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

MANNER OF SUBMITTING APPLICATION AND DOCUMENTATION FOR OBTAINING MARKETING AUTHORIZATION FOR MEDICINES FOR HUMAN USE

Application for issuance of marketing authorization for a medicine for human use shall be submitted to the Institute for Medicines and Medical Devices (hereinafter: CInMED) at a previously scheduled term via telephone: **+382 20 310 280.**

Application for obtaining marketing authorization shall be made in accordance with the Law on Medicines ("Official Gazette of Montenegro" No 80/20) i and the Rulebook on More Detailed Conditions for Issuance of Medicine Marketing Authorization („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* documents (docx), *Excel Worksheets* (xlsx) and PDF, accompanying the CTD format. The Representation Agreement may be submitted in paper form and/or in electronic form.

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

- Name of the medicine, strength, pharmaceutical form, type and size of package;
- Applicant;
- Manufacturer.

In accordance with the Article 46 of the Law, the Institute in the procedure of issuance of Marketing Authorization for a medicine shall not assess whether there is a violation of intellectual, or industrial property. It is not necessary to provide the protection designations of the medicine's name in the documentation submitted with the application for marketing authorization.

Application for Marketing Authorization for a medicine shall be accompanied by:

MODULE 1 – Administrative data

1.0. Cover letter of the application for issuance of Marketing Authorization on the form available on the CInMED portal.

1.1. Content

1.2. Form of the application for issuance of Marketing Authorization on the form available on the CInMED portal.

- Form itself must not be amended. Parts of the form that are not applicable to the application shall be marked with N/A (not applicable) - parts that cannot be completed due to lack of data shall not be deleted;
- Form shall be fulfilled electronically, signed by a person responsible for obtaining marketing authorization, with the seal of the applicant or with an electronic signature and seal in accordance

with the law governing electronic identification and electronic document;
- Applicant shall submit completed application form for each pharmaceutical form, strength, type and size of the package of a medicine;
- When entering the data on the pharmaceutical form, package and route of administration, it is necessary to use EDQM standard terms.

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

➢ **Documentation for manufacturing site(s) of active substance and a medicine**

Flow chart of manufacturers for Montenegro – Name and address of manufacturers involved in all stages of the manufacture of active substance(s) and finished medicine shall be provided in the flow chart (the data shall be in line with the data provided in Module 3). Manufacturers responsible for placing a medicine onto the market in Montenegro shall be specified.

For all sites involved in the manufacturing process of active substance and intermediates (including the site of micronization, if applicable), it is necessary to submit a statement of the Qualified Person (QP) on compliance with GMP requirements of:
- manufacturer that uses active substance as a starting material (if it comes from EEA member states) and
- manufacturer of a medicine responsible for placing a batch of a medicine onto the market.

It is also possible to submit one QP statement on behalf of manufacturers of a medicine that are required to provide a QP statement. QP statement should be prepared in accordance with the 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*".

* If the quality of active substance is in accordance with the CEP certificate (*European Pharmacopoeia certificate of suitability*), a copy of the CEP certificate should be submited with completed *Declaration of Access* part.

**If the documentation on active substance is submitted within the *Active Substance Master File* (ASMF) format, it is also necessary to submit the *ASMF restricted part*; RP. Along the ASMF it is necessary to submit the *Letter of access* and/or *Submission Letter* in accordance with the *Annex 2, and Annex 3* of the *Guideline on Active Substance Master File Procedure*, CHMP/QWP/227/02 Rev 4/ Corr.

Please send ASMF restricted part to the address:
Institute for Medicines and Medical Devices
Boulevard Ivana Crnojevića 64A
81000 Podgorica
Montenegro

Exceptionally, ASMF RP of medicines authorized within centralized procedure in the European Union, shall be delivered upon the request of the Institute only.

For all sites involved in the process of medicines manufacturing, it is necessary to submit the following:

- valid evidence of compliance with requirements of Good Manufacturing Practice (GMP certificate) issued by a regulatory body in one of the EEA member states, or EUMRA
- Manufacturing Authorization.

➢ **Status review of Medicine Marketing Authorizations in other countries**

List of countries in which Marketing Authorization has been issued, withdrawn and in which a medicine is in the process of obtaining marketing authorization. The name under which a medicine was granted a Marketing Authorization, dates and numbers of authorizations should be provided. The list shall contain information in which countries the medicine has been placed onto the market. If the application for Marketing Authorization was rejected in some country, a statement of grounds on which such decision was made should be provided.

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

Along with Marketing Authorization (or decision on the renewal of the Marketing Authorization), it is necessary to submit the latest approved texts of the Summary of Product Characteristics (SPC) and the Package Leaflet (PL).

➢ **Documentation on the applicant**

- Excerpt from the Central Register of Business Entities (CRPS) in Montenegro
- Representation agreement (which must contain representation authorization for the territory of Montenegro, a list of products and established liability insurance for any damage caused by the use of a medicine in Montenegro). Please submit the original in paper, or electronic form in accordance with the law governing electronic identification and electronic document, or notarized copy of the contract.

If the applicant submitted given documentation with one of the previous applications, it is not necessary to submit the same documentation when submitting new applications (as long as given documents are valid), but only to specify with which previous subject/application the documentation in question was submitted.

Qualified persons

Qualified person for obtainment, amendment, supplement and renewal of Marketing Authorization

- Statement of qualified person of the applicant/Marketing Authorization Holder appointing qualified person for obtainment, amendment, supplement and renewal of Marketing Authorization;

- Proof of employment – applicant/Marketing Authorization holder shall submit full-time employment contract concluded with qualified person for obtainment, amendment, supplement and renewal of Marketing Authorization that defines duties of the person appointed to perform tasks regarding obtainment, amendment, supplement and renewal of Marketing Authorization in accordance with the law;
- Evidence of professional qualifications;
- Confirmation from Tax Administration on registered employment insurance;
- CV.

