

INSTRUCTION FOR APPLICANTS FOR REGISTRATION/AMENDMENT/REMOVAL IN THE REGISTER OF MANUFACTURERS, IMPORTERS, OR DISTRIBUTORS OF ACTIVE SUBSTANCES

I Applicant for registration in the Register of manufacturers, importers, or distributors of active substances, in accordance with the Law on Medicines ("Official Gazette of Montenegro", no. 14/26) shall submit the following documentation:

- 1) completed [Application form for Registration/amendment to Registration/removal from the Register of manufacturers, importers, or distributors of active substances](#), available on the Institute's portal (www.cinmed.me) > *Inspectorate* > *Manufacture/import and distribution of active substances* in the section *Instructions and forms for application*;

In the section of form 2A *Import*, it is necessary to enter a list of active substances with the prescribed storage conditions, manufacturers (name and address), and if applicable, wholesalers from third countries.

The list of countries approved by the European Commission for which a written confirmation from the competent authority of the exporting country is not required: https://health.ec.europa.eu/medicinal-products/falsified-medicines/importation-active-substances-listing-third-countries_en;

Note: The names of the active substances in the list must be listed as in the European Medicines Agency database (IRIS database, available at the link: <https://iris.ema.europa.eu/substances/>).

- 2) other documentation proving compliance with the conditions prescribed by the Law and by-laws adopted for its implementation, if necessary.

Upon receipt, the applicant shall be issued an invoice in accordance with the applicable decision determining fees for Institute's business operations in accordance with the Law, based on which payment shall be made with reference to the number of invoice/file. Payment of prescribed fee is a condition for processing the application.

II Applicant for amending the Registration in the Register of manufacturers, importers, or distributors of active substances shall submit the following documentation:

- 1) completed [Application form for Registration/amendment to Registration/removal from the Register of manufacturers, importers, or distributors of active substances](#), available on the Institute's portal (www.cinmed.me) > *Inspectorate* > *Manufacture/import and distribution of active substances* in the section *Instructions and forms for application*;
- 2) appropriate evidence, i.e., documentation from point I of these Instructions related to the amendment.

Upon receipt, the applicant shall be issued an invoice in accordance with the applicable decision determining fees for Institute's business operations in accordance with the Law, based on which payment shall be made with reference to the number of invoice/file. Payment of prescribed fee is a condition for processing the application.

The holder of the registration in the Register of manufacturers, importers, or distributors of active substances is obliged to report to the Institute any changes in the documentation from point I of these instructions once a year.

The holder of the registration in the Register of manufacturers, importers, or distributors of active substances is obliged to submit an application to the Institute for an amendment of the registration decision if the changes may affect the quality or safety of the active substance.

III Applicant for deletion from the Register of manufacturers, importers, or distributors of active substances shall submit:

- 1) completed [*Application form for Registration/amendment to Registration/removal from the Register of manufacturers, importers, or distributors of active substances*](#), available on the Institute's portal (www.cinmed.me) > *Inspectorate > Manufacture/import and distribution of active substances* in the section *Instructions and forms for application*;
- 2) justification of the reasons for the cessation of performing production, import or distributing of active substances.

Upon receipt, the applicant shall be issued an invoice in accordance with the applicable decision determining fees for Institute's business operations in accordance with the Law, based on which payment shall be made with reference to the number of invoice/file. Payment of prescribed fee is a condition for processing the application.

Note: Documentation may be submitted in hard copy to the CInMED Registry Office or in electronic form on a CD through the Registry Office, or by email to: pisarnica@cinmed.me. Documentation submitted by email cannot be sent via external links (e.g., WeTransfer or similar services).

In the case of electronic submission of an Application for the issuance/amendment/supplementation/termination of a medicinal product manufacturing authorization, the application must be electronically signed.