



BULGARIA

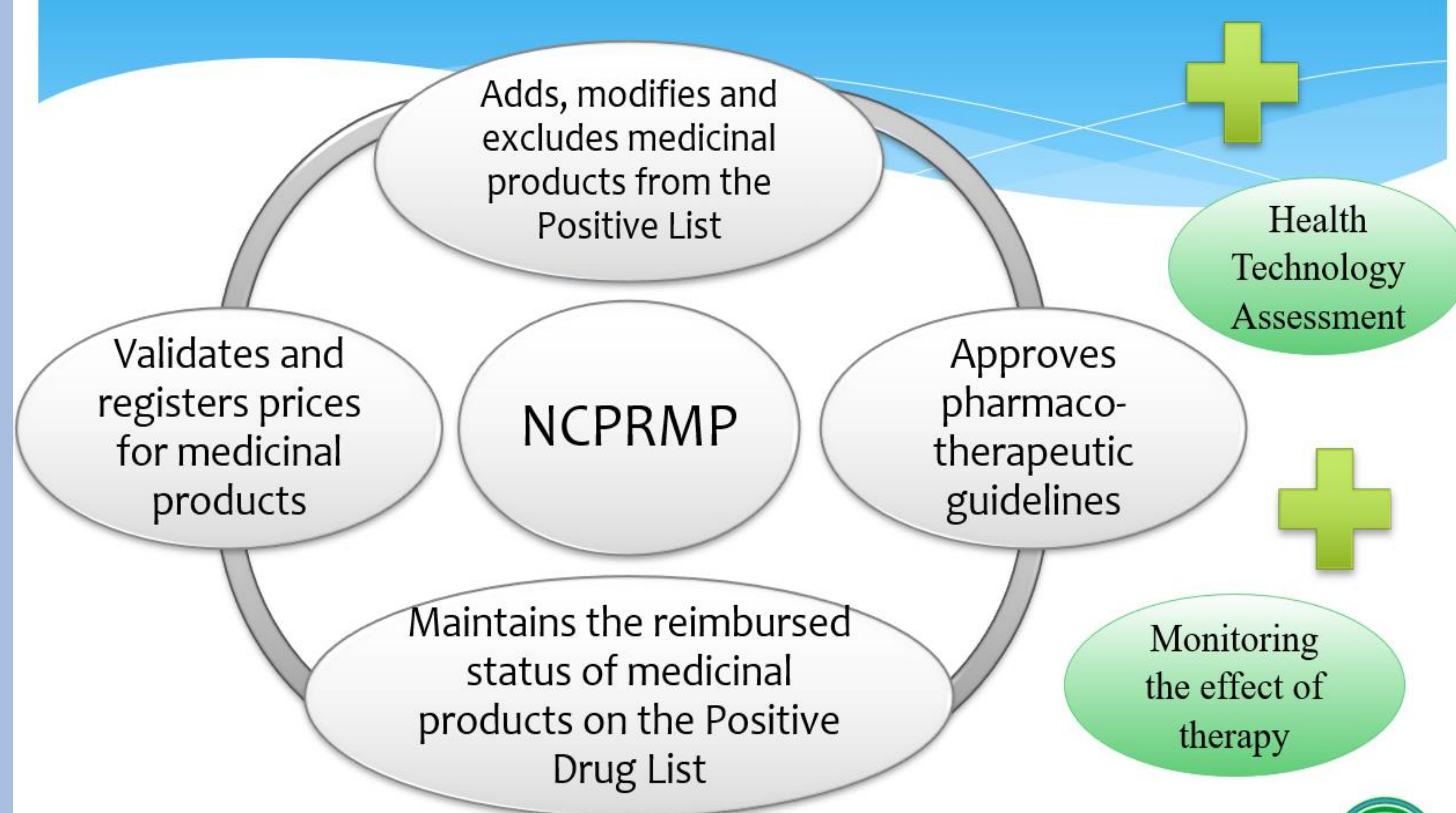
National Council on Prices and Reimbursement of Medicinal Products



Population: 7.2 M
GDP per capita: 8472 €
Health expenditure:
8.2% GDP (2016)
BDA, NHIF, NCPRMP



REGULATION OF PRICES



Ministry of Health
National Council on Prices and Reimbursement of Medicinal Products



Pricing regulation applies for all medicinal products (MP) subject to medical prescription.

External reference pricing - the lowest manufacturer's price in 10 countries (BE, EL, ES, FR, IT, LV, LT, RO, SK, SI).

Free pricing is applied for OTC products.

Wholesale remuneration (e.g. margins)

Regulated regressive margins – 7%, 6% and 4% depending on manufacturing price.

Pharmacy remuneration (e.g. margins)

Regulated regressive margins – 20%, 18% and 16% depending on manufacturing price.

VAT is 20% standard for all products.

Regulatory changes since April 1, 2019

- ✓ **Change of number of the reference countries;**
- ✓ **The price of biosimilar product in PDL is not higher than 80% of the ex-factory price set for the reference biological product.**

HTA: NCPRMP

- MP that belong to a new INN in the PDL, must be evaluated for HTA;
- MP included in the PDL for which an extension of the therapeutic indications has been requested and for which have not yet been paid for, must be evaluated for HTA;

Requirements and conditions for inclusion in PDL:

- The INN, to which the MP or combination belongs to, is paid for the same therapeutic indication in at least 5 of the following 17 countries: BE, EL, DK, EE, ES, IT, LT, LV, PL, PT, RO, SK, SI, HU, FI, FR, CZ;
- Presence of at least one positive HTA from France, Germany, the United Kingdom, or Sweden;
- Discount agreements with NHIF and framework agreements with MH;

Monitoring of Therapeutic effect:

- MP for which no evidence of therapeutic effectiveness has been provided and/or the cost-benefit ratio is unfavourable, are included in the relevant Annex to the PDL with an obligation to monitor the effect of therapy;
- The NCPRMP has an obligation to determine the conditions and criteria for therapeutic monitoring, health care facilities, and the estimated number of patients.

Reimbursement/Coverage in the out-patient sector

Annex 1 of PDL – 2213 medicines

Payer institution - NHIF

Reference price system (RPS) of cluster of substitutable medicines: yes, MP grouped in ATC level 5 and 4.

Internal reference pricing by INN and pharmaceutical form.

Cheapest product being the reference value.

Co-payment

4 levels of reimbursement –25%, 50%, 75% and 100%.

For 100% reimbursed products, NHIF pays 2 BGN per prescription to the pharmacy.

High cost MP are subject to restricted prescription and special requirements set by NHIF.

Reimbursement/Coverage in the in-patient sector

Annex 2 and 3 of PDL - 2794 medicines

Payer institutions - hospitals, Ministry of Health, NHIF.

- ✓ localised tenders by hospitals,
- ✓ centralised tenders for MP, paid by MH.

