CInMED
Institute for Medicines and Medical Devices of Montenegro

MANNER OF SUBMITTING APPLICATION AND DOCUMENTATION FOR OBTAINING MARKETING AUTHORISATION FOR VETERINARY MEDICINES

Application for marketing authorisation for a veterinary medicine shall be submitted to the Institute for medicines and medical devices (CInMED) in the term previously scheduled via phone **+382 20 310 280**.

The content of the application for marketing authorisation and necessary documentation are prescribed by the following legislation:

- Law on medicines *("Official Gazette of Montenegro", No 080/20), and*
- Rulebook on more detailed conditions for issuance of marketing authorisation *("Official Gazette of Montenegro", No. 21/16 and 55/19)*

Data on a medicine shall be identically stated in all submitted documentation, application, proposal of a summary of product characteristics, package leaflet and the packaging (in case that brand name of the medicine in some sections of the documentation differs from the name of the medicine given in other parts of the documentation, that shall be be stated and explained).

In accordance with Article 46 of the Law, the Institute does not assess whether there is a violation of intellectual, or industrial property in the process of marketing authorisation issuance. It is not required to provide protected designation of the name of the medicine in the documents that are submitted along the application for obtaining marketing authorisation.

Prescribed documentation for issuance of marketing authorisation shall be prepared in the following manner:

PART 1

1.A. Administrative data

Cover letter

Cover letter of the application for marketing authorisation shall be submitted on the form for the cover letter for the issuance of marketing authorization for a veterinary medicine and is available here. (*document in Montenegrin*).

If the documentation for several applications is submitted in the same file folder, it is necessary to submit a separate cover letter for each pharmaceutical form, strength, type and size of packaging.

Application for marketing authorisation

Application shall be submitted for each pharmaceutical form, strength, type and size of packaging of the medicine.

Form for the application for marketing authorisation is available here.

Forms must not be changed. Parts of the form that are not applicable to the application shall be marked with N/P (not applicable in Montenegrin) – one must not delete parts that cannot be completed due to lack of data.

The form shall be completed electronically, signed by the person responsible for obtaining marketing authorisation with a seal of the applicant, or signed with an electronic signature and with electronic seal in accordance with the law governing electronic identification and electronic document.

Standard EDQM terms shall be used when providing data on pharmaceutical strength, packaging and route of administration.

Justification of the application type

It is necessary to provide an explanation and evidence for the application type in accordance with Annex 3, Title III of the Rulebook on detailed conditions for issuance of marketing authorization - Requirements for specific marketing authorisation applications.

Legal documentation

Documentation on the applicant

- Excerpt from the Central Register of Business Entities (CRPS) in Montenegro
- Representation agreement (which must contain representation authorization for the territory of
  Montenegro, a list of products and established liability insurance for any damage caused by the
  use of a medicine in Montenegro). Please submit the original in paper, or electronic form in accordance with the law governing electronic identification and electronic document, or notarized copy of the contract.

Qualified pesons

Qualified person for obtainment, amendment, supplement and renewal of marketing authorization

- Statement of qualified person of the applicant/marketing authorization holder appointing qualified person for obtainment, amendment, supplement and renewal of marketing authorization;
- Proof of employment – applicant/marketing authorization holder shall submit full-time employment contract concluded with qualified person for obtainment, amendment, supplement and renewal of marketing authorization that defines duties of the person appointed to perform tasks regarding obtainment, amendment, supplement and renewal of marketing authorization in accordance with the Law;
- Evidence of professional qualifications;
- Confirmation from Tax Administration on registered employment insurance;
- CV.

Qualified persons for pharmacovigilance

- Statement of the qualified person of the applicant/Marketing Authorization holder appointing qualified person for pharmacovigilance and stating that the qualified person for pharmacovigilance is available 24 hours a day. The statement shall provide the 24-hour contact details of qualified person for pharmacovigilance (mobile phone, E-mail);
- Proof of employment – applicant/marketing authorization holder shall submit full-time employment contract concluded with qualified person for pharmacovigilance that defines duties of the person appointed to perform tasks regarding pharmacovigilance in accordance with the Law;
- Evidence of residence - a copy of ID card, or certificate of residence issued by a competent authority;
- Evidence of adequate professional qualifications – Article 44 Paragraph 5 of the Law on Medicines;
- Confirmation from Tax Administration on registered employment insurance
- CV.

If the applicant submitted given documentation with one of the previous applications, it is not necessary to submit the same documentation when submitting new applications (as long as given documents are valid), but only to specify with which previous subject/application the documentation in question was submitted.

