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. For obtaining the import authorisation for precursors and medicines containing precursors applicant shall submit the documentation consisted of the following:

1) The application cover letter;

2) Completed Application form for issuance of the import, export and transit authorisation for precursors and medicines containing precursors (available on the CInMED web portal)

3) User's (applicant's) statement of purpose;

4) Pro-forma invoice or forma invoice;

5) End user's statement of 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 only to precursors)*

6) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine whose import is required.

In addition to the documentation stated previously, for obtaining import authorisation for medicines for human use, that have not previously been granted marketing authorization in Montenegro, the following documentation shall also be submitted:

a) Data on each medicine/batch of the medicine listed in the application:
- Country/countries in which has been granted marketing authorization for the medicine (EU member states/Serbia/BH)
- Country/countries which approved the packaging of the batch of the medicine to be imported into Montenegro as an integral part of marketing authorisation (EU member states/Serbia/BH)
- Country/countries in which batch of the medicine to be imported into Montenegro is released (EU member states/Serbia/BH)
- Whether the specification for the batch to be imported into Montenegro is identical to the specification approved in EU member states

b) Evidence from the competent authority that a medicine has been granted marketing authorisation in the country of a manufacturer, European Union Member States, or in countries having the same standards for issuing marketing authorisation (marketing authorisation, or CPP certificate in English language, or translated into Montenegrin) *(only for medicines that have not previously been granted import authorisation or upon request of the Institute);*

c) Evidence from the competent authority that a medicine has been manufactured in accordance with Guidelines on Good Manufacturing Practice (GMP certificate issued by competent authority of one of the EEA Member States or countries that have signed mutual recognition agreements (MRA) with European Union concerning recognition of GMP inspections) *(only for medicines that have not previously been granted import authorisation or upon request of the Institute)*;

d) Summary of Product Characteristics (SmPC) and Package Leaflet (PL) approved in one of the countries referred to in point b) (in English, or translated into Montenegrin). It is also necessary to submit Mock-up, approved along with the SmPC and PL or developed in line with the approved labelling for immediate and outer packaging *(only for medicines that have not previously been granted import authorisation or upon request of the Institute)*;

e) Justified request of the health institution, i.e. opinion of medical specialiston the need for import of the particular medicine;

f) Statement of the applicant for obtaining import authorisation that medicine will be labelled in accordance with the provisions of the Rulebook on the contents and method of labelling the outer and immediate packaging of a medicine and contents of the package leaflet ("Official Gazette of Montenegro" No 21/16) before placing on the market in Montenegro. Statement must contain batchnumber(s) of the medicine.

Pharmacovigilance of medicines containing precursors that have not previously been granted marketing authorization in Montenegro

If the medicine containing precursors, that have not previously been granted marketing authorisation, requires conduction of risk minimization measures, in order to ensure its safe use, the obligation of the importer is submiting, as part of the import application documentation, a statement containing information on as follows:

-risk minimization measures to be conducted in Montenegro
-type of educational material and for whomit is intended (healthcare professionals, patients);
-safety risks for which it is necessary to conduct risk minimization measures;
-whether the educational material* is approved by ALIMS or HALMED, or is prepared in the Montenegrin language;
-list of healthcare professionals -recipients of the letter to whom the educational materials will be distributed.

In cases of re-importing of the same medicine, a statement with information on conducting of risk minimization measures should be submitted only if there have been changes in risk minimization measures, content and type of educational material, the target group to which educational materials are distributed, in relation to the content of the statement of previously imported medicine.

If there are no changes in risk minimization measures, content and type of educational material, the target group to which educational materials are distributed, in relation to previous import of the medicine, it should be stated in the statement, which should be submitted with the application for obtaining import authorisation.
If the risk minimization measures include sending letters to healthcare professionals, along with the application for import of the medicine, it is necessary to submit the draft letter and the communication plan to CInMED for approval. These documents need to be submitted in Montenegrin.

***Educational material are not submitted to CInMED for approval**

NOTE:

Application for import authorisation for medicines containing precurosrs that have not previously been granted marketing authorization in Montenegro, which are considered to be simmilar/same to medicines which have been granted marketing authorisation (registered) in the Institute in terms of active substance and pharmaceutical form or regarding indications, shall be assessed only in following cases
-shortage on the market of registered medicines (in this case it is necessary to submit a statement from the marketing authorisation holder that the medicine is not on the market in Montenegro, or that there is a deficiency in the supply of the registered medicine, specifying the expected duration of the shortage), or
-provided opinion of medical specialist on the need for import of a non-registered medicine for a particular patient/group of patients justifying the reason why those patients cannot be treated with registered medicines and specifying exact quantity of the non-registered medicine that need to be imported.

