



# CROATIA

## Recent and planned developments in pharmaceutical policies 2023

### CHANGES IN PRICING

Regular price reviews (ERP for all prescription medicines, TRP for medicines that are included in the outpatient reimbursement list).

### CHANGES IN REIMBURSEMENT

No changes.

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

### NATIONAL REGISTER TO REPORT SHORTAGES

In case of circumstances which could result in a disturbed supply of medicines or its shortage on the Croatian market, the MAH is obliged to immediately report it to the register which is held by the Medicines Agency for all prescription medicines and by Croatian Health Insurance Fund (CHIF) for medicines that are included in the reimbursement lists.

Regular updates of the register so that all information about the beginning and the end of the shortage and the reasons for it are publicly available and up-to-date.

Financial sanctions for MAH in case of non-reporting.

In situations where the required medicine is not available on the Croatian market and there is no suitable substitute, additional measures are taken to procure the medicine for the patient's needs. This includes the procurement of medicine through the procedure of extraordinary entry or importation of medicines approved in other countries, as well as special permits for the import of medicines without the need for labelling and patient information leaflet (PIL) in the Croatian language.

Cooperation and information exchange with the European Commission, the European Medicines Agency and other national institutions.

### MEDICINE RESERVE SUPPLIES

National reserves are in place for defined essential medicines.  
Established and maintained by the Ministry of Health.

### PRICE INCREASES

Medicines included in the reimbursement lists:

-MAH applies to the Croatian Health Insurance Fund (CHIF)

-MAH must submit an explanation containing the reasons why the price of the medicine determined in the list is not sufficient to ensure the supply of the Croatian market with the medicine in question

-criteria: medical need, therapeutic alternatives, frequent shortages, public health interest, some other criteria related to the optimal supply of the population with medicine

-the application is evaluated within 90 days

-case-to-case decision

-increase in the number of applications.