CInMED
Institute for Medicines and Medical Devices of Montenegro

MANNER OF SUBMITTING APPLICATION AND DOCUMENTATION FOR GRANTING MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCT

The application for the issuance of a marketing authorization for veterinary medicinal product and the documentation submitted with the application shall be presented in accordance with the Law on medicinal products ("Official Gazette of Montenegro" No. 14/26) (hereinafter: the Law) and the Rulebook on conditions for granting marketing authorization for veterinary medicinal product ("Official Gazette of Montenegro" No. 22/26) (hereinafter: the Rulebook).

The marketing authorisation application for a veterinary medicinal product shall be submitted to the registry office of the Institute for medicines and medical devices (hereinafter: the Institute) every working day between 09:00 and 12:00. Additional documentation may be submitted to the Institute's registry office or via the portal for electronic submission of documentation.

All documentation, except the cover letter (which shall be submitted in paper form) and the application form (which shall be submitted in paper or electronic form), shall be submitted in electronic format, in the following formats: Word document (docx), Excel Worksheets (xlsx) and PDF, following the EU dossier structure. Documentation for each section, i.e. Part (1–4) shall be submitted in a separate folder, clearly labelled with the name of the respective Part (e.g., Part 1, Part 2, Part 3, Part 4), whereby all documents belonging to a specific Part shall be included exclusively within the appropriately named folder. Document titles shall clearly and unambiguously describe the content of the document. The same principle shall apply when submitting additional documentation.

Information on the medicinal product must be identically stated in all submitted documentation, including the application form, the proposed Summary of product characteristics (SPC), the Package leaflet (PL) and the labelling (in the event that the invented name of the medicinal product differs in some parts of the documentation from the name used in other parts of the documentation, such differences must be clearly stated and justified).

If during the assessment of the documentation, corrections to the SPC, PL, immediate, or outer package for Montenegro are requested, each newly revised version of these documents shall be submitted in electronic form. Corrections to the previous version of SPC and PL must be made with the "Track changes" option activated (both the Track Changes and Clean versions of the corrected documents shall be submitted).

In accordance with the Article 221 of the Law, the Institute, in the procedure of issuing a marketing authorization for veterinary medicinal product does not assess whether there is any infringement of intellectual or industrial property rights. Therefore, documents submitted with the application for marketing authorisation do not need to contain trademark protection symbols related to the medicinal product name.

The prescribed documentation for granting a marketing authorisation for veterinary medicinal product shall be prepared as follows:

PART 1 - SUMMARY OF THE DOSSIER
Part 1A
Cover letter Cover letter accompanying the marketing authorisation application for veterinary medicinal product shall be submitted using the template available here (*document in Montenegrin*). If the documentation for several applications is submitted within the same dossier, it is necessary to submit a separate cover letter for each pharmaceutical form, strength, type and size of packaging.

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Application for marketing authorisation for veterinary medicinal product

The of marketing authorization application form for veterinary medicinal product may be downloaded here.

The format of the form must not be modified. Sections of the form that are not applicable to the application shall be marked N/A (not applicable) - sections that cannot be completed due to lack of data shall not be deleted.

The form must be completed electronically and signed by the person responsible for obtaining the marketing authorisation, bearing the stamp of the applicant or signed with an electronic signature and electronic seal in accordance with the law governing electronic identification and electronic document (the form must not be submitted as a scanned copy of an electronically signed document).

A separate application for issuance of marketing authorization for veterinary medicinal product shall be submitted for each pharmaceutical form, strength, type and pack size of the medicinal product.

When completing data related to the pharmaceutical form, packaging and route of administration, standard EDQM terms must be used.

Documentation on the applicant

- Extract from the Central Register of Business Entities (CRPS) in Montenegro
- A written authorisation issued by the marketing authorisation holder in the European Union or by the manufacturer of the medicinal product, confirming that the applicant is authorised to represent them in the procedure for granting a marketing authorisation in Montenegro, using the template available on the Institute's portal. The original document shall be submitted in paper or electronic form, in accordance with the law governing electronic identification and electronic documents, or as a notarized copy.

If the applicant has allready submitted this documentation with the previous applications, it is not necessary to resubmit it, provided that the documents remain valid. In such cases, the applicant shall indicate the previous case/application number under which the documentation was submitted.

Responsible persons

Responsible person for the marketing authorization procedure (granting and variation)

- Statement of the responsible person of the applicant/marketing authorization holder appointing the responsible person for obtaining and varying the marketing authorization for veterinary medicinal product;
- Proof of employment - the applicant/ marketing authorization must have concluded a full-time employment contract with the responsible person defining their duties regarding obtaining, variation and amendment of the marketing authorization, in accordance with the applicable regulations;
- Proof of professional qualifications;
- Confirmation from Tax Administration confirming registration for employment insurance;
- Curriculum Vitae (CV).

