CInMED
Institut za ljekove
i medicinska sredstva Crne Gore
Institute for Medicines and
Medical Devices of Montenegro

MANNER OF SUBMITTING APPLICATION AND DOCUMENTATION FOR THE RENEWAL OF MARKETING AUTHORISATION FOR MEDICINES FOR HUMAN USE

Application for the renewal of a marketing authorization for a medicinal product for human use shall be submitted to the Institute for Medicines and Medical Devices (hereinafter: CInMED) at a pre-arranged appointment. The appointment for submitting the application may be scheduled by phone at +382 20 310 280.

The application for renewal of the marketing authorization shall be prepared in accordance with the Law on Medicines (*Official Gazette of Montenegro*, Nos. 80/20, 84/24 and 35/25) and the Rulebook on Detailed Conditions for the Issuance of a Marketing Authorization (*Official Gazette of Montenegro*, Nos. 21/16 and 55/19).

All documentation, except for the cover letter (which shall be submitted in paper form), must be submitted exclusively in electronic format, in the following file types: Word documents (docx), Excel worksheets (xlsx) and PDF, following the CTD format. The file names must clearly and unambiguously describe the content of the document. If a new Representation Agreement or amendments to an already submitted Agreement are provided, the documentation may be submitted either in paper and/or electronic form.

Documentation submitted in paper form shall be submitted in A4 filing folders, providing the information on the following:

- Name of the medicine, strength, pharmaceutical form, type and pack size;
- Marketing authorisation holder;
- Manufacturer.

In accordance with Article 46 of the Law, the Institute, in the procedure of granting a marketing authorization, does not assess whether there is an infringement of intellectual or industrial property rights. Protection marks of the medicinal product name shall not be indicated in the documents submitted with the application for renewal of the marketing authorization.

The following documentation shall be submitted with the application for renewal of the marketing authorization:

MODULE 1 – Administrative data

1.0. Cover letter of the application for the renewal of marketing authorisation on the form available on CInMED portal.

1.1. Table of contents

1.2. A duly filled-in Application form for the renewal of the marketing authorisation, available on the CInMED portal.

- Application form template must not be altered. Sections of the form that are not applicable to the

application shall be marked as N/A (Not Applicable) – parts that cannot be filled in due to lack of data must not be deleted;

- Application form shall be filled in electronically, signed by the person responsible for the renewal of the marketing authorization, and stamped by the applicant, or signed with an electronic signature and 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);
- The applicant shall submit a duly filled-in application form for each pharmaceutical form, strength, type and pack size of the medicinal product;
- When filling in the data on the pharmaceutical form, packaging and route of administration, standard EDQM terms must be used;
- In the section "List of variations" of the form, a chronological list shall be provided of all variations submitted/approved in CInMED (type IA/IB, type II, variations for which a new authorization has been issued), indicating the reference number under which each variation was received in CInMED. The list must also include information on all notifications, urgent safety measures and PSURs submitted during the period of validity of the marketing authorization (unless they are part of any of the variations listed).

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

- **Overview of the status of marketing authorisations in other countries**
  List of countries which authorised a medicine in question for marketing and the information in which countries the medicine has been placed on the market. If the application for marketing authorisation was rejected in a certain country, it is necessary to provide reasons for it.

- **Chronological list of all conditions/obligations after the issuance/last renewal of marketing authorisation,** with the date of submission of documentation to CInMED (if applicable).

- **Revised list of remaining conditions and specific obligations** (if applicable)

- **Documentation for the manufacturing site of the active substance and the medicine**
  Flow chart for Montenegro – The flow chart must indicate the names and addresses of the manufacturers involved in all stages of the manufacturing of the active substance(s) (including the sites of intermediate production of the active substance, as well as micronisation and sterilisation sites, where applicable) and of the finished product. In cases where the chart lists only the marketing sites for the EU, it is necessary to explicitly indicate whether the same manufacturers are responsible for placing the medicinal product on the market in Montenegro as well.

