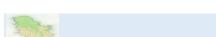




REPUBLIC OF SERBIA

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

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Population: 6.9 mil (3.6 mil female, 3,4mil male) GDP: 5226 €/cap. (SORS, 2017.)

Total health expenditure of GDP: 8.8% (Institute for Publ. Heath of Serbia, 2015.)

Health care insurance: mandatory and voluntary. Mandatory health insurance is provided by

National Health Insurance Fund

Authorities competent for price setting: Ministry of Health (MoH), Ministry of Trade (MoT), for all medicines for human medical use with marketing authorization and dispensed on prescription. National Health Insurance Fund (NHIF), for reimbursable medicines.

Law on Medicinal Products and All bylaws Medical Devices regulating prices need consent of Government in adopting procedure. Regulation on Maximum Prices of Medicines for Human Med. Use List on Maximum Prices of Medicines Dispensed on Prescription (MoH, for Human Med. Use Dispensed on Prescription (MoH, MoT) MoT) Centralized public procurement is conducted for state healthcare institutions by Reimbursed medicines: Rulebook on NHIF. Healthcare institutions criteria for introducing medicines in the in private sector are not in List of Reimbursable Med→ List of central procurement system. Reimbursable Med. (official prices, NHIF)

Reference price system

External

1° basket: Slovenia. Croatia. Italy:

2° basket: Estonia, Bulgaria, Romania, Lithuania, Latvia, Hungary...

Methodology of calculation is defined by Regulation on Maximum Prices.

Margins are regulated by Regulation on Maximum Prices: Wholesale margins: 6%

Retail margins:

Non-reimbursable medicines: regressive, depending on price level. Reimbursable medicines: up to 12%

Challenges in process of prices policy changing:

- 1. More efficient procedures of price settings.
- 2. Insuring the affordability of medicines and continual supply.

List of reimbursed medicines: yes; List A, List A1, List B, List C and List D.

2542 registered medicines on the list (710 INNs, 2017.)- Nearly 55% of all medicines with MA. List D: non-registered medicines (220 on the list).

Reference price system (RPS): yes; the lowest price in reference countries + additional mechanisms for price decreasing (next added generics decrease price of existing medicines in INN at least by 10%).

Managed Entry Agreements (volume cap and cross-product types for placing new medicines on reimbursement list). Centralized public procurement (since 2014; project supported by World Bank).

Reimbursement of medicines in the out-patient sector

List A and A1 and List D-partly (medicines dispensed in public pharmacies). Procurement: centralized, by proprietary name of medicine.

Co-payment: yes. A List: 50, 00 RSD (0.4 €)/pack. A1 List: 10%-95% of retail price

Mechanism for vulnerable groups:

Law on Health Insurance and Rulebook on List of Reimbursable Medicines

stipulate vulnerable groups free of co-payment for medicines on A List.

Reforms and challenges:

- 1. Improving mechanisms in order to get better affordability of medicines
- 2. Improvement in procurement system in order to strengthen the competitiveness among manufacturers.

Reimbursement of medicines in the inpatient sector

According to Financial Plan NHIF - amount of money allocated for hospital medicines. All medicines for in-patient use (List B, List C and List D-partly) are procured by NHIF open centralized procedure of procurement, INN procurement.

Co-payment in hospitals: no.

Reforms and challenges:

- 1. Ensuring stable supply of essential medicines
- 2. DRG for acute care- ongoing project (supported bvWB)

REIMBURSEMENT

PRICING