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

A. Applicant for obtaining import authorisation for medicines for human use which do not marketing authorisation shall submit to the Institute for medicines and medical devices the following documentation:

1. Application for import authorisation for a medicine for human use that does not have marketing authorisation on the form published on the portal of the Institute (www.cinmed.me).

2. Table containing list of medicines to be imported completed in line with the Instruction for using excel table for import of medicines that do not have marketing authorisation, available on the portal www.cinmed.me in the section Human medicines/Import and export of medicines.

3. Evidence that the medicine is authorised for marketing (marketing authorisation, or CPP certificate in English, or translated into Montenegrin language) from the competent authority of an European Union Member State, or a country that has the same, or similar requirements as the EU for issuance of marketing authorization (provided that the medicine is manufactured in line with Guidelines of Good Manufacturing Practice, i.e. it has a GMP certificate defined in item 5 of this Instruction), and which approved the packaging for which the application for import into Montenegro was submitted.

4. Summary of Product Characteristics (SmPC) and Package Leaflet (PIL) approved by the competent authority of the country defined in item 3 (in English or translated into Montenegrin). It is also necessary to submit Mock-up, approved along with the SmPC and PIL or developed in line with approved labelling for immediate and outer packaging. If the mock-up is not available, it is necessary to submit photos of the packaging (photos of all sides of the packaging are required).

5. Evidence from the competent authority that a medicine has been manufactured in accordance with Guidelines on Good Manufacturing Practice (GMP certificate issued by competent authorityof one of the EEA Member States or countries that have signed mutual recognition agreements (MRA) with European Union Member States regarding GMP inspections).

6. Batch release certificate in accordance with *Internationally harmonised requirements for batch certification*) for each batch the import of which is applied for.

7. When the import of an immunological medicine or a medicine derived from human blood and plasma is applied for, the following shall also be submitted:
   a) Certificate of analysis of one of the member laboratories of the Official Medicines Control Laboratory (OMCL) or countries that have signed an agreement with European Union Member States regarding the recognition of batch certification, for the same batch/es for which the manufacturer's certificate referred to in item 6 has been submitted;
   b) Manufacturing and control summary protocol (for vaccines), for the batch/es for which the certificates of analysis referred to in items 6 and 7(a) have been submitted.

8. Justified application of the import proposer referred to in the Article 5 of the Law on Medicines ("Official Gazette of Montenegro", No 80/20) on the form published on the portal of the Institute

(www.cinmed.me) in the section Human medicines/Import and export of medicines.

9. Pro-forma invoice, or invoice of the supplier.

Note regarding the documentation referred to in the section A:

1. **If the applicant had submitted the appropriate documentation referred to in items 3, 4 and 5 of this Instruction to the Institute within one of previous imports of a medicine, it is not necessary to submit the same documentation when submitting new applications for import of the same medicine (as long as given documents are valid and refer to specific batches for which applications for import into Montenegro are submitted).**

2. In case of applying for import of the same batch of the medicine that was previously approved for import by the Institute, the applicant shall refer to the file number within which the documentation for a particular batch was submitted: manufacturer's batch release certificate, certificate of analysis from one of the laboratories that are OMCL members (for immunological medicines and medicines derived from blood and plasma) and manufacturing and control summary protocol (for vaccines).

3. Application for import of medicines referred to in item A of this Instruction, which are generic parallels in relation to medicines authorised for marketing in Montenegro, will be considered only in case of the following:
   - shortage of medicines that have marketing authorisation in Montenegro (in accordance with the Law on medicines, marketing authorisation holder is obliged to inform the Institute that a medicine is not on the market in Montenegro, i.e. that it is in short supply, with a specified period of time for the shortage).
   The above mentioned also applies to some therapeutic parallels (which is assessed by the Institute).

4. Obligation of the manufacturer, i.e. the applicant for the issuance of import authorization for medicine for human use is to label the unregistered medicine being imported 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 and 67/18)*, i.e. to ensure that the reference information on the medicine is in a language that is understandable to healthcare professionals and patients in Montenegro.

PHARMACOVIGILANCE:

If the medicine whose import is applied referred to in item A of this Instruction requires conduction of additional risk minimization measures, in order to ensure its safe use, the obligations of the importer are as follows:

As part of the import documentation, it is necessary to submit a statement containing information on:
- additional risk minimization measures to be conducted in Montenegro;
-type of educational material and for whom it is intended (healthcare professionals, patients);

-safety risks which additional risk minimization measures refer to ;
-whether the educational material approved by ALIMS, or HALMED will be distributed, or the one in Montenegrin language will be prepared;
-list of healthcare professionals to whom the educational materials will be distributed.

Educational materials are not submitted to CInMED for approval.

A statement containing information on conducting of additional risk minimization measures should be submitted in cases of re-import of the same medicine, **if there have been changes in additional risk minimization measures, content and type of educational material, or the target group which educational materials are distributed to**, compared to previously imported medicine.

If there have been no changes in additional risk minimization measures, content and type of educational material, or the target group which educational materials are distributed to, compared to previously imported medicine, it should be provided in the statement, which should be submitted along with the application for obtaining import authorisation.

