

## MANNER OF SUBMITTING APPLICATION FOR ISSUANCE OF THE CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP CERTIFICATE)

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**Applicant for issuance of the Certificate of a Pharmaceutical Product shall submit to the Institute the following documentation:**

1. Cover letter for issuance of the certificate containing the following:

- logo, name and address of the applicant
- subject: Application for issuance of the Certificate of a Pharmaceutical Product (CPP certificate)
- data on a medicine (brand name, INN or generic name, pharmaceutical form, strength, size and type of the packaging)
- information on the status of the medicine in terms of the procedure for obtaining marketing authorisation in Montenegro. Number of the Decision on issuance of marketing authorisation, or number of the application under review should be provided, depending on whether a medicine has been granted marketing authorisation, or the assessment procedure is in progress
- data on the applicant (name and headquarter of the legal person)
- date and signature of a responsible person of the applicant.

Cover letter shall be submitted:

- in paper form through the Registry Office or
- in electronic form, in accordance with the law governing electronic identification and electronic document, through the Registry Office on a CD or to the e-mail address: [pisarnica@cinmed.me](mailto:pisarnica@cinmed.me)

2. Completed application form for issuance of the certificate

Application form that is available on the portal of the Institute in the section - About CInMED/Expert opinions and CPP shall be completed electronically (on a CD or sent to the e-mail address: [pisarnica@cinmed.me](mailto:pisarnica@cinmed.me)) and submitted to the Institute along with a cover letter).

After receiving the application, an invoice in accordance with the [Decision on the payment method and amount of fees for the exercise of competences of the institute for medicines and medical devices that are determined by the law](#) shall be issued to the applicant on the basis of which it is necessary to make payment with a reference to the invoice number/file number.

Payment of prescribed fee is a condition for processing the application.