  For all sites involved in the manufacturing process of the active substance and intermediates (including the site of micronization, if applicable), a declaration by the Qualified Person (QP) confirming compliance with GMP requirements shall be provided from:
  - manufacturer of the medicine that uses the active substance as a starting material (if it is from an

EEA member state) and
- manufacturer of the medicine responsible for placing the batch of the medicine on the market.

It is also possible to submit one QP declaration on behalf of the medicine manufacturers that are required to provide a QP declaration. QP declaration shall be prepared in line with 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 all sites involved in the manufacturing process of the medicine, it is necessary to submit a valid proof of the fulfillment of conditions envisaged by the Good Manufacturing Practice (GMP certificate) issued by the regulatory body of one of the EEA or EUMRA member states.

- **Information and documentation about the marketing authorisation holder and the person responsible for renewal of the marketing authorisation and pharmacovigilance** (it is necessary to submit the documentation, in case that the marketing authorisation holder has not submit it along with some of previous applications for marketing authorisation, amendments to it, or its renewal).

1.3. Summary of product characteristics, labelling and Package leaflet

Proposals of the Summary of product chaqracteristics (SPC) and Package leaflet (PL) in Montenegrin are required to be submitted using the forms available on CInMED portal (Word, docx).

Proposal of labelling of outer and immediate packaging shall be submitted in accordance with Rulebook on the contents and method of labelling the outer and immediate packaging of a medicine and contents of the package leaflet ("Official Gazette of Montenegro" No 21/16 and 67/18) (hereinafter: Rulebook on labelling).

Proposal of the labelling for packaging labelled in Montenegrin shall be submitted using the form available on CInMED portal (Word, docx).

For medicinal products whose outer packaging is labelled in a foreign language, the following shall be submitted:
- mock-up/labelling of an approved foreign packaging;
- proposal of additional sticker in accordance with Article 25 of the Rulebook on labelling.

For medicinal products whose outer packaging is labelled in a language in official use in Montenegro, the following shall be submitted:
- mock-up/labelling of approved package;
- proposal of additional sticker in accordance with Article 26 of the Rulebook on labelling..

1.4. Information on experts

Curricula Vitae (CVs) of the experts who prepared the expert summaries on the pharmaceutical-chemical-biological, pharmacological-toxicological, and clinical documentation shall be submitted, together with signed declarations of the experts indicating the date of preparation of the submitted expert summaries.

1.8. Documentation pertaining to pharmacovigilance

- Summary of the EU PSMF (or global PSMF summary) and the local PSMF summary. The PSMF summary shall contain the information prescribed by the Law on Medicines, Article 46, paragraph 1, point 12;
- The most recent PSUR/PBRER for medicinal products for which submission is required under the Law on Medicines. The submission frequency of the PSUR/PBRER shall be aligned with the EURD list. If the submission frequency of the PSUR/PBRER is not determined by the EURD list, the marketing authorization holder is obliged to submit to CInMED, together with the PSUR/PBRER, a statement on the proposed submission frequency of the PSUR/PBRER.
- The most recent RMP. For medicinal products without an RMP, the marketing authorization holder shall provide a statement declaring that the RMP has not been submitted and explaining the reasons for its non-submission (e.g. not required, in preparation, etc.).
- A statement on additional risk minimization measures, including a plan for their implementation, if such implementation is required.

MODULE 2 - Expert summaries on quality, safety and efficacy:

2.3. Addendum to Quality Overall Summary *(Addendum to QOS)*

2.4. Addendum to Non-clinical Overview *(Addendum to NCO)*

2.5. Addendum to Clinical Overview *(Addendum to CO)*

Prepared in line with the *Guideline on the processing of renewals in the centralised procedure* EMEA/CHMP/2990/00 Rev.5 from 14 June 2016. In case of any deviation of the submitted documentation from the above-mentioned guideline, a justification shall be provided.

Marketing authorisation holder shall submit a statement undertaking to deliver the standards and samples necessary for quality control at the request of the Institute, within 30 days at the latest.