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 renewal of marketing authorisation for a medicine for human use shall be submitted to the Institute for medicines and medical devices (hereinafter: CInMED) in the term previously scheduled via phone **+382 20 310 280.**

Application for renewal of marketing authorization shall be made in accordance with the Law on Medicines („Official Gazette of Montenegro", No 80/20) and the Rulebook on More Detailed Conditions for Issuance of Marketing Authorisation for a Medicine („Official Gazette of Montenegro", No 21/16 and 55/19).

All documentation, except for the cover letter (which is submitted in paper form), shall be submitted exclusively in electronic form in the following formats: *Word* document (docx), *Excel Worksheets* (xlsx) and PDF, following the CTD format. When submitting a new Representation Agreement, or amendments to an already submitted Agreement, the documentation may be submitted in paper and/or electronic form.

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

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

In accordance with the Article 46 of the Law, within the process of issuance of marketing authorisation for a medicine, CInMED does not assess whether there is a violation of intellectual or industrial property. Documentation submitted along with the application for renewal of marketing authorisation is not required to contain the protection designation of the name of the medicine.

Along the application for the renewal of marketing authorisation, it is necessary to submit the following:

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. Application form for the renewal of marketing authorisation available on the CInMED portal.

- Application form itself must not be changed. Parts of the form that cannot be completed due to missing data should be marked N/P („not applicable" in Montenegrin);
- Application form must be filled out electronically, signed by the person responsible for the renewal of marketing authorisation, with the seal of the applicant, or signed with an electronic signature and electronic seal in accordance with the law governing electronic identification and electronic documents. The applicant shall submit an application form separately for each dosage form, strength,

type and package size;

- When filling out data on dosage forms, package and administration route for a medicine, standard terms published on the EDQM website should be followed.
- In the part of the form - List of variations, it is necessary to submit a chronological list of all variations that have been reported to/approved by CInMED. The list should also contain data on all notifications, emergency safety measures and PSUR that were submitted during the period of validity of the marketing authorisation (if they are not an integral part of one of variations provided in the list).

The following documentation shall be in electronic form attached to the application form:

- **Overview of the status of marketing authorisations in other countries**
  It is necessary to submit a list of countries where a particular medicine is authorised and 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(s) of active substance and a medicine**
  Flow chart for Montenegro – It is necessary to submit a flow chart with precisely stated names and addresses of manufacturers involved in all stages of the manufacture of active substance/s and finished product. It is necessary to specify the manufacturers responsible for placing the medicine on the market in Montenegro.

  For all sites involved in the manufacturing process of the active substance(s) and intermediates (including the site of micronization, if applicable), it is necessary to submit a declaration from the Qualified Person (QP) on compliance with GMP requirements of:
  - 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 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 compliance with requirements of 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 Characteristics (SmPC) and Package Leaflet (PL) are required to be submitted using the forms available on CInMED portal (Word (docx)).
- Proposal of labelling of outer and immediate package shall be submitted in accordance with Rulebook on the contents and method of labelling the outer and immediate package 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 in Montenegrin shall be submitted using the form available on CInMED portal (Word (docx)).

  If the proposed package is labelled in foreign language, the following shall be submitted:
  - mock-up/labelling of approved foreign package;
  - proposal of additional label in accordance with Article 25 of the Rulebook on labelling;
  - a statement on identity of the documentation approved by the competent authority in the country of origin of proposed package and the documentation submitted to CInMED. If there are differences in the documentation, they should be listed and explained.

  If the proposed package is labelled in one of languages that are in official use in Montenegro, the following shall be submitted:
  - mock-up/labelling of approved package;
  - proposal of additional label in accordance with Article 26 of the Rulebook on labelling;
  - a statement on identity of the documentation approved by the competent authority in the country of origin of proposed package and the documentation submitted to CInMED. If there are differences in the documentation, they should be listed and explained.

1.4. Information on experts

Biographies (CVs) of experts who have prepared expert summaries on pharmaceutical-chemical-biological, pharmacological-toxicological and clinical documentation and expert statements on the date of completion of submitted expert summaries shall be provided.

1.8. Documentation pertaining to pharmacovigilance

- Summary of EU PSMF (or the Summary of global PSMF for medicines that are not authorised for marketing in the EU) and the Summary of local PSMF. Summary of PSMF shall contain information prescribed by the Law on Medicines, Article 46, paragraph 1, item 12;
- Last version of PSUR/PBRER for medicines for which submission of mentioned document is prescribed by the Law on Medicines. The frequency of submission of PSUR/PBRER shall be in line

with the EURD list. In case that the time period between DLP (Data lock point) and the date of submission of apllication for renewal to CInMED is longer than 90 days, marketing authorisation holder shall submit a statement that they:

- continuously monitor and evaluate safety of the medicine in order to detect signals and inform CInMED on it in a timely manner, in case of changes in the benefit/risk ratio of use of the medicine
- continuously monitor the latest scientific knowledge, current safety assessments and submit variations, with the aim of harmonizing reference information on the medicine with the latest scientific knowledge.

If the frequency of submission of PSUR/PBRER is not determined by the EURD list, marketing authorisation holder shall, in addition to PSUR/PBRER, submit a statement with a proposal of frequency of submission of PSUR/PBRER to CInMED.

- Last version of RMP. If last version of RMP has already been submitted to CInMED, marketing authorisation holder shall submit a statement stating that the last version of RMP has been submitted to CInMED. For medicines that do not have RMP, marketing authorisation holder shall state that the RMP was not submitted with a justification for not submitting it (e.g. it is not required, it is in preparation phase...).
- Statement on additional risk minimization measures with a proposal 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.

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.

Along with the application for renewal of marketing authorisation issued under the accelerated procedure (medicines that have already received marketing authorisation in European Union member states through centralized procedure, mutual recognition procedure or a decentralized procedure), it is necessary to submit a statement from the applicant that the dynamics of documentation changes in Montenegro followed the dynamics of documentation changes in the corresponding procedure in the EU.