

REPUBLIC OF MOLDOVA

Recent and planned developments in pharmaceutical policies 2022/2023

CHANGES IN PRICING

The Law no. 1409/1997 regarding the drugs has been amended and stipulates the following:

April 2023

- The Medicine and Medical Devices Agency (MMDA) is responsible for developing and monitoring the National Price Register, which should be completed with prices that are approved by the General Director in each first working day of the month.
- The manufacturer's price for the drugs is calculated according to the average exchange rate of the Moldovan National Bank, that is calculated for the previous last 12 months of the submitted records and is approved by the Medicine and Medical Devices Agency in the national currency (lei, MDL).
- Manufacturer's prices are valid for one year from the date of the approval and can be reduced at any time at the request of the applicants, regardless of the exchange rate fluctuations.
- In order to make the Moldovan pharmaceutical market more attractive and to increase the number of the authorized drugs, has been decided by law to exclude the lowest price from the list of the reference countries.

The approval of the manufacturers' prices for drugs is carried out as follows:

- If the drug price is registered in 4 or more reference countries, the lowest price is excluded from the calculation and the average of the next 3 lowest prices are considered as the eligible price for the registration;
- If the drug price is registered in 3 reference countries, the lowest price is excluded and the average of the next 2 lowest prices are considered as the eligible price for the registration;
- If the drug price is registered in 2 reference countries, the lowest price is excluded and the next price is considered as the eligible price for the registration;
- In case the price is registered in one country of reference or in the country of origin, the Medicine and Medical Devices Agency has the right to initiate direct negotiation procedures;
- If the price has been approved following the direct negotiation procedures, the price validity period can be extended until 3 years;
- Manufacturer prices for the drugs can be increased by up to 15% annually.

CHANGES IN REIMBURSEMENT

- **The methodology for calculating** the fixed amounts has been **changed** for the partially reimbursed drugs, as a result has increased the compensation rate from 89.75% in 2021 to 94.14% in 2022.
- **The cost of the treatment** per the patient has been increased from 778,0 MDL (41,5 euro) in 2020 to 1003,38 MDL (53,53) in 2022. The average exchange rate for 1 euro = 20,16 MDL.
- **The list of the priority diseases** has been defined (diabetes, palliative care, oncological diseases) for the extension of the positive list of the compensated drugs and the medical devices.
- **Three Governmental Decisions have been approved** with the impact on the reimbursement system:
 - regarding the approval of the Regulation on the mechanism for including the medical devices in the reimbursement list of the mandatory health insurance funds;
 - regarding the approval of the negotiating mechanism for including the drugs and/or the medical devices in the compensation list from the mandatory health insurance funds;
 - regarding the prescription and releasing the reimbursed drugs and medical devices for the outpatient treatment of the persons which are registered to family doctor.
- **The negotiation procedure** has been implemented for the following products: medical devices, expensive drugs, biological, innovative, with an uncertain cost-effectiveness, new drugs that will bring an increase in the budget impact compared to the current standard of the treatment, submitted for the evaluation in order to be included in the compensation system and/or compensated from the mandatory health insurance funds that will be included in compensated list.
- **Three types of medical device are included in the reimbursement list:** test for determining blood glucose, lancets, collecting bags for urostomes, collecting bags for intestinal stomas. The compensation rate constitutes 85% from the mandatory health insurance fund.
- **The compensated drug list has been extended with the following:**
 - 9 INN for the diabetes treatment (including 100 % compensation for the insulin analogues);
 - new disease has been included for the compensation - palliative care treatment (100 % compensation for 14 INN).
- **The number of the INN** in the reimbursement List has been increased from 158 in 2020 to 169 in 2022.
- **The allocated fund for the drugs reimbursement** has been increased in 2023 compared to 2022:
 - for the outpatient treatment, purchased from the community pharmacies - 35%
 - for the expensive treatments in day hospital, centrally purchased – 48%
 - for the expensive treatments in hospital care, centrally purchased - 20%
- **The list of the compensated drugs for the episodic treatment (acute illnesses) in the outpatient sector** has been completed for the following diseases: respiratory system, digestive system, nervous system, osteoarticular system, muscles and connective tissue, urinary system, endocrine, nutritional and metabolic diseases, infectious diseases, cerebrovascular diseases, oncological diseases (cancer pain) and palliative care.

2022

January 2022

February 2022

May 2022

June 2022

June – December 2022

December 2022

January 2023

March 2023

OTHER CHANGES

The list of the priority diseases in the outpatient treatment has been established to which new drugs will be included for the reimbursement in 2023 (cardiovascular, rheumatological, neurological, dermatological, ophthalmological diseases) and the negotiation procedures has started with the manufacturers regarding the examination of the ICD in order to be included in the positive list.

February 2023

The e- Prescription has to be implemented by the end of the 2023 year.

The implementation of e-Prescription will provide the possibility of monitoring online the prescription, issuing and displaying the drugs and medical devices stocks in the pharmacies.

End of 2023

Review the reimbursement mechanisms for the expensive (biological) drugs for the treatment of orphan and oncological diseases. Implementation of the negotiation procedure for the commercial names included in the positive list.

End of 2023

SPECIAL TOPIC:

Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

- Improving the procurement mechanisms for drugs and medical devices in the hospital sector, in order to increase the access to innovations.
- Automated drug evidence in order to monitor the medicines trade on the national market for identifying stocks and to prevent its default.
- Decreasing the out-of-pocket payments (patient co-payments) by capping the maximum retail price in the pharmacy for the partially compensated drugs per commercial name, as a result of negotiations with the producers.