If additional risk minimization measures include **sending letters to healthcare professionals (DHPC)**, 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.

B. Applicant for the issuance of export authorisation for immunological medicines, or medicines derived from human blood and plasma that do not have marketing authorisation, but were previously imported into Montenegro on the basis of import authorisation issued by the Institute, shall submit the following documentation:

1. Application for the issuance of export authorization for immunological medicines or medicines derived from human blood and plasma, which do not have marketing authorisation containing the following information:
   - logo, name and address of the applicant, contact details, date, signature of the responsible person and seal (or electronic signature/seal)
   - subject of the application
   - name of the supplier
   - purpose of export
   - name and address of the buyer/recepient
   - information on medicines to be exported (name of the medicine, pharmaceutical form, strength, type and size of packaging, manufacturer, number of the batch(es), quantity)

2. Table containing list of medicines to be exported completed in line with the Instruction for using excel table for import of medicines that do not have marketing authorisation, available on the portal www.cinmed.me in the section Human medicines/Import and export of medicines.

3. Pro-forma invoice, or invoice of the buyer.

4. Copy of the Decision by which the consent for import of a medicine that is the subject of export was issued.

C. Applicant for obtaining import authorisation for medicines derived from blood and plasma and immunological medicines, which have marketing authorisation, shall submit the following documentation:

1. Application for obtaining import authorisation for medicines derived from blood and plasma and immunological medicines, which have marketing authorisation containing the following information:
   - logo, name and address of the applicant, contact details, date, signature of the responsible person and seal (or electronic signature/seal)
   - subject of the application
   - name of the supplier
   - name of the user, i.e., health institution
   - information on the medicines to be imported in line with the information contained in marketing authorization, as follows:

     Name of the medicine:
     INN:
     Pharmaceutical form, strength, packaging:
     Manufacturer(s): if more than one manufacturing site is approved for batch release within marketing authorisation, then it is necessary to specify from which of the approved sites batch(es) that are the subject of the application are released onto the market
     Number and date of the marketing authorisation:

     Batch(es) number:
     Quantity:

     Country/countries in which the packaging of the medicine for the batch to be imported into Montenegro is approved as an integral part of the marketing authorisation:

     Country / countries in which the batch of the medicine to be imported into Montenegro is placed on the market:

   Note: If there had been a change in one of the above data after the issuance of marketing authorisation, it is necessary to indicate the number and date under which the amendment to the authorisation (variation) was submitted to Institute.

2. Batch release certificate in accordance with *Internationally harmonised requirements for batch certification*) for each batch the import of which is applied for.

3. Certificate of analysis of one of the member laboratories of the Official Medicines Control Laboratory (OMCL) or countries that have signed an agreement with European Union Member States regarding the recognition of batch certification, for the same batch/es for which the manufacturer's certificate referred to in item 2 has been submitted;

4. Manufacturing and control summary protocol (for vaccines), for the batch/es for which the certificates of analysis referred to in items 2 and 3 have been submitted.

5. Mock-up which was approved along with the Summary and Leaflet, i.e. developed according to the approved wording of the packaging (Labelling) in which the import of a batch of medicine to Montenegro is planned to be performed. If the mock-up is not available, it is necessary to submit photos of the packaging (photos of all sides of the packaging are required).

6. Pro-forma invoice, or invoice of the supplier.

Note regarding the documentation refered to in the section C:

In case of applying for import of the same batch of the medicine that was previously approved for import by the Institute, the applicant shall refer to the file number within which the documentation for a particular batch was submitted: manufacturer's batch release certificate, certificate of analysis from one of the laboratories that are OMCL members and manufacturing and control summary protocol (for vaccines).

D. Applicant for the issuance of export authorisation for immunological medicines, or medicines derived from human blood and plasma, which have marketing authorisation, and which were previously imported into Montenegro on the basis of an import authorisation issued by the Institute, shall submit the following documentation:

1. Application for the issuance of export authorisation for immunological medicines, or medicines derived from human blood and plasma, which have marketing authorisation containing the following documentation:
   - logo, name and address of the applicant, contact details, date, signature of the responsible person and seal (or electronic signature/seal)
   - subject of the application
   - name of the supplier
   - purpose of export
   - name and address of the buyer/recipient
   - information on medicines to be exported (name of the medicine, INN, pharmaceutical form, strength, type and size of the packaging, manufacturer, number and date of the marketing authorisation in Montenegro, batch number/s, quantity)

2. Pro-forma invoice, or invoice of the buyer.

3. Copy of the Decision by which the consent for import of a medicine that is the subject of export was issued.

GENERAL NOTES (applicable to all sections of this Instruction (A, B, C and D)):

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

After receiving the application with the documentation given in the sections A, B, C and D, 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 the prescribed fee is a condition for processing the application.

The application, as well as all documentation original of which is required (all prescribed statements, justified application of the import proposer, or other documents, at the request of the Institute) shall be submitted:
- in paper form to the Registry Office or
- in electronic form, in accordance with the law governing electronic identification and electronic document, to the Registry Office on a 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 uvozljekovi@cinmed.me with reference to the file number).

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