

REPUBLIC of KOSOVO

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

- The 2019 administrative instruction on prices has been repealed, while the Law on Prices of Medicinal Products is expected to be approved in 2023.
- This law shall apply to retail and wholesale distributors of medicinal products, the representative of the marketing authorization holder, the marketing authorization holder and public institutions.
- EPR is expected to be used in both sectors (inpatient and outpatient)
- Reference Countries: **primary:** Albania, Montenegro, North Macedonia, Croatia and the country of origin. **secondary:** Slovenia, Estonia, Bulgaria and the country of origin.
- Calculate method: The price of the medicinal product is determined by calculating the average wholesale price of the two lowest prices of that product from the reference countries
- Type of comparator price – Wholesale price and CIP import prices
- Source of Pricing Information – Public official sources; Market Authorization Holders

CHANGES IN REIMBURSEMENT

- ❖ The Republic of Kosovo has started developing a primary care Outpatient Drug Benefit Scheme (OPDBS). The implementation of the OPDBS is a demanding reform that will require substantial investments and efforts in developing Kosovo's modest capacity to regulate pharmaceutical sector.
- ❖ The introduction of the Outpatient Drug Benefit Scheme (OPDBS) is planned to implemented as a component of Kosovo's mandatory health reform. It is a policy priority for the MoH / HIF
- ❖ The OPDBS will be introduced to ensure that HIF is able to manage effectively and to match the revenues available.
- ❖ The Health Insurance Law is in the process of being amended and is expected to be finalized during 2023.

OTHER CHANGES

- Kosovo health care authorities has contracted a company in developing a reliable system in primary health care and Hospitals e.g. volume control, prescription monitoring, prescription budgets, measures to improve prescribing performance. The e-prescription is expected to come into operation at the moment of the implementation of the outpatient drug benefit scheme (OPDBS).
- Ministry of Health is in final phase of revision of National Essential Medicine List (NEML). Final **NEML list 2023**

SPECIAL TOPIC:

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

Medicine shortages:

- National register to report shortages: No
- Medicine reserves supplies: No
- Regulatory measures: no changes
- Financial measures: no changes
- Other: monitoring drug shortages from the list of essential drugs

Price increases:

- An increase in prices has been observed due to inflation
- Medicines: no pricing regulations set