B. The applicant for issuance of the export and transit authorisation for precursors and medicines containing precursors shall submit the documentation consisted of the following:

1) Cover letter of the application for obtaining authorisation;
2) Completed Application form for issuance of the import, export and transit authorisation for precursors and medicines containing precursors (available on the CInMED web portal)
3) User's (applicant's) statement of purpose;
4) Pro forma invoice;
5) Import authorisation issued by the competent institution of the importing country (in the case of export/transit from/through Montenegro) and export authorisation issued by the competent institution of the exporting country (in case of transit through Montenegro);
6) Batch release certificate in accordance with Internationally harmonised requirements for batch certification for each batch of the medicine whose import is required.

Upon receipt of the application with the documentation referred to in points A and B, the applicant shall be issued an invoice in accordance with the Decision on the payment method and fees for performing the competencies of the Institute for Medicines and Medical Devices established by law, based on which payment shall be made with reference to the number of invoice/file.

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

All documentation, except the cover letter (which is submitted in paper form) shall be submitted in electronic form (on a CD, or by e-mail to the address kontrolisanesupstance@cinmed.me with reference to the file number).

All documentation original of which is required (completed application form for issuance of the import, export and transit authorisation for drugs, all prescribed statements, opinion of medical specialist on the need for import of the particular medicine, or other documents, at the request of the Institute) shall be submitted in paper form (signed and stamped), or in electronic form, in accordance with the law governing electronic identification and electronic document, which shall be confirmed by the applicant in the cover letter.

C. Instruction for the 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 for issuance of authorisation of_____precursors or medicines containing precursors
   - state whether import, export or transit of precursors or medicines containing precursors is in request.
3) Importer data
   - state the full legal name of legal entity and address (street and number, country), TIN number; incase of legal entity in Montenegro state contact data (tel, fax and email address),
4) Exporter data
   - state the full legal name of foreign supplier, address and country, in accordance with pro-forma), in case of legal entity in Montenegro state contact data (tel, fax and email address), TIN number; in case of legal entity in Montenegro state contact data (tel, fax and email address), state the country into which precursor or medicine containing precursor is imported.
5) Manufacturer
   - state name, address and country of a manufacturer of precursors or medicines containing precursors.
6) Name of the substance or the product
   - state brand name of the product or medicine being imported, exported or transported, dosage form (solution, tablets, drops...), strength and packaging.
7) Precursor name
   - state international name of precursor (in case of medicine provide INN).
8) HS code and CAS number
   State in accordance with the internationally-standardized system -
9) Quantity of packaging of product being imported
   - precise quantity (number of packaging) of product being imported, exported or transported (in accordance with proforma invoice).
10) Content %
   - provide content of the pure base of precursor in percentage (provided by the manufacturer); it is also available in the following INCB list: - https://www.incb.org/documents/PRECURSORS/RED_LIST/Red_List_2022_19th_edition_E.pdf
11) Total mass / volume of precursor in product
   - state quantity/content of pure active substance (precursor) for total quantity of product being imported, exported or transported (expressed in grams or millilitres)

12) Batch number
- state the batch number in accordance with the batch analysis certificate of 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 drugs will be performed.

16) Mode of transport, data on transportation vehicle:
- specify mode of transport, provide the number of registration plates and name of the transporter

17) Import authorisation number:
- in case of request for export, provide number of the import authorisation issued by competent authority of the country into which drug is imported.

18) End user
- in the request for import, if the legal entity in Montenegro (manufacturer of the drug) imports precursor for further processing, it is necessary to state its own data (name, seat and address); if a legal entity in Montenegro (wholesaler) imports a medicines from the group of drugs for the needs of pharmacies or health care institutions, it is necessary to state "for the needs of pharmacies (private or ZU Apoteke Monetfarm) or health care institutions". This data should be in accordance with the data stated on the User's statement of purpose.
- in the request for export it is necessary to state the legal entity (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 production of medicine.**

After the completion of the import / export / transit procedure, the Institute shall be provided with proof of the realization of one of the mentioned processes within 15 days.
In case that the import is not performed, **the authorisation must be returned to the Institute**. The importer must submit to the Institute data on annual demands for import of precursors and medicines containing precursorss for the next year until 31 January of the current year at latest.