CInMED
Institut za ljekove i medicinska sredstva Crne Gore

INSTRUCTION FOR APPLICANTS FOR OBTAINING/AMENDING/CESSATION OF VALIDITY OF THE MANUFACTURING AUTHORIZATION FOR MEDICINES

I In accordance with the Law on Medicines ("Official Gazette of Montenegro" No. 80/20, 84/24 and 35/25) and Rulebook on more detailed conditions and manner of determining fulfilment of conditions for performing the manufacture of medicines ("Official Gazette of Montenegro" No. 75/15), the applicant for manufacturing 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 manufacturing authorisation, available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate* > *Manufacturing/Good Manufacturing Practice* in the section *Instructions and forms*;
2. Evidence that the responsible persons (responsible person for manufacturing, responsible person for quality control and responsible person for batch release) meet all the requirements prescribed by the Law on Medicines 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 on the application of the Guidelines for Good Manufacturing practice, 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. A written statement by the applicant declaring that the Qualified Person (QP) responsible for batch release will be enabled to perform their duties independently and provided with all necessary resources for that purpose;
5. A written statement by the applicant declaring that, in the manufacture of the medicinal product, only active substances produced in compliance with Good Manufacturing Practice (GMP) requirements will be used;
6. Proof of availability of appropriate premises (property deed or lease agreement);
7. Study on the fulfilment 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, certified by a licensed architect;
8. Sanitary approval;
9. A list of medicinal products and pharmaceutical forms for which the manufacturing authorization is requested;
10. Name and registered address of the manufacturer, manufacturing site, quality control site, as well as the site of batch release;
11. Description of the manufacturing process or part of the process, including the procedures for subdivision, packaging, and labelling of the medicinal product for which the authorization is requested;
12. List of the equipment and technical data on it;
13. List of employees (name and surname, position, level of education);
14. SMF (*Site Master File*);

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15. A plan on the procedure for the destruction of medicinal products and a written statement by the applicant undertaking further handling of medicinal products classified as pharmaceutical waste, in accordance with the regulations;
16. Other documentation proving the fulfilment 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 psychotropic substances, which is issued for a period of 5 years in accordance with a special law. Exceptionally, if the conditions are not fully met, a conditional manufacturing authorization may be issued, with the obligation to fulfil precisely defined requirements either prior to the issuance of the authorization or within the prescribed period after the issuance of the manufacturing authorization.

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

1) Completed Application form for obtaining/amending/cessation of validity of the manufacturing authorisation, available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate* > *Manufacturing/Good Manufacturing 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 cessation of validity of the manufacturing authorisation for medicines shall submit the following documentation:

1) Completed Application form for obtaining/amending/cessation of validity of the manufacturing authorisation, available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate* > *Manufacturing/Good Manufacturing Practice* in the section *Instructions and forms*;

2) Justification for the cessation of performing manufacturing 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.

Copies of documents shall be submitted, except for the completed Application for the obtaining/amending/cessation of validity of the manufacturing authorization for medicinal products, which shall be submitted in the **original version**. In the case of submitting the electronic form of the Application for the obtaining/amending/cessation of validity of the manufacturing authorization for medicinal products, it must be electronically signed.