CROATIA

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

All news relates to the changes brought by the amendment to the regulations from 2023.

"100% rule"

If the comparative price of a medicine at wholesale in one of the three reference countries differs to such an extent that it is 100% or more higher than the calculated comparative prices of the medicine at wholesale in the other two countries, it is not included in the calculation.

"No limit" rule

The maximum allowed price of a medicine calculated during the annual calculation is the final price, meaning there is no limit to how much the price can rise, except the above.
(before this rule, the price could not be higher than the already calculated one)

New, differentiated, wholesale margins

The wholesale price of the medicine in EUR	Wholesale margin up to %
< 49,99	8,5
50,00– 299,99	7,5
300,00 – 599,99	6,5
600,00 – 1.199,99	6,0
1.200,00– 5.999,99	5,5
6.000,00– 25.999,99	5,0
26.000,00– 66.000,00	4,5

CHANGES IN REIMBURSEMENT

All news relates to the changes brought by the amendment to the regulations from 2023.

Current Lists of Medicines CHIF

The CHIF List of Medicines have 4877 medicines (update 15.3.2025)

The Particularly Expensive Medicines

Reimbursement price – up to the lowest price of the same drug in EU member states (based on which the price of the medicine was calculated)
A new department has established to monitor clinical outcomes of medicines included in the list of particularly expensive medicines
The possibility of exclusion - cases where there is an absent clinical outcome and the price proposal has not been accepted

New criteria

The Health Technology Assessment (HTA) analysis is proposed as part of initial documentation for reimbursement
New criteria for reimbursement – previous use of the medicine as part of a completed clinical trial conducted in Croatia, in the indication for which the medicine is proposed for inclusion in the list of medicines

OTHER CHANGES

The "eMedicines – Integrated IT System for Medicine Management" project in 2025

- successfully integrated data from the Agency for Medicinal Products and Medical Devices (HALMED) and the Croatian Institute for Health Insurance (CHIF)
- The system architecture and data models have been developed in accordance with ISO IDMP standards, as accepted through the SPOR project (synchronization with EMA SPOR data)
- enhanced transparency by providing centralized access to information about medicines available on the Croatian market
- facilitates easier access to up-to-date regulatory information, both for patient and healthcare professionals, boosting trust in the Croatian healthcare system

SPECIAL TOPIC:
Current advances in HTA

- Experts working group from all relevant institutions (Ministry of Health, Agency for Medicinal Products and Medical Devices of Croatia, Croatian Health Insurance Fund, Croatian Institute of Public Health is a central public health institute in the Republic of Croatia) has been formed to draft the proposal for the implementation of Regulation (EU) 2021/22/82 of the European Parliament and Council on health technology assessment
- The drafts for the proposal on amendments to the Health Care Quality Act and a regulation on health technology assessment have been developed
- The Act on the Implementation on Regulation (EU) 2021/22/82 is adopted by Croatian Parliament. Harmonization of Croatian legislation with the EU legislation is achieved.
- Further responsibilities related to these initiatives fall under the Ministry of Health.