



PPRI
Pharmaceutical Pricing and
Reimbursement Information



CNAM
COMPANIA NATIONALA
DE ASIGURARI IN MEDICINA



REPUBLIC OF MOLDOVA

Recent and planned developments in pharmaceutical policies 2025/2026

CHANGES IN PRICING

- 1. External Reference Pricing Calculation:** If listed in ≥ 4 reference countries: lowest price excluded, average of 2nd–4th applied. If 3 countries: lowest excluded, average of 2 used. If 1 country: direct negotiation possible.
 - 2. Annual Price Increase:** Manufacturer prices may increase by up to +15% per year.
 - 3. Price Approval Duration:** Can be extended up to 3 years via direct negotiation.
 - 4. Generic Price Cap:** Capped at 75% of originator price, with automatic re-evaluation if originator price changes.
 - 5. Direct Negotiation Procedure:** Conducted via a structured negotiation commission.
 - 6. Alternative Price Comparison:** Fallback when reference prices unavailable: (1) country of origin; (2) lowest 3 prices in other markets; (3) National Price Catalogue.
 - 7. Price Negotiation for Reimbursed Medicines & Devices:** 44 INNs and 6 categories of medical devices negotiated to date. Average discount in 2025: 12.75%. Negotiation by multi-institutional Committee (MoH, NHIC, MMDA).
- Results:** improved affordability, expanded patient access, more efficient use of public funds, reduced patient co-payments.

CHANGES IN REIMBURSEMENT

Recent developments:

- 1. Updated List** of reimbursed drugs, which currently includes 173 INN.
In 2025: +8 INNs included
+1 INN with extended indications
–4 INNs excluded (market absence)
 - In 2025, 728,813 people benefited from medicines and medical devices, which is 30.6% of the total population residing in the Republic of Moldova
 - 3. Reimbursement Update** - 01 Nov 2025
 - Fixed reimbursement amounts recalculated (National Catalogue + negotiated prices);
 - Increase for most medicines and Reduced patient co-payments.
 - 4. Health Technology Assessment (HTA)**
 - Methodological guideline developed;
 - 3 oncology dossiers submitted;
 - Draft Government Decision pending approval.
- Planned developments:** reimbursement reviews
- Development and implementation of a clear, transparent, and evidence-based procedure for determining medicine reimbursement rates, including the establishment of a standardized evaluation scale.
 - Implementation of the „pay-back” mechanism in order to ensure financial sustainability and risk sharing with marketing authorization holders.

OTHER CHANGES

- In June 2025, a **new Law on Medicines was adopted**, establishing general provisions on clinical trials in humans, marketing authorization procedures, manufacturing and import (including parallel import), labelling and package leaflets, wholesale distribution, advertising, manufacturer pricing, pharmacovigilance, and quality control of medicines, and other important topics.
- On 23 December 2025, the **Order of the Minister of Health and the general director NHIC on medicines and medical devices for special purposes** financed from the Mandatory Health Insurance funds was approved, establishing the regulation on the financing mechanism and the List of special-purpose medicines (19 INNs) and medical devices (4 items).
- **Revision of the reimbursed antibiotics list**, including the expansion of therapeutic indications for antibiotics in the “Access” category (according to the WHO AWaRe classification) and the introduction of measures to restrict indications for “Watch” category antibiotics—by integrating an alert message into the “ePrescription” information system requiring prescription based on confirmed therapeutic need through antimicrobial susceptibility testing, with the aim of promoting the rational use of antibiotics.
- **The electronic prescription system** for reimbursed medicines and medical devices was implemented in the Republic of Moldova in April 2024, marking a major milestone in the digital transformation of healthcare services.
- Scale (2024–2026): • **2,500 doctors** • **3,000 pharmacists** • **~900,000 beneficiaries** • **>2.5 billion MDL processed** • **over 16 million prescriptions**.
- Ensures **validation and compliance** (prescriber rights, patient insurance status, blocking expired prescriptions and dispensing when pharmacy license/contract expires, respecting negotiated prices). Enhances **treatment safety** with alerts on therapeutic duplication, early repeats, and dose/quantity limits. Provides **clinical support** through patient prescription history and diagnosis linkage to reimbursed INNs. Delivers **automation and integration** with pharmacy software, automatic updates of reimbursed trade names and prices, and auto-generation/cloning/correction of prescriptions. Secures **financial accuracy** with automatic co-payment calculation, enforcement of reimbursement rules, and prevention of excess quantities or prices. Strengthens **access and monitoring** with multi-visit dispensing, third-party pickup, reporting, and full dispensing traceability.

SPECIAL TOPIC:

Regulation, pricing and reimbursement of pharmaceutical combination products

Regulation:

- **Authorization** - ORDER of the Ministry of Health No. 739 on the regulation of authorization of medicinal products for human use and introduction of post-authorization changes

- Section 4. **Provisions applicable to medicinal products submitted by application for a fixed combination**

In the case of medicinal products containing active substances that are included in authorized medicinal products but have not yet been used in a combination for therapeutic purposes, the results of non-clinical and clinical trials for this proposed combination for authorization should be provided as set out in Annex 2 to this Regulation, but it is not necessary to provide scientific references for each active substance.

- **Requirements of the authorization file** - The compatibility of the active substance with the excipients, as well as the key physico-chemical characteristics of the active substance which may influence the realisation of the finished product or the compatibility of the various active substances with each other, in the case of the combination products, must be supported by documents.

Reimbursement

- ORDER No 600/320 on the mechanism for the inclusion of medicinal products for compensation from mandatory health insurance funds

- In the analysis of the budgetary impact for a combined drug containing 2 active substances from the List of compensated drugs, the cost minimization analysis is applied. A fixed-dose combination medicine may be included in the reimbursement list only if it demonstrates a clearly superior cost-effectiveness profile compared to the separate alternatives already listed.

- Currently the List of reimbursed medicines includes 17 INN of combined drugs.