

Medicines and Medical Devices Agency of Serbia (ALIMS)

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Institution

Regulatory Authority

Institution identification

Institution ID

1000000459

Institution countries

Serbia

Type of institution

Regulatory Authority

Institution role

Other

Institution website

<https://www.alims.gov.rs>

ENCePP partner

Yes

Institution description

ALIMS is responsible for following activities:

- issuing marketing authorizations for medicinal products and medical devices;
- performing laboratory quality control of medicinal products and medical devices;
- issuing authorizations for clinical trials of medicinal products and medical devices and controlling the conduct of clinical trials;
- monitoring adverse reactions of medicinal products and medical devices;
- issuing certificates on compliance with guidelines on Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice in clinical trials of medicinal products and medical devices;
- authorizing the import of non-registered medicinal products and medical devices for the treatment of a particular patient or group of patients and medicinal products and medical devices for scientific research;
- classification of medicinal products and medical devices;
- collecting and processing statistical data on trade and consumption of medicinal products and medical devices;
- providing information and promotion of rational use of medicinal products and medical devices;
- integration into international networks of information on medicinal products and medical devices and integration into international agencies associations;
- other tasks in accordance with this Law

Institution details

Experience with collecting data directly from individual patients or respondents:

Yes

Interest in carrying out research that is funded by pharmaceutical companies:

No

Contact

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