

INSTRUCTIONS FOR SUBMISSION OF AN APPLICATION FOR THE ISSUANCE OF A GMP CERTIFICATE

An application for the issuance of a GMP certificate shall be submitted to the Institute no later than 180 days prior to the expiry date of current certificate or, where the application is submitted for the first time, at least 180 days in advance of the planned inspection.

I GMP inspections of manufacturers in Montenegro

Applicants for the issuance of a GMP certificate are required to submit an application in accordance with the *Law on medicinal products* („Official Gazette of Montenegro“, No 14/26) and *Rulebook on conditions for granting marketing authorisation for medicinal products* („Official Gazette of Montenegro“ No 22/26), or *Rulebook on conditions for granting marketing authorisation for veterinary medicinal product* (“Official Gazette of Montenegro” No 22/26) and the following documentation:

1. Cover letter on the letterhead of the applicant;
2. Completed form [*Application for the issuance of GMP certificate*](#), available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate > Manufacturing/Good Manufacturing Practice > Instructions and forms*;
3. Site Master File (SMF)

Upon receipt of the application, the applicant will be issued an invoice in accordance with the applicable decision establishing the fees for services performed by the Institute pursuant to the Law. Payment shall be made with reference to the invoice number/reference number. Payment of prescribed fee is a prerequisite for processing the application.

Note: Documentation may be submitted in paper or electronic form (Application for the issuance of GMP certificate shall bear a valid electronic signature), either on a CD and submitted to the CInMED Registry Office or via e-mail address to: pisarnica@cinmed.me. Documentation submitted by e-mail shall be attached directly to the message and may not be provided through external file-sharing links (e.g. WeTransfer or similar services).

II GMP inspections of manufacturers located outside of the territory of Montenegro

Pursuant to Article 84 of the Law on medicinal products (“Official Gazette of Montenegro”, No. 14/26), applicants for a GMP certificate shall submit an application together with the following documentation:

1. Cover letter on the letterhead of the applicant;
2. Completed form *Application for the issuance of GMP certificate*, available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate > Manufacturing/Good Manufacturing Practice > Instructions and forms*;
3. Current manufacturing authorisation;
4. Site Master File (SMF).

In the case of an application for a GMP inspection of a manufacturer located outside Montenegro, the Application for the issuance of a GMP certificate shall be completed by the manufacturer's authorised representative.

The cover letter shall clearly identify the responsible contact person authorised to communicate with CInMED on behalf of the manufacturer and provide their contact details, including an e-mail address and telephone number.

Upon receipt of the application, the applicant will be issued an invoice in accordance with the applicable decision establishing the fees for services performed by the Institute pursuant to the Law. Payment shall be made with reference to the invoice number/reference number. Payment of prescribed fee is a prerequisite for processing the application.

The cover letter shall clearly specify whether the invoice is to be issued to the applicant (i.e. the MAH in Montenegro) or directly to the manufacturer.

Note: Documentation may be submitted in paper or electronic form (Application for the issuance of a GMP certificate shall bear a valid electronic signature), either on a CD and submitted to the CInMED Registry Office or via e-mail address to: pisarnica@cinmed.me. Documentation submitted by e-mail shall be attached directly to the message and may not be provided through external file-sharing links (e.g. WeTransfer or similar services).

