



CROATIA



AUTHORISATION

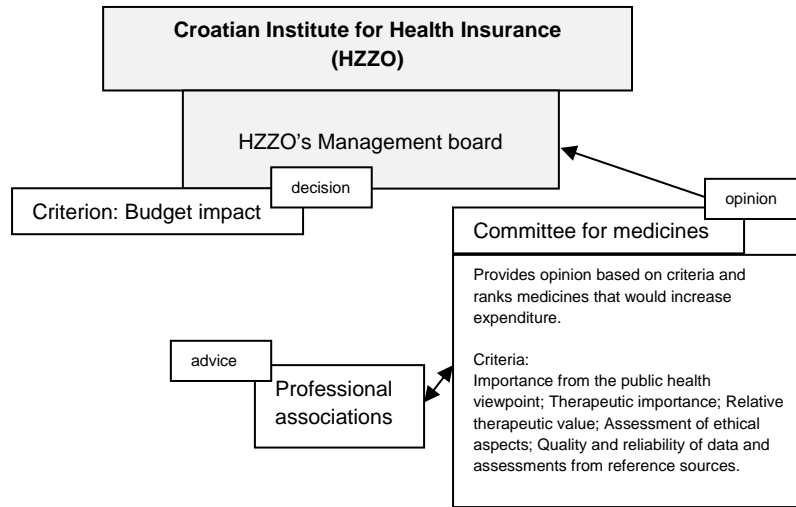
Croatian Agency for Medicinal Products and Medical Devices (ALMP)

Decision on authorization and registration
Quality, safety, efficacy - Croatian medicines Act and associated ordinances

ALMP is also in charge of pharmacovigilance

VIGILANCE

REIMBURSEMENT



PRICING

HZZO

External price referencing and internal price referencing

- Original breakthrough products: up to 100% of the average price in Italy, France and Slovenia.
- Original me-too products: up to 90% of the price of equivalent products in Croatia
- Generic products: up to 70% of the average price in Italy, France and Slovenia and/or up to 90% of the price of the last bioequivalent generic introduced to the list.

DISPENSING

Pharmacy

No mark up for HZZO reimbursed medicines
Service charge paid for dispensing instead.

Hospital pharmacy

Price negotiations or tendering; HZZO reimburses as listed

2009/2010 REFORM

1. Pharmaceutical expenditure on the decline 3rd year in a row
2. 47 innovative products listed from July 2009 to July 2010 (45 in total from 2002 to 2009)
3. Pay back and cross product agreements introduced for innovative medicines
4. ISPOR aligned criteria for Budget Impact Analysis introduced
5. Reimbursement process made public on HZZO's web site
6. ePrescriptions introduced nationwide by January 2011
7. Ethical promotion agreement introduced with substantial penalties in place
8. Mandatory personalized reporting of all pharma expenditure on publicly employed