Documentation for manufacturing site(s) of active substance and a medicine

Flow chart of manufacturers for Montenegro

It is necessary to submit a flow chart with names and addresses of manufacturers involved in all stages of the manufacture of active substance(s) and finished medicine. Manufacturers responsible for placing a medicine onto the market in Montenegro shall be specified.

All manufacturing and control sites mentioned throughout the documentation shall be consistent in terms of name, detailed address and activity, i.e. manufacturing stage (flow chart, Part 2, application for marketing authorisation and package leaflet). If there are any differences, please provide a justification.

Manufacturing sites of active substance(s)

For all sites involved in the manufacturing process of active substance and intermediates it is necessary to submit the statement of the Qualified Person (QP) on compliance with GMP requirements of:

- manufacturer that uses active substance as a starting material (if it comes from EEA member states) and
- manufacturer of a medicine responsible for placing a batch of a medicine onto the market.

It is also possible to submit one QP statement on behalf of manufacturers of a medicine that are required to provide a QP statement. QP statement should be prepared in accordance with current version of the EMA guideline: *Guidance for the template for the qualified person's declaration concerning good manufacturing practice (GMP) compliance of active substance manufacture "The QP declaration template*" that is available here.

CEP

If the quality of active substance is in accordance with the CEP certificate (*European Pharmacopoeia*
certificate of suitability), a copy of the CEP certificate shall be submited with completed Declaration
of Access part.

ASMF

If the documentation on active substance is submitted within the *Active Substance Master File* (ASMF) format, it is also necessary to submit the *ASMF restricted part*; RP. Along the ASMF it is necessary to submit the *Letter of access* and/or *Submission Letter* in accordance with the *Annex 2*, and *Annex 3* of the *Guideline on Active Substance Master File Procedure*, EMEA/CVMP/134/02 Rev 4/ Corr.

Please send ASMF restricted part to the address below:

Institute for Medicines and Medical Devices
Boulevard Ivana Crnojevića 64A
81000 Podgorica
Montenegro

Exceptionally, ASMF RP of medicines authorized within centralized procedure in the European Union,
shall be delivered upon the request of the Institute only.

Manufacturing sites

For all sites involved in the process of medicines manufacturing, it is necessary to submit the following:

- GMP certificate in line with the Article 118 of the Law on medicines and

- Manufacturing authorisation.

Status review of Medicine Marketing Authorizations in other countries

List of countries in which a marketing authorisation has been issued, in which an application for marketing authorisation was submitted, or rejected and in which the application for marketing authorisation was submitted, or rejected for the same medicine as the medicine for which the application was submitted in Montenegro. The name under which a medicine was granted a marketing authorization, dates and numbers of authorizations shall be provided. The list shall contain information in which countries the medicine has been placed onto the market. If the application for marketing authorization was rejected in some country, a statement of grounds on which such decision was made shall be provided.

Marketing authorisations issued in other countries

Along with marketing authorization (or decision on the renewal of marketing authorization), it is necessary to submit the latest approved texts of the Summary of Product Characteristics (SmPC) and the Package Leaflet (PL).

PART 1

B. Summary of product characteristics, labeling and package leaflet

Proposals of Summary of product characteristics and Package leaflet for Montenegro

Proposals of Summary of product characteristics (SmPC) and Package leaflet (PL) shall be submitted in the following forms:

- SmPC form for a veterinary medicine
- SmPC form for an immunological veterinary medicine
- PL form for a veterinary medicine

Forms shall be submitted in Word (docx), with specified data on the marketing authorization holder in Montenegro and aligned with texts of reference documents (approved in the country of origin, i.e. the reference medicine). The translation must be done by a professional using terminology specific for the area in question.

Proposals of SmPC and PL for Montenegro should refer only to those pharmaceutical forms, strength and/or package sizes of the medicine for which the application was submitted to CInMED.

In addition to the proposed text of the SmPC and PL for Montenegro, it is necessary to submit the reference documents that were used in the preparation of the proposal of the SmPC and PL for Montenegro: last approved versions of texts of the SmPC and PL in the country of origin of the reference medicine, in English (with the information in which country and when it was approved as such), i.e. in Serbian, Croatian or Bosnian language if these are countries of origin.

If the medicine is approved in the EU, it is necessary to submit the last approved SmPC and PL from the EMA (for CP procedure), from the reference country (for MRP, or DC procedure), or from the EU member state (for national procedure).

For a generic medicine, it is necessary to submit the last approved SmPC and PL (in English) of the reference medicine which the applicant refers to.

Proposal of labelling of outer and immediate package

Proposal of labelling of outer and immediate package shall be submitted in accordance with Rulebook on the contents and manner of labelling packaging of a veterinary medicine (“Official Gazette of Montenegro” No 44/16).

Labelling in Montenegrin shall be submited in Word (docx) using the Labelling form for a veterinary medicine. The labelling form shall be used **solely** for proposals of package in Montenegrin.

