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. Cover letter of the 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 medicine 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 from the competent authority that a medicinal product has been granted marketing authorization in country of a manufacturer, European Union Member States, or in countries having the same standards for issuing marketing authorization (marketing authorization, or CPP certificate in English language, or translated into Montenegrin)

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 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);

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 OMCL laboratories, or from the national control laboratory

of the Agency for medicines and medical devices of Serbia, for the same batch(es) which the manufacturer's certificate from item 6 was 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;

9. Evidence of payment of prescribed fees.
   Payment is to be made to the Institute's gyro account, after issuance of the invoice. When making payment, it is necessary to make reference to the invoice number..

Note:

1. Application for import authorisation for medicinal products which are generic, or therapeutic parallel of medicines authorised for marketing by the Institute, shall be assessed only in following cases:
   - shortage of authorised medicinal products (when it is necessary to submit a statement from the marketing authorisation holder of the authorised medicinal product that the medicine is not on the market in Montenegro, that is, that there is a deficiency in the medicine supply, specifying the duration of 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.

2. If during the previous import of the medicine 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 medicine (as long as the specified documents are valid).

3. 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 *("Official Gazette of Montenegro" No 44/16)*, 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.

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.