

MEDICINE SHORTAGE – SERBIAN EXPERIENCE

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Background: The unavailability of medicines continues to be on the rise in Europe and it has a tremendous impact on patients. Medicine shortages occur across all healthcare settings and involve both essential life-saving medicines and very commonly used medicines.

Medicine shortage means a situation in which the supply of a medicinal product that is authorized and placed on the market in a Member State does not meet demand for that medicinal product at a national level, whatever the cause (Regulation (EU) 2022/123).

Medicine shortages can result from different economic, manufacturing, or regulatory causes.

In our country has been performed an assessment of the regulatory framework to increase preparedness for the forthcoming situation. By changing several regulations import proponent for centralized public procurement become Institute of Public Health of Serbia (IPHS).

Methods and Objectives: We have analyzed Health Technology Assessment Department's data of import proposal for missing medicines from September 2023. to July 2024. in order to ensure a continuous supply of medicines and provide quality health care.

Results: In accordance with the changes, so far 23 medicines have been imported this way. The largest number of them belong anti-infective medicines (benzylpenicillin, tobramycin, rifampicin, acyclovir), then medicines with an effect on the nervous system – antipsychotics: fluphenazine, lithium and disulfiram used in alcohol dependence. Respiratory system medicines including fluticasone and adrenergics in combination with anticholinergics (salbutamol and ipratropium bromide). Also, zoledronic acid as drug affecting bone structure and mineralization and pemetrexed as antineoplastic agent were imported, as well as antihemorrhagics drugs tranexamic acid and phytomenadione.

Conclusions: The main causes of medicine shortages are diverse and multi-factorial, so the analysis is important for adequate supply that enables continuous performing of healthcare, defining priorities and calculating the impact on National health insurance fund (NHIF) resources.

Keywords: medicine shortage, regulatory framework, IPHS, reimbursement, health care