BULGARIA

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

- The prices of medicinal products included in the PDL intended for cytotoxic and hormonal treatment of malignant diseases (essential oncology products) and which are alone in the therapeutic group shall be revised by NCPR on twenty-four months basis (currently on twelve months basis)

- Within 12 months from deregistration of the price of OTC medicinal product, the latter may register new price exceeding previously registered price only with the inflation rate for the period from the deregistration of the price to the registration of the new price.

CHANGES IN REIMBURSEMENT

- The Law on the NHIF Budget for 2025 stipulates a differentiation of NHIF expenditure for inpatient essential oncology medicines in order to avoid clawbacks by MAHs.

- As from March 2024 medicines intended for outpatient treatment of cardiovascular diseases are reimbursed at 100 percent in accordance with the internal price reference within the therapeutic group.

ATC code "C": C01 treatment of heart disease; C02 antihypertensive products; C03 diuretics; C07 beta-blockers; C08 calcium channel blockers; C09 medicinal products affecting the renin-angiotensin system.

OTHER CHANGES

- **volume control, prescription monitoring, prescription budgets, measures to improve prescribing performance, gain-sharing models**

Since 16 October 2023, medicines for treatment of diabetes, as well as antibiotics, are prescribed and purchased only with an electronic prescription. The aim of the change: to make the whole process of prescribing and dispensing these two kinds of medicines more transparent and to ensure control over frequent and inappropriate use. Paper prescriptions have so far made it impossible to track the dispensing of medicines and the overuse of antibiotics leading to antibiotic resistance.

- **horizon scanning and forecasting activities**

Some legislative changes are under consideration aiming to impose requirement to MAH who intends to include innovative MP in the PDL to notify the NCPR within 10 days from submission of the application for marketing authorization.

- **measures to address and/or mitigate medicines shortages**

Measures are being discussed to address the shortages of MP through the Specialized Electronic Tracking and Analysis System (SESPA). MAHs and distributors will be obliged to report in real time comprehensive data (code and serial number of MP) for all supplied medicines subject to medical prescription, as well as to appoint their quantities.

- **IT projects (e.g. registers to collect real-world data, e-prescribing)**

Since 2019 NCPR has introduced a mechanism to provide informed P&R regulatory decisions. Therefore for some MP it was imposed obligations for monitoring of the effect of the therapy. The approach is only applicable to innovative products for which no evidence of therapeutic effectiveness has been demonstrated and/or the cost-benefit ratio has not been cost-effective when included in the PDL.

SPECIAL TOPIC:
Current advances in HTA
(for EU Member States: Implications from EU-HTA Regulation)

In Bulgaria the National Health Technology Assessment Authority (HTA) is NCPR, which from 01.01.2019 performs the HTA of medicinal products with a new INN and a new therapeutic indication. The HTA report is submitted to the NHIF for making an informed decision regarding the reimbursement of the innovative medicinal products. Legislative proposals are ongoing, according to which for MP with JCA the time limit for inclusion in the PDL is reduced from 180 days to 120 days. A change is foreseen regarding the criteria for inclusion in the PDL, whereby for all MP excluding generics and MP with well-established use, the INN to which the MP belongs will be required to be paid for by public funds or with public resources at least in 5 among all MS.

The PICO study can be identified as one of the biggest challenges for the HTA authorities. **1.** The lack of or limited national data sources represents one of the biggest uncertainties in the Bulgarian perspective. **2.** Risks that country-specific needs may not be considered or may be incorrectly accounted for in the JCA report which may lead to inadequate national reimbursement decisions. **3.** As it is crucial the decision-making to reflect all national circumstances and clinical practice, the country may be faced with the need to carry out JCA independently. Such an assumption would result in delayed access to innovative therapies for Bulgarian patients. **4.** Selecting medical specialists who are independent and impartial in providing national input to PICO will be another challenge for Bulgaria given that we have limited expert resources.