

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

An application for the issuance of a GDP 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.

In accordance with the *Law on medicinal products („Official Gazette of Montenegro“ No. 14/26) and the Rulebook on detailed conditions and manner of determining the fulfillment of conditions for performing wholesale of medicines for human use (“Official Gazette of Montenegro” No 45/21)*, an applicant for the issuance of a GDP certificate is required to submit the following documentation:

1. Cover letter on the letterhead of the applicant;
2. Completed form [Application for the issuance of GDP certificate](#), available on the portal of the Institute (www.cinmed.me) in the section *Inspectorate > Wholesale/Good Distribution Practice > Instructions and forms*;
3. Quality Manual, or other equivalent document.

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 a GDP 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).