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

REQUIRED DOCUMENTATION FOR IMPORT OF VETERINARY MEDICINAL PRODUCTS THAT DO NOT HAVE MARKETING AUTHORIZATION AND EXPORT OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Applicant for obtaining import authorisation for veterinary medicinal produsts that do not have marketing authorisation shall submit the following documentation:

1. Application for obtaining import of veterinary medicinal products which contains the following:
   - name and address of the applicant and contact information;
   - subject of the application;
   - name and adress of the distributor;
   - name of the user, i.e. veterinary institution, which the medicinal product is being imported for;
   - total value of the import;
   - date, stamp and signature of the responsible person;

2. Table containing list of medicinal products to be imported, completed in line with the Instruction for completing table for import of veterinary medicinal products that do not have marketing authorisation and export of immunological veterinary medicinal products, available on the portal www.cinmed.me in the section Legislation/Instructions/Import/export of medicines. Completed table shall be submitted both in paper, along with the application (stamped and signed), and in electronic form to the e-mail address uvozljekovi@cinmed.me;

3. Evidence that the medicinal product 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 and which approved the packaging for which the application for import into Montenegro was submitted.

4. Evidence from the competent authority that a medicinal product has been manufactured in accordance with Guidelines on Good Manufacturing Practice (GMP certificate), in line with the Law on medicinal products;

5. Approved Summary of product characteristics and Package leaflet by the competent authority from one of countries refered to in item 3 (in English, or translated into Montenegrin). Additionally, it is necessary to provide Mock-up approved along with the summary and package leaflet, i.e. developed according to the approved text of the packaging (Labelling); If the Mock-up of the packaging of the medicinal product for which the import application has been submitted is not available, it is necessary to submit photos of the packaging (all sides of the packaging must be photographed).

6. Batch release certificate in accordance with *Internationally harmonised requirements for batch certification* for each batch of medicinal product to be imported;

7. When immunological veterinary medicinal product are being imported, in addition to the documentation from item 6, it is necessary to submit the following:
   - certificate of analysis from one of the laboratories belonging to the OMCL Network (Official Medicines Control Laboratory), for the same batch(es) which the manufacturer's certificate from item 6 has been submitted for;

- summary of manufacture and control protocol, for batch(es) which certificates of analysis were submitted for;

8. Pro-forma invoice, or invoice of the distributor;

Note:

1. If during the previous import of the medicinal product the applicant submitted to the Institute relevant documentation from items 3 - 5 of this Instruction, it is not necessary to submit the same documentation when submitting new applications for import of the same medicinal product (as long as the specified documents are valid).

2. In case of applying for import of the same batch of the medicinal product 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)

3. The application for import authorisation for medicinal products which are generic, or therapeutic parallel of medicinal products authorised for marketing by the Institute, shall be assessed only in following cases:

   - shortage of medicinal products authorised for marketing in Montenegro (in accordance with the Law on medicinal products, marketing authorisation holder is obliged to inform the Institute that a medicinal product is not on the market in Montenegro, i.e. that it is in short supply, with a specified period of time for the shortage), or

   - providing opinion of a veterinarian on the necesity to import an unauthorised medicinal product for a particular animal/group of animals justifying the reason why those animals cannot be treated with authorised medicinal product and specifying the exact quantity of the unauthorised medicinal product needed.

4. Obligation of the applicant for issuance of import authorisation for a veterinary medicinal product is to label the unauthorised imported medicinal product in accordance with provisions of the Rulebook on the contents and manner of labelling packaging of a veterinary medicine and contents of the package leaflet *("Official Gazette of Montenegro" No 82/23)*, i.e. to provide reference information on the medicinal product in a language understandable to veterinary professionals and persons administering veterinary medicinal product to animals in Montenegro.

5. The Institute retains the right to request additional documentation that is not specified in this Instruction in the course of issuing approval/authorization for import/export.

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Applicant for the issuance of export authorization for the immunological veterinary medicinal product shall submit the following documentation:

1. Cover letter of the application for export authorization for the immunological veterinary medicinal product containing the following:
   - logo, name and address of the applicant and contact information;
   - subject of the application;
   - name of the distributor;
   - name of the manufacturer;
   - name and address of the buyer/recipient;
   - purpose of export;
   - total value of export;
   - date, stamp and signature of the responsible person;

2. Table containing list of medicinal products to be exported, completed in line with the Instruction for completiting table for import of veterinary medicinal products that do not have marketing authorisation and export of immunological veterinary medicinal products, available on the portal www.cinmed.me in the section Legislation/Instructions/Import/export of medicines. Completed table should be submitted both in paper, along with the application (stamped and signed), and in electronic form to the e-mail address uvozljekovi@cinmed.me;

3. Pro-forma invoice, or invoice of the distributor;

4. Copy of the decision approving the import of the veterinary medicinal product which export is required for.