Qualified person for pharmacovigilance

- Statement of the qualified person of the applicant/Marketing Authorization holder appointing qualified person for pharmacovigilance and stating that the qualified person for pharmacovigilance is available 24 hours a day. The statement shall provide the 24-hour contact details of qualified person for pharmacovigilance (mobile phone, E-mail);
- Proof of employment – applicant/Marketing Authorization holder shall submit full-time employment contract concluded with qualified person pharmacovigilance that defines duties of the person appointed to perform tasks regarding pharmacovigilance in accordance with the law;
- Evidence of residence - a copy of ID card, or certificate of residence issued by a competent authority;
- Evidence of adequate professional qualifications – Article 44 Paragraph 5 of the Law on Medicines;
- Confirmation from Tax Administration on registered employment insurance;
- CV.

If the applicant submitted given documentation with one of the previous applications, it is not necessary to submit the same documentation when submitting new applications (as long as given documents are valid), but only to specify with which previous subject/application the documentation in question was submitted.

1.3. Summary of product characteristics, labeling and package leaflet

Proposals of Summary of product characteristics (SmPC) and Package leaflet (PL) shall be submitted on forms available on CInMED portal (in Word format (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 No 67/18) (hereinafter: Rulebook on labelling).

Labelling in Montenegrin shall be submitted on the form available on CInMED portal (in Word format (docx)).

For medicines outer package of which is labelled in a foreign language, it is necessary to submit the

following:

- mock-up/*labelling* of approved foreign package;
- proposal of additional label in accordance with the Article 25 of the Rulebook on labelling;
- statement on the identity of the documentation approved by competent authority in the country of origin of proposed package and the documentation submitted to CInMED. Statement shall contain information that the documentation, including any amendments, is identical to the documentation approved by competent authority in the country of origin of proposed package. If there are differences in the documentation, they shall be stated and explained;
- statement by the applicant that the consumption of the medicine in Montenegro will be less than 5000 packages per year.

For medicines outer package of which is labelled in one of languages that are in official use in Montenegro, it is necessary to submit the following:

- mock-up/*labelling* of approved package;
- proposal of additional label in accordance with the Article 26 of the Rulebook on labelling;
- statement on the identity of the documentation approved by competent authority in the country of origin of proposed package and the documentation submitted to CInMED. Statement shall contain information that the documentation, including any amendments, is identical to the documentation approved by competent authority in the country of origin of proposed package. If there are differences in the documentation, they shall be stated 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 statements of experts on the date of completion of submitted expert summaries shall be provided.

1.5. Specific conditions for different types of application (explanation for the type of application)

It is necessary to submit explanation and evidence of the type of application in accordance with Annex 2, part II of the Rulebook on More Detailed Conditions for Issuance of Marketing Authorization for a Medicine ("Official Gazette of Montenegro" No 21/16 and 55/19) - Specific Marketing Authorization dossiers and requirements.

1.6. Environmental Risk Assessment, in accordance Rulebook on More Detailed Conditions for Issuance of Marketing Authorization for a Medicine, or justification for the omission of it.

1.7. Information on medicines for the treatment of rare diseases in humans ("*Orphan*" medicines), if applicable.

1.8. Documentation pertaining to pharmacovigilance

- Summary of EU and local PSMF. Summary of EU and local PSMF shall contain information

prescribed by the Law on Medicines, Article 46, paragraph 1, item 12;

- Latest PSUR/PBRER for medicines for which they are requested to be provided by the EURD list;
- If the frequency of submission of PSUR/PBRER is not determined by the EURD list, it is necessary to provide a statement with a proposal of frequency of submission of PSUR/PBRER after obtaining marketing authorization;
- Latest RMP. For medicines that do not have a RMP, Marketing Authorization holder shall provide a statement with a justification for not submitting it;
- Statement on additional risk minimization measures with a proposal for their implementation, if such implementation is required.

1.9. Information on clinical trials, if applicable

- Statement confirming that clinical trials conducted outside of European Union Member States meet ethical requirements in accordance with regulations on clinical trials in the European Union.

Module 2 – Expert summaries on quality, safety and efficacy

2.1. Table of Contents
2.2. Introduction
2.3. Quality Overall Summary
2.4. Nonclinical Overview
2.5. Clinical Overview
2.6. Nonclinical Written and Tabulated Summaries
2.7. Clinical Summary

Module 3 - Quality

Module 4 – Nonclinical Study Reports

Module 5 – Clinical Study Reports

Applicant shall enclose a statement committing to submit standards and samples necessary for quality control at the request of the Institute, no later than 30 days.

Application for obtaining Marketing Authorization within a fast-track procedure in accordance with the Article 62 of the Law on medicines shall be accompanied by the following:

- Assessment Report issued by EMA, or reference member state, for medicines authorized within centralised procedure (CP), decentralised procedure (DC), or mutual recognition procedure (MRP);
- List of other member states that were involved in DC, or MRP procedure;
- Statement of the applicant that the documentation on the basis of which marketing authorization is applied for in Montenegro is identical to the documentation on the basis of which the Assessment Report was created and issued, including all changes approved until the day of submitting the

application, that is, that submitted documentation is valid in European Union Member States; and

- Statement of the applicant committing to inform the Institute without delay on any permanent, or temporary withdrawal of the marketing authorization in the European Union, as well as on all emergency safety measures.

If the applicant possesses *Quality, Non-clinical and Clinical Assessment of the response to the (outstanding) questions raised by RMS and CMSs* from MRP, or DC procedure, or Asessment Reports of the medicine documentation issued by the competent authority in the country of origin of proposed package, they shall be submitted within the documentation of Module 1.