CInMED
Institute for Medicines and Medical Devices of Montenegro

GUIDANCE ON THE SUBMISSION OF APPLICATION AND DOCUMENTATION FOR THE CONTINUATION OF VALIDITY OF A MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCT

Pursuant to Article 353a of the Law on Medicinal Products (*Official Gazette of Montenegro*, Nos. 14/26 and 94/26) (hereinafter: the Law), the marketing authorisation holder (hereinafter: the MAH) of a veterinary medicinal product for which a marketing authorisation was granted in accordance with the legislation in force prior to the entry into force of this Law shall submit to the Institute for Medicines and Medical Devices (hereinafter: the Institute) an application for the continuation of the validity of the marketing authorisation no later than six months before the expiry of the validity period of the marketing authorisation.

The application shall be submitted to the Registry Office of the Institute.

Documentation shall be submitted exclusively in electronic form, in the following formats: *Word* document (docx), *Excel Worksheets* (xlsx) and PDF, following the EU veterinary marketing authorisation dossier format. Document titles shall clearly and unambiguously describe the content of the respective document.

In addition to the documentation submitted in electronic form, the following shall be submitted:
– a cover letter in paper form (bearing the signature and stamp of the applicant), in two copies;
– a completed Application Form for the continuation of the validity of the marketing authorisation for a veterinary medicinal product, in paper form (bearing the signature and stamp of the applicant), or in electronic form, signed with an electronic signature and sealed with an electronic seal in accordance with the law governing electronic identification and electronic documents.

In accordance with Article 221 of the Law, in the procedure for granting a marketing authorisation for a veterinary medicinal product, the Institute does not assess whether there is an infringement of intellectual property rights, i.e. industrial property rights. In the documentation submitted with the application for the continuation of validity of the marketing authorisation for a veterinary medicinal product, trademark protection symbols related to the medicinal product name shall not be included.

The application for the continuation of validity of the marketing authorisation for a veterinary medicinal product shall be accompanied by the following:

PART 1 - Summary of the dossier

1.0. Cover letter of the application for the continuation of validity of marketing authorisation using the template available on CInMED portal.

1.1. Table of contents

2. Completed Application form for the continuation of validity of marketing authorisation available on the CInMED portal.

- The format of the application form shall not be altered. Sections of the form that are not applicable to the application shall be marked with N/A (not applicable); sections that cannot be completed due to lack of data shall not be deleted;
- The form shall be completed electronically and signed by the person responsible for communication in the procedure for the continuation of validity of the marketing authorisation for a medicinal product, bearing the applicant's stamp, or signed with an electronic signature and sealed with an electronic seal in accordance with the law governing electronic identification and electronic documents (the form shall not be submitted as a scanned copy of an electronically signed document);
- MAH shall submit a completed application form for each pharmaceutical form, strength, type and pack size of the medicinal product;
- When entering data on the pharmaceutical form, packaging and route of administration, it is necessary to use standard EDQM terms;
- In the *List of Variations* section of the form, a chronological list of all variations submitted / approved by the Institute shall be provided, including the reference number under which each variation was received by the Institute. The information may also be submitted as an annex to the application form, in a separate document entitled *List of Variations in Montenegro*.

As an attachment to the application form, the following documentation shall also be submitted in electronic format:

- **Overview of the marketing authorisation status of the medicinal product in other countries**
  An overview shall be provided of the countries in which a marketing authorisation has been graned, as well as information on the countries where the medicinal product has been placed on the market, including the date of first placing on the market. If the application for MA has been rejected in any country, or a marketing authorisation has been revoked by a competent authority, a justification describing the reasons for such decision shall be provided.