Responsible person for pharmacovigilance

- Statement of the responsible person of the applicant/ marketing authorization holder appointing the person responsible for pharmacovigilance;
- Proof of employment or other form of engagement with the marketing authorisation holder;

- Proof of residence - a copy of identity card, or certificate of residence issued by a competent authority;
- Proof of appropriate qualifications – Article 220 Paragraph 6 of the Law or proof of permanent and continuous assistance from a veterinarian if the person responsible for pharmacovigilance does not hold a degree in veterinary medicine;
- Confirmation from Tax Administration confirming registration for employment insurance
- Curriculum Vitae (CV).

If the applicant has already submitted this documentation with a previous application, it does not need to be resubmitted, provided the documents remain valid). In such cases, the applicant shall indicate the previous case/application number under which the documentation was submitted.

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

Flow chart of manufacturers for Montenegro

It is necessary to submit a flow chart with names and addresses of all manufacturers involved in all stages of the manufacture of active substance(s) (including the sites of production of intermediate(s), as well as micronization and sterilization sites, where applicable) and finished medicinal product. Manufacturers responsible for placing the medicinal product on the market in Montenegro shall also be specified.

All manufacturing and control sites mentioned throughout the documentation must be consistent regarding name, detailed address and activity, i.e. manufacturing stage (flow chart, Part 2, application for marketing authorisation and package leaflet). Any discrepancies must be explained.

Sites of production of the active substance(s)

For all sites involved in the manufacturing process of active substance and intermediates (including the site of micronization, where applicable), a Qualified Person (QP) declaration confirming compliance with GMP requirements shall be provided, from:

- the manufacturer of the medicinal product using active substance as a starting material (if located in an EEA member state) and
- the manufacturer responsible for batch release of the medicinal product.

It is also possible to submit a single QP declaration on behalf of manufacturers of a medicinal product who are required to provide a QP declaration. QP declaration shall 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.

For manufacturing sites of sterile active substances, a valid GMP certificate issued by the regulatory authority of an EEA or an EUMRA country must also be provided.

CEP

If the quality of active substance is supported by a CEP certificate (*European Pharmacopoeia Certificate of Suitability*), a copy of the CEP certificate with the completed *Declaration of Access* must be provided in Part 1, in addition to Part 2, or a *Letter of Access* using the template available on the EDQM website (where applicable).

ASMF

If the documentation on the active substance is submitted in the *Active Substance Master File* (ASMF) format, in addition to being an integral part of Part 2 submitted by the local representative of the manufacturer, the ASMF holder must submit the ASMF *Applicant's part* (AP) and ASMF *restricted part* (RP). The AP version submitted by the ASMF holder must be identical to the version submitted within Part 2 of the dossier. A *Letter of Access* and/or *Submission Letter* must

also be submitted in accordance with Annex 2 and Annex 3 of the *Guideline on Active Substance Master File Procedure (EMEA/CVMP/134/02 Rev 4/ Corr.).*

The AP and RP of the ASMF shall be submitted electronically by the ASMF holder, via the following link: https://secure.cinmed.me//eservis/strani-korisnik.

When submitting AP and RP of the ASMF, in the "short description" field, the procedure concerned (e.g. marketing authorization, variation, response during clock stop, etc.), as well as the name of the medicinal product and the reference number (if available) must be clearly indicated.

Exceptionally, for medicinal products authorized through the centralized procedure in the European Union, the ASMF RP shall be submitted upon request of the Institute.

Manufacturing sites

For all sites involved in the manufacturing process of the medicinal product, the following shall be submitted:

- valid evidence of compliance with Good Manufacturing Practice requirements (GMP certificate) issued by the regulatory authority of an EEA or EUMRA country
- manufacturing authorization.

Pharmacovigilance data

The documentation on pharmacovigilance shall be submitted in accordance with the Law, Rulebook and Rulebook on pharmacovigilance system for veterinary medicinal products ("Official Gazette of Montenegro" No. 23/26)

Overview of the marketing authorization status of the medicinal product in other countries

List of countries in which a marketing authorisation has been granted, revoked, as well as the countries in which an application has been submitted or refused shall be provided.

For each country, the approved name of the medicinal product, the marketing authorization number and date, and information on whether the product has been placed on the market shall be specified.

If the application for a marketing authorization has been refused in any country, a decision refusing the application together with the justification must be provided.

Copies of the Marketing Authorization(s) (or decision on the renewal of Marketing Authorization) issued in other countries

Copies of the marketing authorisation (or renewal decision) issued in other countries shall be submitted together with the latest approved SPC and PL texts in those countries.

PART 1B

Summary of product characteristics, labeling and package leaflet

Proposed summary of the product characteristics and package leaflet

Proposed texts of Summary of product characteristics (SPC) and Package leaflet (PL) shall be submitted in Montenegrin language, using the templates available on the Institute's portal.

