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 documentation to the Institute for medicines and medical devices, in accordance with Rulebook on more detailed conditions for the issuance of import authorization for a medicine that does not have marketing authorization.

* Requests for the import of immunological medicines, blood and plasma-derived medicines, and radiopharmaceutical medicines should be submitted separately from other medicines that do not fall into these categories.

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:

     Is the medicine being imported into Montenegro in the latest approved packaging in Montenegro, and which packaging is it?

     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, including the Certificate of analysis for each batch the import of which is applied for.

3. Certificate of analysis issued by one of the laboratories belonging to the Official Medicines Control Laboratory network, or the countries that have signed the agreement with the 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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