM published on the website www.fzo.org.mk

Companies can appeal the proposed RP within 15 days

The final proposal for determining the new RPM goes to the director and the Management Board of HIF for a final decision.

### Decision on new RPMs

- is adopted by the Management Board of the Health Insurance Fund
- is published in the Official Bazette after the Fund receives the consent of the Minister of Health
- HIF Codelist (medicines codes are generated from HIF's IT system) is published on the website - www.fzo.org.mk