Proposed texts shall be submitted in Word format (docx), with specified datils on the marketing authorisation holder in Montenegro and aligned with texts of reference documents (approved in the country of origin, i.e. the reference medicinal product). The translation must be performed by a professional using appropriate scientific and regulatory.

Proposals of SPC and PL for Montenegro should refer only to those pharmaceutical forms, strength and/or package sizes of the medicinal product for which the application has been submitted to the Institute.

In addition to the proposed text of the SmPC and PL for Montenegro, it is necessary to submit the reference documents used in the preparation of the proposaed texts of the SmPC and PL for Montenegro, namely: the latest approved versions of the SmPC and PL in the country of origin of the reference medicinal product, in English (with the information of the country and the date of approval), or in Serbian or Croatian if these are countries of origin.

If the medicinal product has been authorised in the European Union, it is necessary to submit the last approved SPC and PL from the EMA (for the Centralised Procedure- CP), the reference Member State (for MRP, or DC procedure), or a member state of the European Union (for the national procedure).

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

Proposed labelling of immediate and outer packaging

The applicant shall submit the proposed outer and immediate packaging labelling of the medicinal product, in accordance with the Rulebook.

The proposed text for packaging labelled in the Montenegrin language shall be submitted using the template available on the Institute's portal, in Word format (docx). The template for outer and immediate packaging labelling shall be used solely for proposals of packaging texts in Montenegrin.

For medicinal products whose outer packaging is labelled in a foreign language, the following shall be submitted:

- mock-up/labelling of approved foreign packaging;
- draft of the additional label in accordance with the Article 23 of the Rulebook;
- a statement of identity of the documentation approved by competent authority in the country from which the proposed package originates and the documentation submitted to Institute. The statement shall confirm that the documentation, including all variations and amendments, is identical to the documentation approved by the competent authority in the country from which the proposed packaging originates. If there are differences in the documentation, they must be clearly described and justified;
- a statement by the applicant on the annual consumption of the medicinal product in Montenegro.

For medicinal products whose outer package is labelled in a languages in official use in Montenegro, the following shall be submitted:

- mock-up/labelling of approved packaging;
- proposal of additional label in accordance with Article 24 of the Rulebook on labelling;
- a statement of identity of the documentation approved by the competent authority in the country from which the proposed packaging originates and the documentation submitted to the Institute. The statement must include confirmation that the documentation, including all variations and amendments, is identical to the documentation approved by the competent authority in the country from which the proposed packaging. If there are differences in the documentation, they must be clearly described and justified.

PART 1C

Expert reports on quality, safety and efficacy

Expert reports shall be prepared in accordance to the Rulebook, and must be signed and dated. The information about professional qualification, training and work experience of reports authors (curriculum vitae) shall also be submitted.
PART 2 Quality documentation (physicochemical, biological or microbiological information)
PART 3 Safety documentation (safety and residues tests)
PART 4 Efficacy documentation (pre-clinical studies and clinical trial(s))
Applicant's statement The applicant shall submit a statement confirming that standards and samples necessary for quality control will be provided upon request of the Institute, no later than 30 days from the date of such request.

For applications for a marketing authorization submitted under the accelerated procedure in accordance with Article 232 of the Law, for medicinal products already authorised in the European Union through Centralised Procedure (CP), Mutual Recognition Procedure (MRP) or Decentralised Procedure (DCP) the applicant shall submit documentation in accordance with Article 10 of the Rulebook, including:

- identical documentation (a consolidated file covering Parts 1 - 4) that has been approved in the centralized procedure (CP), decentralized procedure (DC) or mutual recognition procedure (MRP);
- a statement confirming that the documentation submitted for the marketing authorization application in Montenegro is identical to the documentation used to prepare and issue the Assessment Report, including all variations approved up to the date of submission of the application, i.e. that the submitted documentation is currently valid in the Member States of the European Union. If differences exist compared to the documentation approved in CP, DC or MRP procedures, they must be clearly described and justified;
- a list of variations submitted and approved in the CP, DC or MRP up to the date of submission of the application to the Institute, including information on the status of each variation in the procedure, as well as whether they have been implemented in the dossier submitted to the Institute. For variations that have been approved and implemented, the relevant approvals from the CP, MRP or DC procedure shall be submitted;
- the *Assessment Report* issued by the EMA or by the reference Member State in the DC or MRP procedure, as well as *Assessment of the responses to the outstanding questions raised by the RMS and CMSs*, as well as the preliminary reports from all stages of the MRP or DC procedure, where available;
- a statement by the applicant confirming that the Institute will be informed without delay in the event of a permanent or temporary suspension or withdrawal of the marketing authorization in the European Union, as well as of any urgent safety measures.