

# BULGARIA

## Recent and planned developments in pharmaceutical policies 2023

### CHANGES IN PRICING

No changes

### CHANGES IN REIMBURSEMENT

No changes

### OTHER CHANGES

- **Collect real-world data and real-world evidence (monitoring of the effect of the drug therapy)**

The main purpose of collecting RWD and RWE through the monitoring is to analyze the effectiveness of drug therapy in real-world therapeutic practice.

- Innovative MPs with HTA report - mainly oncology and oncohematology;
- No evidence of therapeutic effectiveness and/or the cost-effectiveness ratio is cost-ineffective;
- MP which is a comparator to the MP - subject to monitoring of the effect of the therapy;

Important role in making decisions about payment with a public resource for MP.

The data is provided to NCPR from the hospital records which is reported to the National Health Insurance Fund. An Artificial Intelligence (AI) software product analyses and unifies the data received from the hospitals. Data processing is done by software (Danny Platform, based on SAP HANA), a platform for analyzing huge amounts of structured and unstructured RWD using various sources.

Danny is a system with regularly changing data as the information is processed in real time. This platform is outdoors activity.

Endpoints for RWE - Overall Survival (OS); Progression-Free Survival (PFS); Clinical Benefit Rate (CBR); Objective Response Rate (ORR).

- Comparison of the effect of therapy between different MPs (direct comparators) for the same ICD code;
- Comparison of the effect of therapy between endpoints in RWE and clinical trials.

To account the differences is applied iterative proportional fitting (IPF) to balance a set of chosen characteristics. IPF works by, for a given characteristic, deriving weights to adjust the underlying distributions in order to match a target distribution.

- ✓ RWD for at least 1 calendar year - for a statistically significant analysis.
- ✓ Limited number of patients for some MPs - no statistically significant conclusions.

- **e-prescribing**

Electronic prescribing of reimbursed outpatient medicinal products has been introduced since June 1, 2021.

### SPECIAL TOPIC:

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

- 1) The problem of **medicine shortages** (i.e. especially in certain product groups like antibiotics) seems to have intensified:
  - Specialized electronic system
  - Responsible body - Bulgarian Drug Agency
  - Prescription-only medicines (POM), paid with public funds
  - Report - MAH, wholesalers retailers and authorization holders for parallel import
  - Deadline for notification - MAH and authorization holders for parallel import - on a weekly basis, wholesalers and retailers - on a daily basis
  - Shortage - the quantities of the relevant medicinal product available in Bulgaria are less than 65 percent of the necessary quantities to satisfy the public health needs for a period of one month calculated on the basis of the average monthly consumption of the relevant medicinal product for the previous 6 months.
  - Export ban for medicines in shortage
- 2) **Price increases:**
  - For the Prescription-only medicines, included in the PDL and outside of it:
    - 1) Higher price in reference countries;
    - 2) In the absence of the lower price in the reference countries - with % inflation for the period since the last approval one.
 Minimum 12 months for a new change.
  - For OTC products, the price increase is only possible with % inflation for the period from the last registered price.

Over the past year, a significantly higher number of MAH requests for price increases have been reported, especially for OTC products.

In cases of asking very high prices, meetings are held with the MAH and new lower prices are achieved.

Currently no discussion of price freezes or other measures in this crisis situation.
- 3) At the moment no discussion of **other measures related to current challenges** (high inflation rates, budget caps, high-priced medicines, introduction of production sites in Europe).