

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

Application for issuance of the Certificate of a Pharmaceutical Product shall contain the following:

1. Cover letter for issuance of the certificate
2. Completed form for issuance of the certificate, available at the portal of the Institute (www.cinmed.me)
3. Proof of payment of fees.

1. Cover letter for issuance of the certificate shall contain the following:

- logo, name and address of the applicant
- subject: Application for issuance of the Certificate of a Pharmaceutical Product (CPP certificate)
- data on the medicinal product (brand name, INN or generic name, pharmaceutical form, strength, ATC code)
- information on the status of the medicinal product 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 procedure of evaluation is in progress
- data on the applicant (name and headquarter of the legal person)
- date and signature of responsible person of the applicant.

2. Completed form for issuance of the certificate

The form should be downloaded from the portal of the Institute i.e. section Legislation/Forms – Medicines/Certificates and expert opinions/Form for issuance of the Certificate of a Pharmaceutical Product (CPP).

The form should be completed in an electronic form (on a CD) and submitted to the Institute.

3. Proof of payment of fees

Payment is to be made on the Institute's gyro account, after issuance of the invoice. When making payment, it is necessary to quote the invoice number.