CInMED
Institut za ljekove i medicinska sredstva Crne Gore
Institute for Medicines and Medical Devices of Montenegro

DOCUMENTATION REQUIRED FOR ISSUANCE AUTHORISATION FOR IMPORT, EXPORT AND TRANSIT OF DRUGS AND INSTRUCTION FOR COMPLETING THE APPLICATION FORM

A. When applying for the import authorization for drugs, the applicant shall submit the following documentation:

1. Application form for import, export and transit of drugs available on the portal of the Institute (www.cinmed.me) in the section Human medicines/Controlled substances;
2. User's (applicant's) statement on the purpose;
3. Pro-forma invoice, or invoice of the supplier;
4. Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine the import of which is applied for.

In order to obtain the import authorisation for medicines from the group of drugs that do not have marketing authorization in Montenegro, the applicant shall, in addition to the listed documentation, also submit the documentation prescribed by the instruction - Required documentation for issuance of import authorisation for medicines that do not have marketing authorisation and import/export of immunological medicines and medicines derived from blood and plasma.

B. When applying for the authorization for export and transit of drugs, the applicant shall submit the following documentation:

1) Application form for import, export and transit of drugs available on the portal of the Institute (www.cinmed.me) in the section Human medicines/Controlled substances
2) User's statement on the purpose
3) Pro-forma invoice
4) Import authorization from the competent authority of the importing country, which issued the aauthorisation (in case of export/transit from Montenegro) and export authorization from the competent authority of the exporting country that issued the authorisation (in case of transit through Montenegro)
5) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine the export/transit of which is applied for.

After receiving the application with the documentation given in the sections A and B, 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.

In case of applying for import/export/transit of the same batch that was previously approved for import/export/transit by the Institute, the applicant shall refer to the file number within which the batch release certificate was submitted.

The Institute shall retain the right to request additional documentation that is not listed in this instruction during the procedure of issuing the import/export/transit authorisation.

Application, as well as all documentation original of which is required (all official statements of the applicant, or other documents, at the request of the Institute) 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 CD or to the e-mail address: pisarnica@cinmed.me.

All other documentation shall be submitted in electronic form (on a CD, or by e-mail to the address pisarnica@cinmed.me , or to kontrolisanesupstance@cinmed.me with reference to the file number).

B. Instruction for completing the application form

Application form must be fulfilled in the following manner:

1) Applicant
- state the name, address and TIN number of the applicant and contact details (telephone, fax and e-mail address)

2) Application form for the issuance of authorisation of ____drugs
- state whether import, export or transit of drugs is in question

3) Name and address of the importer
- state the full legal name and address (street and number) of the importer,

4) Country of the importer
- state the country into which narcotic drug is imported

5) Name and address of the exporter
- state the full legal name and address (street and number) of the exporter (in line with pro-forma invoice).

6) Country of the exporter
- state the country of exporter

7) Manufacturer
- provide the name of the manufacturer of narcotic drug

8) Name of the substance or the product
- provide brand name of the product being imported, exported or in transit, dosage form (solution, tablets, drops...), strength and packaging.

9) International name
- provide international name of narcotic drug (INN when a medicine is in question).

10) Quantity of the packagings
- provide quantity (number of packagings) of product being imported, exported or in transit (in line with pro-forma invoice).

11) Content %
- provide content of the base of the drug in percentage (data provided by the manufacturer but also available in the following INCB lists):
  - https://www.incb.org/documents/Narcotic-Drugs/Yellow_List/60th_edition/60_Yellow_List_EN_rev1.pdf -narcotic drugs
  - https://www.incb.org/documents/Psychotropics/forms/greenlist/2021/Green_list_ENG_V2 1.pdf - psychotropic susbtances

12) Total amount of the base of the drug
- state the amount or the content of pure active substance (drug) in grams, found in total amount of the product that is imported, exported or in transit;

13) Batch number
- state the batch number in accordance with the batch analysis certificate/certificate of compliance of the batch

14) Customs authority
- specify the customs office

15) Movement direction of goods and the name of border crossing
- specify the movement direction of goods and the name of border crossing that will be used during entering, or exiting

16) Time frame within which the import/export/transit will be performed
- specify period of time within which the import/export/transit of drugs will be performed.

17) Mode of transport, data on transportation vehicle:
- specify the type of traffic (road/air or sea traffic) as well as the means of transport (truck, plane, ship, etc.)

18) Import authorisation number:
- in case of export, state the number and date of the import authorisation issued by the competent authority from the importing country, with the name of the issuing authority.

19) End user
- if the legal person in Montenegro (manufacturer of the drug) imports the drug for further processing, it is necessary to state its data (name, seat and address) in the application for import; if a legal person in Montenegro (wholesaler) imports a medicine from the group of drugs for the needs of pharmacies or health institutions, it is necessary to state "for the needs of pharmacies (private or ZU Apoteke Montefarm) or health institutions". This information should be in line with the data stated on the User's statement on the purpose.
- it is necessary to state the legal person (manufacturer, wholesaler, etc.) from the exporting country in the application for export.

20) End use of goods
- In case the drug is a medicine, it is necessary to specify **for therapeutic use**, without indications, while in cases where the drug is a raw material, it is necessary to specify **for further processing, or for the manufacturing of a medicine.**

After the completion of the import/export/transit procedure, the Institute shall within 15 days be provided with the proof of the realization of one of mentioned procedures.
In case that import is not performed, **the unused authorisation must be returned to the Institute**.
Importer (wholesaler that has the authorization to perform marketing of drugs) shall submit to the Institute the data on annual needs for drug import for the next year no later than by 31 March of the current year.