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 PRECURSORS AND MEDICINES CONTAINING PRECURSORS AND INSTRUCTION FOR COMPLETING THE APPLICATION FORM

A. When applying for the import authorisation for precursors and medicines containing precursors, the applicant shall submit the following documentation:

1) Application form for import, export and transit of precursors and medicines containing precursors available on the portal of the Institute (www.cinmed.me) in the section Human medicines/Controlled substances;

2) User's (applicant's) statement on purpose;

3) Pro-forma invoice, or invoice;

4) End user's statement on purpose of precursors, in accordance with the Rulebook on the form and content of statement of end user on the purpose of precursors ("Official Gazette of Montenegro", No 4/2015) (applies to precursors only) and

5) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine containing precursor the import of which is applied for.

In order to obtain the import authorisation for medicines containing precursors 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 issuance of export and transit authorisation for precursors and medicines containing precursors, the applicant shall submit the following documentation:

1) Application form for import, export and transit of precursors and medicines containing precursors 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;
4) Import authorisation issued by the competent authority of the importing country (in case of export/transit from/through Montenegro) and export authorisation issued by the competent authority of the exporting country (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 containing precursor 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 for 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).

C. Instruction for the completing the application form

Application form shall be completed 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 issuance of authorisation of_____precursors or medicines containing precursors
   - state whether import, export or transit of precursors or medicines containing precursors is in question.
3) Importer data
   - state the full legal name of a legal person, seat, address, country, TIN number; in case of legal person in Montenegro provide contact information (tel., fax and email address),
4) Exporter data
   - state the full legal name of a foreign supplier, seat, address, in accordance with pro-forma invoice); in case of a legal person in Montenegro, provide contact information (tel., fax and email),
5) Manufacturer
   - state name, address and country of a manufacturer of precursors or medicines containing precursors.
6) Name of the substance or the product
   - provide brand name of the product or medicine being imported, exported or in transit, dosage form (solution, tablets, drops...), strength and packaging.
7) Precursor name
   - provide international name of a precursor (provide INN when a medicine is in question).
8) HS code and CAS number
   - stated in accordance with internationally-standardized system
9) Quantity of packagings, being imported, exported or in transit
   - state number of packagings from the pro-forma invoice.
10) % of the anhydrous basis
   - provide content of the pure base of precursor in percentage (data provided by the manufacturer and also available on INCB list): - https://www.incb.org/documents/PRECURSORS/RED_LIST/2023/RedList_20th_edition_E.pdf
11) Total mass/volume of precursor in a product
   - state amount/content of pure active substance (precursor) in grams or millilitres found in total quantity of the product being imported, exported or in transit

12) Batch number
- state the batch number in accordance with the batch analysis certificate of a medicine/precursor

13) Customs authority
- specify the name of the entry/import or exit/export customs office

14) 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

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

16) 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.); in case of precursors, state the means of transport that will be used for transport, plates number and the name of the transporter.

17) Import authorisation number:
- in case of application for export, provide the number of the import authorisation issued by competent authority of the importing country and the name of the issuing authority.

18) End user
- if the legal person in Montenegro (manufacturer of the medicine) imports the precursor for own needs as raw material 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 containing precursor 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.
- in the application for export it is necessary to state the legal person (manufacturer, wholesaler, etc.) from the exporting country.

19) End use of goods
- In case of medicines containing precursor, it is necessary to specify **for therapeutic use**, without indications, while in cases where the precursor is a raw material, it is necessary to specify **for further processing or for the manufacturing of 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 (distributor) shall submit to the Institute the data on annual needs for precursors import for the next year no later than by 31 January of the current year.

Updated: June, 2023.