

INSTRUCTION FOR APPLICANTS FOR OBTAINING/AMENDING/CESSATION OF VALIDITY OF WHOLESALE AUTHORISATION FOR MEDICINES

I In accordance with the Law on Medicines ("Official Gazette of Montenegro" No 80/20) 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 for human use shall submit to the Institute the following documentation:

1) Completed [Application form for obtaining/amending/cessation of validity of the wholesale authorisation](#), 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) 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;

3) 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);

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

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

6) 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;

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

8) Sanitary approval;

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

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

11) Quality assurance policy or other equivalent document;

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

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

14) 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 shall be issued for an indefinite period of time, except for medicines containing narcotic drugs.

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

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

Expertise and science in service of health

T: + 382 (0) 20 310 280
+ 382 (0) 20 310 281
+ 382 (0) 20 310 580

M: info@cinmed.me
W: www.cinmed.me
A: Bulevar Ivana Crnojevića 64a,
81000 Podgorica, Crna Gora

PIB: 02739658
ŽR: 520-3603-33 - Hipotekarna Banka
520-3603-33 - NLB Banka

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 cessation of validity of the wholesale authorisation for medicines shall submit the following documentation:

1) Completed [Application form for obtaining/amending/cessation of validity of the wholesale authorisation](#), 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.

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.

