

INSTRUCTION FOR APPLICANTS FOR OBTAINING/AMENDING/EXTENSION/CESSATION OF VALIDITY OF WHOLESALE AUTHORISATION FOR MEDICINES CONTAINING NARCOTIC DRUGS

I In accordance with the Law on Medicines ("Official Gazette of Montenegro" No 80/20), Law about preventing drugs abuse (Official Gazette of Montenegro No 28/11 and No 35/13) and Rulebook on more detailed conditions and manner of determining fulfillment of conditions for performing wholesale of medicines ("Official Gazette of Montenegro" No 45/21), the applicant for wholesale authorisation for medicines containing narcotic drugs shall submit to the Institute the following documentation:

1) Completed [Application form for obtaining/amending/cessation of validity of the wholesale authorisation for medicines containing narcotic drugs](#), available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate > Wholesale/Good Distribution practice* in the section *Instructions and forms*;

2) Copy of wholesale authorisation for veterinary medicinal products issued by competent authority;

3) Evidence that the responsible person meets the requirements prescribed by law and secondary legislation adopted for its implementation – evidence on completed education, evidence on work experience (copy of employment record book and CV) and completed training, marriage certificate, if applicable;

4) Full-time employment contract concluded with the responsible person, statement of continuous availability (24 hours) of the responsible person with contact details (mobile phone, e-mail), as well as Confirmation from Revenue Administration on work insurance; temporary work permit for the responsible person (applicable only for foreigners);

5) Evidence of disposal of means of transportation of medicines (e.g. evidence of ownership of the vehicle, use of vehicles, entrusting transportation activities);

6) Evidence of ownership, lease, outsource of storage activities or some other manner of having business premises at disposal;

7) Study on the fulfillment of minimum technical and construction conditions in the area for performing activities with a sketch of the space and the legend of the premises with marked measures;

8) Evidence of having a backup power supply (aggregate, UPS (uninterruptible power supply));

9) Sanitary approval;

10) List of the equipment and technical data on it;

11) List of employees (name and surname, position, level of education);

12) Quality assurance policy or other equivalent document;

13) Procedure for emergency recall of medicines from the market ;

14) Evidence of the existence of the computerized or other record keeping system;

15) Evidence of the existence of a specially secured space, lockable, at the entrance of which there is a clearly displayed notice that unauthorized persons are prohibited from accessing, for storing and holding active substances belonging to narcotic drugs or psychotropic substances, as well as finished medicines containing these substances defined by the Rulebook on determining the list of drugs, psychotropic substances and herbs that can be used for drug manufacture ("Official Gazette of Montenegro" No 041/18 from 28.06.2018, 057/18 from 10.08.2018). This does not apply to preparations containing drugs defined in Part II of the List of Drugs, nor to drugs containing psychotropic substances defined in Group 4 of the List of psychotropic substances and herbs, which are part of the Annex to the Rulebook on determining the list of drugs, psychotropic substances and

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herbs that can be used for drug manufacture, and **they are not required** to be stored in a specially secured space.

16) Other documentation proving the fulfillment of the conditions prescribed by the Law and secondary legislation 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.

Wholesale authorisation for medicines containing narcotic drugs shall be issued for a period of five years and cannot be transferred to another legal person.

The Institute shall obtain the following confirmations from the competent authority, ex officio.

For the purpose of obtaining of Confirmation from competent authority that the legal person and the founder have not been punished in criminal proceedings for the offence of drug abuse and money laundering (Article 26 of the Law about preventing drugs abuse), the applicant shall submit:

- extract from Central registry of commercial entities for the legal person;
- copy of ID of the responsible person in the legal person.

For the purpose of obtaining of Confirmation from competent authority that the responsible person has not been punished in criminal proceedings for the offence of drug abuse and money laundering (Article 26 of the Law about preventing drugs abuse), the applicant shall submit:

- copy of ID of the responsible person for wholesale of medicines containing narcotic drugs.

II Applicant for amending the wholesale authorisation for medicines containing narcotic drugs shall submit the following documentation:

1) Completed [Application form for obtaining/amending/cessation of validity of the wholesale authorisation for medicines containing narcotic drugs](#), available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate > Wholesale/Good Distribution practice* in the section *Instructions and forms*;

2) Appropriate evidence, i.e. documentation from point I of this Instruction in relation 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.

III Applicant for the extension of the wholesale authorisation for medicines containing narcotic drugs shall submit the following documentation:

1) Completed [Application form for obtaining/amending/cessation of validity of the wholesale authorisation for medicines containing narcotic drugs](#), available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate > Wholesale/Good Distribution practice* in the section *Instructions and forms*

2) Documentation referred to in points 2–15 of this Instruction.

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.

IV Applicant for cessation of validity of the wholesale authorisation for medicines containing narcotic drugs shall submit the following documentation:

1) Completed [Application form for obtaining/amending/cessation of validity of the wholesale authorisation for medicines containing narcotic drugs](#), available on the portal of the Institute

(www.cinmed.me) in the section *Inspectorate > Wholesale/Good Distribution practice* in the section *Instructions and forms*

2) justification for the cessation of performing wholesale of medicines containing narcotic drugs.

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 can be submitted in paper form through Registry office or in electronic form (e-signed), through Registry office via CD or sent to the e-mail address: pisarnica@cinmed.me.

