

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

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Required documentation for obtaining import authorisation for veterinary medicines 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 medicines.

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 medicines.

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 medicines/Import/export of medicines.

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 medicines that do not have marketing authorisation*, available on the portal [www.cinmed.me](http://www.cinmed.me), in the section Veterinary medicines/Import/export of medicines.

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 medicines 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 medicines).
3. Application for import of medicines 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 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 the contents and method of labelling the outer and immediate packaging of the veterinary medicine and contents of the package leaflet of the veterinary medicine* (“*Official Gazette of Montenegro*” No 82/23), 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 medicines 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 medicines to be exported, completed in line with the Instruction for completing table for import of veterinary medicines that do not have marketing authorisation available on the portal of the Institute [www.cinmed.me](http://www.cinmed.me), in the section Veterinary medicines/Import/export of medicines.
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.