Hrvatski zavod za zdravstveno osiguranje — Croatian Health Insurance Fund

PPRI Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

CROATIA

Recent and planned developments in pharmaceutical policies 2016
Special topic: Pricing and reimbursement policies for biosimilars

Biosimilar

= a biological medicine which is similar to another biological medicine that has already been authorised for use

- biosimilar and its reference medicinal product are expected to have the same safety and efficacy profile
- can only be marketed following the patent expiry of the reference medicine
- may offer a less-costly alternative to existing biological medicinal products that have lost their exclusivity rights

DEVELOPMENTS

CHANGES IN PRICING

Price reviews – External price referencing (ERP) – ongoing - conducted in accordance with the Ordinance establishing the criteria for wholesale pricing of medicinal products and the method for reporting wholesale prices

Managed entry agreements and discounts or pay-back volume agreements (in-patient) - ongoing

CHANGES IN REIMBURSEMENT

Amandment proposal for the Ordinance – planned changes related to changes/modifications in the reference price system (methodology) for process of reimbursement reviews (IRP), ERP and Therapeutic Reference Pricing (TRP)

- decision depends on Ministry of Health

OTHER MEASURES

- ✓ **prescription monitoring –** Committee in hospital & Croatian Health Insurance Fund
- ✓ **guidelines for economic prescribing –** non binding recommendations for prescribing cheaper (INN) medicines from reimbursed lists
- ✓ budgets for biosimilars (medicines on the Basic list) are intergrated in the sums which can be generated for reimbursement through diagnosis-oriantated case groups (DRG)
- ✓ **separate budget for some biosimilars – for medicines on the List of high priced medicines**
- ✓ **educational and information activities** (HALMED – Agency for Medicinal Products and Medical Devices of Croatia)
- ✓ **IT projects for improved prescription monitoring** (hospitals & CHIF)
- ✓ **IT projects for statistical data on consumption of medicinse on real time basis** (CHIF)

P&R POLICES

The **PRICE** for biosimilars is set on the same procedure as for generics (External Price Referencing)

(in the Ordinance – **price linkage between originals and follower products - biosimilars:**

- max price for original drug – average price from 5 countries (Ita, Slo, Czs, Esp, Fra)
- **1st biosimilar** – at least **15% priced below** originator
- 2nd and every next follower – at least 10% priced below previous biosimilar

The **REIMBURSEMENT** procedure for biosimilars is the same as for all other medicines.

- MAH applies for inclusion of its medicine and CHIF takes a decision based on pharmacological, medical-therapeutic, health-economic and the budget impact analysis.
- Once a year is conducted therapeutic referencing by CHIF.
- The availability of biosimilar medicines enhances competition, with the potential to improve patient access to biological medicines and to contribute to the financial sustainability of healthcare system.

TENDERS for biologicals/biosimilars are conducted in medical health institutions.

INTERCHANGEABILITY or switching biosimilars (the medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting):

- ✓ **allowed**, but **decision** for replacement must be recommended and monitored **by a treating physician.**
- Switches occur in in-patient sector (for high priced medicines allowed by hospital drug comitee).

SUBSTITUTION (practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber):

- **NOT allowed** in community pharmacies (out-patient sector)
- allowed for new/naive patient (in-patient sector) when decision is depending on tender

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