

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

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Required documentation for obtaining import authorisation for veterinary medicinal products that do not have marketing authorisation is prescribed by the *Rulebook on more detailed conditions for the issuance of import authorization for a medicine that does not have marketing authorisation* (“Official Gazette of Montenegro” No 19/24 from 5.03.2024, 034/24 od 12.04.2024) available on the portal of the Institute [www.cinmed.me](http://www.cinmed.me), in the section Legislation/ Medicines/ Veterinary medicinal products.

The application for import of the veterinary medicine that does not have marketing authorisation shall, in the name and for the account of the import proposer, be submitted by the legal person possessing the wholesale authorisation for veterinary medicinal products.

The application for import, as well as the import proposer’s justified proposal, shall be submitted using the forms available on the portal of the Institute [www.cinmed.me](http://www.cinmed.me), in the section Veterinary medicinal products/ Import/export of medicinal products.

The excel table that is an integral part of the application shall be completed in line with the document - *Instruction for completing excel table for import of veterinary medicinal products that do not have marketing authorisation*, available on the portal [www.cinmed.me](http://www.cinmed.me), in the section Veterinary medicinal products/ Import/export of medicinal products.

Note:

1. If the applicant had submitted the appropriate documentation to the Institute within one of previous imports of the medicine, it is not necessary to submit the same documentation when submitting new applications for import of the same medicine, as long as mentioned documents are valid and refer to specific batches for which applications for import into Montenegro are submitted, except for the import proposer’s justified proposal, excel table with the list of medicinal products which the applications are submitted for and a proforma invoice, or invoice of the supplier.
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 and manufacturing and control summary protocol (for immunological medicinal products).
3. Application for import of medicinal products which are generic parallels in relation to medicinal products authorised for marketing in Montenegro, will be considered only in case of the following:
  - shortage of medicinal products that have marketing authorisation in Montenegro (in accordance with the Law on medicinal products, 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 abovementioned also applies to some therapeutic parallels (which is assessed by the Institute).

4. The applicant for the issuance of import authorization for the veterinary medicine shall label the medicine unauthorised for marketing that is to be imported in accordance with the provisions of the *Rulebook on conditions for granting marketing authorisation for veterinary medicinal product* (“*Official Gazette of Montenegro*” No 22/26 and 24/26), i.e. ensure that the reference information on the medicine is in the language that is understandable to veterinary professionals and persons administering the veterinary medicine to animals in Montenegro.

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

1. Cover letter of the application for export authorization for the immunological veterinary medicine containing the following:
  - logo, name and address of the applicant and contact information;
  - subject of the application;
  - name of the supplier;
  - 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 completing table for import of veterinary medicinal products that do not have marketing authorisation available on the portal of the Institute [www.cinmed.me](http://www.cinmed.me), in the section Veterinary medicinal products/ Import/export of medicinal products.
3. Pro-forma invoice, or invoice of the supplier;
4. Copy of the decision approving the import of the veterinary medicine the export of which is requested.