- Chronological list of all variations submitted / approved in the EU (if applicable)

- **Documentation for the manufacturing site(s) of the active substance and a medicinal product**
  Flow chart for Montenegro – The chart must indicate the name and addresses of the manufacturers involved in all stages of active substance manufacturing (including the sites for the manufacture of active substance intermediates, as well as micronisation and sterilisation sites, where applicable) and of the finished product. In cases where the flow chart lists only batch release sites for the EU, it is necessary to explicitly indicate whether the same manufacturers are responsible for batch release in Montenegro as well.

  For all sites involved in the manufacturing process of the 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 which uses the active substance as a starting material (if established in the EEA member states), and

- the manufacturer of a medicinal product responsible for batch release.

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. The QP declaration shall be prepared in accordance with the current version of 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"*.

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

For all sites involved in the manufacturing process of the medicinal product, it is necessary to submit a valid GMP certificate issued by the Institute or by the competent authority of an EEA Member state or EUMRA.

- **Information and documentation about the MAH and the person responsible for pharmacovigilance** (it is necessary to submit the documentation, in case that the MAH has not submit it along with some of previous applications for MA). The documentation shall be submitted in accordance with the guidance *Manner of submitting application and documentation for obtaining marketing authorisation for veterinary medicinal product*, available on the CInMED portal.

- A statement undertaking to provide the standards and samples necessary for quality control, upon the request of the CInMED, no later than within 30 days.

3. Summary of product characteristics, labelling and Package leaflet

An updated versions of Summary of Product Characteristics (SmPC), Package Leaflet (PIL) and Labelling shall be submitted, using the templates available on the Institute's website. All proposed changes shall be clearly indicated using the *Track Changes* function in comparison with the currently approved texts.

A statement from the MAH shall be provided confirming that the product information has been updated in accordance with the latest scientific knowledge, including the conclusions of assessments and recommendations published in the European Union. The statement shall include information on when the product information was last updated prior to the submission of the application for the continuation of validity of the marketing authorisation, with reference to the most recent variation through which the change was implemented.

During the procedure, Institute may, based on the assessment of the submitted documentation, request amendments to the texts of the SmPC, PIL and labelling. In such cases, the MAH shall be required to submit a separate application for the approval of a variation, in accordance with the guidance Manner of submitting application and documentation for variations for veterinary medicinal product, available on the Institute's website.

4. Information on experts

- ***Quality Expert Statement*** confirming that the quality of the medicinal product, with regard to manufacturing and control methods, has been regularly updated through variation procedures to take into account scientific and technical innovations, and that the quality of the product complies with applicable requirements, including relevant monographs of the European Pharmacopoeia (Ph. Eur.) and applicable EU and VICH quality guidelines. The statement shall also include the currently approved specifications for the active substance and the finished product, as well as the qualitative and quantitative composition in terms of active substances and excipients.

- ***Clinical Expert Statement on the Benefit-Risk Evaluation*** confirming that:
  - all relevant data necessary for the assessment of the risk - benefit balance of the medicinal product have been submitted to the Institute;
  - no new safety or efficacy data are available that would alter or lead to a new assessment of the risk - benefit balance of the medicinal product;
  - that, based on the available safety data, the validity of the marketing authorisation may continue for an unlimited period;
  - the product information is in line with current scientific knowledge, including relevant conclusions and recommendations applicable in the European Union.

The statements shall be signed and dated and accompanied by the curriculum vitae (CV) of the expert who signed the statement.

Note: If, during the assessment of the documentation, it is considered that the submitted statements are insufficient, the Institute shall require the submission of the complete Part 2, Part 3 and Part 4 documentation.

A statement from the marketing authorisation holder shall be submitted confirming that, upon request by the Institute, the complete Part 2, Part 3 and Part 4 documentation will be provided.

5. Pharmacovigilance documentation

- The summary of the PSMF, which should contain the information prescribed by article 24 of the Rulebook on pharmacovigilance system for veterinary medicinal products (“Official Gazette of Montenegro” No. 23/26)
- Annual Signal Management Report or PSUR for the period from the issuance of marketing authorisation up to two months before the submission of the application for continuation of validity of marketing authorisation.