

Republic of Serbia Ministry of Health

Sector for Inspection Affairs
Sector for European Integration and
International Cooperation

*Models of National Regulatory Authorities
Interaction patterns in case of splitting
the functions between regulatory agencies*

Ministry of Health -Organization

- Ministry of Health is organised in accordance with the Law on Ministries
- Ministry of Health has 8 departments
- Sector for Inspection Affairs and Sector for European Integration and International Cooperation are one of them
- Part of the Sector for inspection affairs is Department for inspection of medicines and medical devices and psychoactive controlled substances and precursors

National Regulatory authorities of Republic of Serbia:

According to national Law in the field of medicines for human use in Serbia two institutions are responsible:

- **Ministry of Health**
- **Agency for medicines and medical devices**

Legal framework:

- Law on Medicines and Medical Devices ("Official Gazette of the Republic of Serbia" No. 30/10, 107/12, 113/17 and 105/17).
- Rulebooks regarding Law on Medicines and Medical Devices
- Law on Inspection Control ("Official Gazette of the Republic of Serbia" No. 36/15, 44/18 and 95/18) .
- Healthcare law ("Official Gazette of the Republic of Serbia" No. 25/19)
- Guidelines for Good Manufacturing Practice and Annexes 1 - 19 ("Official Gazette of the Republic of Serbia" No. 97/17 and 19/23)
- Guidelines of Good Laboratory Practice ("Official Gazette of the Republic of Serbia" No. 28/08)
- Guidelines of Good Distribution Practice ("Official Gazette of the Republic of Serbia" No. 13/16 and 44/16)

Scope of Activities

The Ministry of Health (MoH) is responsible for issuing license:

- Manufacturing license for medicines for human used
- Manufacturing license for medical devices for human used
- License for wholesale distribution of medicines and medical devices
- License for retails for medical devices
- License for preparation of galenic medicines
- License for pharmacy

The Ministry of Health (MoH) is responsible for inspection all subject above

Inspector:

- Supervision the documentation
- Control the condition of premises, equipment and personnel to assess compliance with the Law, Regulations and Guidelines
- Sampling

Scope of Activities

Agency for medicines and medical devices is responsible for (the main duties):

- Marketing authorisation
- Carrying out the registration in the Register of traditional herbal medicines and homeopathic remedies
- Issuing approvals for performance of clinical trials
- Pharmacovigilance
- Granting the import of medicines that do not have the MA in Serbia
- Quality control of medicines (National Control Laboratory is in its integral part)
- Approving the advertising of medicines and medical devices

Agency is responsible to the government.

Supervision of the Agency performs the Ministry of Health in carrying out delegated tasks.

Bilateral Cooperation - Republic of Serbia and Russian Federation

- 2014. signed Memorandum of Understanding and Cooperation between the Agency for Medicines and Medical Devices of Serbia (ALIMS) and the Federal Service for Surveillance in Healthcare of the Russian Federation (Roszdravnadzor)
- Scientific cooperation was established between the Clinical Center Kragujevac and the Moscow State Health Institution for Budgetary Protection, the N.B. Sklifosobski Emergency Research Institute, the Department of Health of the City of Moscow;
- The Torlak Institute for Virology, Vaccines and Serums and the Pasteur Institute from Saint Petersburg signed a Memorandum of Understanding. The "Pasteur" Institute donated equipment, reagents and laboratory plastics to the Torlak Institute for the purpose of diagnosing smallpox, rubella and other infectious diseases;
- 2021. signed Cooperation Agreement between Ministry of Health Republic of Serbia, Agency for Medicines and Medical Devices and State Institute of Drugs and Good Practices;
- April-May 2020: medical-epidemiological teams of Russian army visited all medical institutions and cities where the Covid 19 epidemic was registered and disinfected about 500,000 m² of hospitals and 25 streets and squares;
- June 2022: joint production of Sputnik V
- In preparation: Memorandum of Understanding in the field of infectious disease control & Memorandum of Understanding between in the field of health care



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