

## MANNER OF SUBMISSION OF APPLICATIONS AND DOCUMENTATION FOR VARIATIONS

An application for the variation for a veterinary medicinal product shall be submitted to the Institute for Medicines and Medical Devices (hereinafter: the Institute).

All documentation, except for the cover letter and the application form (which shall be submitted duly signed and stamped in paper form and in electronic format), must be submitted exclusively in electronic format, in the following formats: Word documents (docx), Excel worksheets (xlsx) and PDF, following the EU dossier structure.

The application shall be prepared in accordance with the Law on Medicines (“Official Gazette of Montenegro”, No. 14/26) and Rulebook on conditions for granting marketing authorisation for veterinary medicinal product (“Official Gazette of Montenegro”, No. 22/26) (hereinafter: Rulebook).

The following shall be submitted together with the application for notification/approval of a variation:

- A cover letter for the notification/approval of the variation, indicating the medicinal products concerned and providing a brief summary of the proposed changes. If the variation is submitted at the request of the Institute, arising as an obligation following the granting of the marketing authorisation or a previous variation, this shall be clearly stated in the cover letter;
- The application form for notification/approval of the variation (using the template available on the Institute’s portal);
- A checklist indicating compliance with the conditions for classification of variations, in accordance with the guidance on the classification of variations requiring assessment (where applicable);
- Documentation relating to the variation and containing sufficient data to enable its assessment. For variations for which the Rulebook or the guidance on the classification of variations requiring assessment does not specify the required documentation, relevant data/documentation supporting the requested change shall be submitted;
- A document (Word or PDF) containing a comparative presentation of the current and proposed data (“present/proposed”), where the changes are too extensive to be fully detailed in the application form.

For changes concerning the restricted part of the Active Substance Master File (ASMF restricted part; RP), the restricted part of the ASMF shall be submitted to the Institute’s address (Institute for Medicines and Medical Devices of Montenegro, Bulevar Ivana Crnojevića 64A, 81000 Podgorica, Montenegro) or via the link <https://secure.cinmed.me/eservis/strani-korisnik>. The ASMF shall be accompanied by a Letter of Access and/or a Submission Letter in accordance with Annex 2 or Annex 3 of the Guideline on Active Substance Master File Procedure, EMEA/CVMP/134/02 Rev 4/Corr. Exceptionally, for medicinal products authorised through the centralised procedure in the European Union, the ASMF RP shall be submitted only upon request of the Institute.

Where the general description of a variation is included in the Annex V to the Rulebook, establishing a list of variations not requiring assessment (VNRA), but any of the relevant requirements laid down therein is not fulfilled, an application for a variation requiring assessment (VRA) shall be submitted and classified in accordance with the guidance on the classification of variations requiring assessment referred to in Article 32 to the Rulebook, available at the link [EMA/CMDv/7381/2021 - Guidance on the details of the classification of variations requiring assessment](#).

Where a particular variation is not listed in the Annex to the Guidance on the details of the classification of variations requiring assessment, and it is not listed in the Annex V to the Rulebook, it should be classified under the relevant code level of the appropriate classification code from the Annex to the guidance on the classification of variations requiring assessment, using the “z” variation.

Grouping of variations shall not apply to variations not requiring assessment, nor may such variations be included in the groupings of variations requiring assessment, even if they are consequential to or related to a variation requiring assessment.

In order to ensure more efficient processing of applications, marketing authorisation holders are kindly requested to comply with the following instructions and notes when preparing variation applications:

- The date of implementation of the change must be indicated in the designated field of the application form;
- For medicinal products authorised in the EU through the CP/MRP/DCP procedures (assessed under the accelerated marketing authorisation procedure in Montenegro), where available, the variation approval issued by EMA/RMS together with the Assessment Report shall be submitted, where applicable; if the medicinal product is not authorised in the EU, but a variation approval is available in the country of manufacture/origin of the packaging, it shall be attached to the application;
- For changes resulting from the outcome of a referral procedure, the relevant report/recommendation shall be submitted;
- For changes relating to updates of product information (SmPC, PIL, labelling), the updated document shall be submitted in Word format with tracked changes, as well as a clean version incorporating the changes into the latest version approved by the Institute, in accordance with the SmPC/PIL/labelling template. In the case of simultaneous submission of multiple variations (within one or more applications), this shall be indicated in the document by way of comments;
- For changes concerning updates of the CEP certificate for the active substance, a document/statement providing information on the changes in the documentation that led to the CEP update shall be submitted (it is not sufficient to indicate only the certificate numbers in a present/proposed comparison), as well as information on whether the update results in changes to the quality documentation of the active substance from the finished product manufacturer;
- If not all CEP revisions for the active substance have been notified to the Institute, justification for non-notification of all revisions shall be provided;
- For variations involving changes to the medicinal product packaging, where the last approved graphical layout of the packaging in Montenegro has been authorised by the Institute, the proposed packaging text shall be submitted using the template available on the Institute's portal.