

REPUBLIC OF NORTH MACEDONIA

Health Insurance Fund of RNM

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Population, million	2022	2.1
GDP, current \$ billion	2022	13.6
GDP per capita, current \$	2022	6,597.7
GDP%, Health Expenditures	2020	7.9
Life Expectancy at Birth, years	2022	74.5

Health insurance: Mandatory national and private optional
World Bank data

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

PRICING
Maximal and approved wholesale and retail prices, mandatory for all medicines, excluding OTC.

Law on medicines and medical devices - Methodology on forming of medicines prices

AGENCY FOR MEDICINES AND MEDICAL DEVICES
<https://malmed.gov.mk/>
Registration of medicines or approval of import and market distribution of unregistered medicines.

MINISTRY OF HEALTH
<https://zdravstvo.gov.mk/>;
<https://lekovi.zdravstvo.gov.mk/>
Price approval by the minister is mandatory for all prescription medicines. Revised maximal prices are published on 15-th of march every year on MoH's web site. Consequently, new

Criteria

- External Price Referencing (reference countries: Serbia, Slovenia, Croatia, Bulgaria, Greece, or other EU countries or the producer country).
- Average medicines price - by INN, pharmaceutical dosage form and strength and package, per country
- Average of two lowest comparing prices from the countries
- Originator prices, Generics prices and Biosimilar prices (85% of originators price)
- Methodology on forming of medicines prices, defines only retail prices margins; Wholesale price includes ex-factory price and costs of the wholesale drug turnover, customs costs, and other import costs.
- VAT 5% on medicines, national value added tax law.

Public procurement tender prices Contract MEA prices of medicines.
MoH and/or public healthcare facilities in secondary and tertiary level, in-patient, and out-patient. The electronic system for public procurement is on the website of the Ministry of Finance - Public Procurement Bureau
<https://e-nabavki.gov.mk/PublicAccess/Home.aspx#/home>

Government Committee on price increase – acts upon requests submitted by pharma companies for increase of maximal and approval of new formed higher price, up to 20% of average price.

MoH Department for Pharmacy
Maximal prices calculation. Once a year - price revision Acts upon requests with proposed prices submitted by pharma companies for prices approval. Negotiations are applied when/if considered necessary.
20 days timeframe for final price.

REIMBURSEMENT
DECISION MAKING PROCESSES (registered, unregistered, OTC drugs)

Health insurance law

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.

Criteria: 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

Healthcare law

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

REIMBURSEMENT PRICES

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

Criteria

- 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.

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