For medicines outer package of which is labelled in a foreign language, it is necessary to submit the following:

- mock-up/labelling of approved foreign package;
- proposal of additional label for Montenegro in accordance with the Article 2 of with Rulebook on the contents and manner of labelling packaging of a veterinary medicine ("Official Gazette of Montenegro" No 44/16);
- statement on the identity of the documentation approved by competent authority in the country of origin of proposed package and the documentation submitted to CInMED. Statement shall contain the information that the documentation, including any amendments, is identical to the documentation approved by competent authority in the country of origin of proposed package. If there are any differences in the documentation, they shall be stated and explained;
- statement of the applicant on the consumption of the medicine in Montenegro.

For medicines outer package of which is labelled in one of languages that are in official use in Montenegro, it is necessary to submit the following:

- mock-up/labelling of approved package;
- proposal of additional label which shall contain information on the name and address of the marketing authorisation holder in Montenegro and the space intended for the marketing authorisation number and the date of its issuance. If technically possible, medicine's name, pharmaceutical form, strength and package size may be provided on the additional label;
- statement on the identity of the documentation approved by a competent authority in the country of origin of proposed package and the documentation submitted to CInMED. Statement shall contain information that the documentation, including any amendments, is identical to the documentation approved by competent authority in the country of origin of proposed package. If there are any differences in the documentation, they shall be stated and explained.

PART 1

C. Expert summaries on quality, safety and efficacy

It is necessary to submit expert summaries on results of pharmaceutical (physico-chemical, biological or microbiological) tests, of the safety tests and residue tests, of the pre-clinical and clinical trials and of the tests assessing the potential risks posed by the veterinary medicinal product for the environment, with a justification for the use of relevant scientific data from the literature.

Expert summaries shall be signed and dated. Please provide the information about professional qualification, training and work experience of reports authors (CV).

PART 2

Quality

Pharmaceutical (physical-chemical, biological or microbiological) data

PART 3

Data on studies of safety and residues

PART 4

Data on pre-clinical and clinical trials

Documentation pertaining to pharmacovigilance in accordance with the Law
Statements of applicants Applicant shall attach to the application a statement on undertaking to submit standards and samples necessary for quality control at the request of the Institute, no later than 30 days.

Notes important for the preparation and submission of of applications:

The documentation submitted in paper form shall be prepared in A4 file folders with hard covers, with the following information available on the side (information must be printed - handwritten applications shall not be accepted):

- name of the medicine, strength, pharmaceutical form, package size and type;
- applicant;
- manufacturer.

The documentation shall be assembled according to the scheme and sequence referred to in the Annex 3 of the Rulebook on more detailed conditions for issuance of marketing authorisation.

If during the documentation assessment procedure, corrections of SmPC, PL, immediate, or outer package for Montenegro are required, each new corrected version of these documents shall be submitted in electronic form. Corrections to the previous version of SmPC and PL shall be done using the "*Track changes*" option (submit both "Track Changes" and "Clear" versions of corrected documents).

All documentation, except for the cover letter (which is submitted in paper form) and the application form (which is submitted in paper and electronic form), should preferably be submitted in electronic form, in the following formats: Word documents (docx), Excel Worksheets (xlsx) and PDF.

The application for marketing authorisation under the fast-track procedure in accordance with the Article 62 of the Law on medicines (that already obtained marketing authorisation in the EU member states within centralised procedure (CP), mutual recognition procedure (MRP), or decentralised procedure (DC)), shall be accompanied by:

- Assessment report issued by the EMA, or reference member state, for medicines authorized within centralised procedure (CP), mutual recognition procedure (MRP), or decentralised procedure (DC);
- Information on other member states that participated in DC, or MRP procedure;
- Statement of the applicant that the documentation on the basis of which marketing authorization is applied for in Montenegro is identical to the documentation on the basis of which the Assessment Report was created and issued, including all amendments approved until the day of submitting the application, that is, that submitted documentation is valid in European Union Member States; and
- Statement of the applicant committing to inform the Institute without delay on any permanent, or temporary withdrawal of the marketing authorization in the European Union, as well as on all emergency safety measures.

If the applicant possesses assessment reports for certain parts of the documentation (quality, safety and efficacy, or BE studies and PSUR) issued by competent regulatory bodies in the country of origin (regulatory bodies in neighboring countries with which CInMED signed cooperation agreements, or from the registration procedures in the EU), they may be submitted within Part 1. In this case, it is also necessary to submit a statement by the applicant/manufacturer on the identity of the documentation submitted to CInMED with the documentation approved by the regulatory body in the country which the assessment report was submitted from. If there are any differences in the documentation, they shall be stated and explained.