







Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

| CHANGES IN PRICING | CHANGES IN REIMBURSEMENT |
|---|--|
| Croatian competent authority for ERP has been changed from Croatian Health Insurance Fund to Agency for Medicinal Products and Medical Devices of Croatia 11.4.2019 • Earlier: mandatory pricing only for reimbursable medicines – conducted by Croatian Health Insurance Fund • Since 11.4.2019 – mandatory pricing for all Rx medicines (OTC excluded) – conducted by Agency for Medicinal Products and Medical Devices of Croatia | Changes of reimbursement rates: 11.4.2019 Original products: price up to 100 % of EPR-determined price Me-too products: - - price up to 95% of the price of the cheapest similar product on the list - price up to 100% of the price of the cheapest similar product on the list - price up to 100% of the price of the cheapest similar product on the list for added value Biosimilars: - - 1st biosimilar – price up to 80% of the price of the original product - every each and other: price up to 95 % of the price of the cheapest biosimilar on the list Generic products: - - first generic: price up to 70 % of the price of the original product - every each and other: price up to 95 % of the price of the cheapest generic on the list |

OTHER CHANGES

Change in VAT on medicines:

Earlier: 5% VAT on Rx medicines, 25% VAT on OTC medicines

1.1.2019

Since 1.1.2019 – 5% VAT on all medicines

SPECIAL TOPIC: patient-based reimbursement decisions

Reimbursement of medicines that are not included in the reimbursement list (both in-patient and out-patient):

- if for medical reasons an insured person cannot be treated with a medicinal product included in the Croatian Health Insurance • Fund's basic and supplementary reimbursement lists of medicinal products, he/she may claim a right to receive a medicinal product not included in these lists, provided that the need to use this medicinal product has been approved by the commission for medicinal products in hospital in which the insured person is being treated, at the expense of the hospital's fund, which shall be obliged to procure this medicinal product.
- under the conditions and in the manner laid down in previous paragraph, an insured person may also claim a right to use a ٠ medicinal product that is included in the Fund's basic and supplementary reimbursement lists of medicinal products, but for which the insured person does not fulfil conditions with respect to medical indications specified in the lists of medicinal products
- the medical specialist in the hospital who proposed that the insured person be treated with a medicinal product referred to in . previous paragraphs shall forward his/her proposal to the hospital's commission for medicinal products