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

INSTRUCTION ON THE MANNER OF SUBMITTING RISK MANAGEMENT PLAN (RMP)

Risk Management Plan (RMP) approved in the EU within these procedures must be submitted for the following medicines:

1) medicines authorised in the EU via centralised procedure (CP)
2) medicines authorised in the EU via mutual recognition procedure (MRP) and via decentralised procedure (DCP) and for medicines authorised via national procedure (NP).

EU RMP and RMP for a medicine that is not approved in the EU shall be submitted to the Institute for Medicines and Medical Devices (CInMED) at any point of life cycle of a medicine, as part of the documentation for obtaining marketing authorisation and after obtaining the authorisation.

1. Medicines that are in the procedure for obtaining marketing authorisation

The latest approved version of EU RMP is required to be submitted as part of the documentation for obtaining marketing authorisation (Module 1).

In case that within the course of the procedure for obtaining marketing authorisation in CInMED new version of RMP is approved in the EU, it must be submitted as additional documentation.

If a new version of RMP is available at the same time as PSUR, it shall be submitted to CInMED together with PSUR. If not, it shall be submitted separately.

Notice: If EU RMP for medicines processed by CInMED is not submitted, it is necessary to amend the documentation before the end of the procedure.

When submitting the documentation that refers to RMP, applicants is obliged to follow the instructions listed below:

1) EU RMP should be submitted to CInMED in electronic form, on a CD. The name of the document on a CD should be given according to the following principle: Brand name of a medicine and name of the document type (RMP)
2) If marketing authorisation holder submits approved EU RMPs for several different medicines (different INN) at the same time, documents refering to one INN should be on a separate CD, with a separate cover letter
3) Cover letter signed by responsible person of MAH and submitted together with EU RMP should include the following information:
   - **subject:** EU RMP, with stated version and date of approval in the EU and EU competent authority which approved RMP and educational material, i.e. other risk minimisation measures if envisaged by EU RMP
   - medicines **(brand name, strength, pharmaceutical form, packaging)** that EU RMP refers to, including numbers of cases for medicines which are in the procedure for obtaining marketing authorisation

- if applicable, overview of additional risk minimisation measures from approved EU RMP which will be implemented in Montenegro, stating related safety risks for which additional risk minimisation measured need to be conducted
- information on whether the documents that are part of additional risk minimization measures that will be implemented in Montenegro, are approved or pending approval in ALIMS and HALMED
- if EU RMP envisages distribution of educational materials and etc., to healthcare professionals, it is necessary to submit the proposal of the communication plan, stating health institutions/ healthcare professionals to whom the material will be distributed, manner of communication and date of communication
- in case that additional risk minimization measures are implemented after the issuance of the marketing authorisation, and based on the RMP submitted during the process of obtaining the authorisation, the marketing authorization holder is obliged to, upon the implementation, notify CInMED on it. **In this case, the RMP on the basis of which additional risk minimization measures have been implemented should be submitted to CInMED and as a post-authorisation RMP, accompanied by an appropriate cover letter containing detailed information on safety risks, additional minimization measures, as well as the manner and dynamics of their implementation in Montenegro.**

2. Medicines that obtained marketing authorisation in montenegro

The latest version of EU RMP shall be reported/submitted to CInMED through appropriate variation.

When submitting the documentation that refers to RMP, the applicant is obliged to follow the instructions listed below:

1) EU RMP should be submitted to CInMED in electronic form, on a CD. The name of the document on a CD should be given according to the following principle: Brand name of a medicine and name of the document type (RMP)
2) If marketing authorisation holder submits approved EU RMPs for several different medicines (different INN) at the same time, documents refering to one INN should be on a separate CD, with a separate cover letter
3) Cover letter signed by responsible person of MAH and submitted together with approved EU RMP **should be addresed to Pharmacovigilance Department and include the following information:**
   - **subject:** EU RMP, with stated version and date of approval in the EU and EU competent authority which approved RMP and educational material, i.e. other risk minimisation measures if envisaged by EU RMP
   - medicines **(brand name, strength, pharmaceutical form, packaging)** that EU RMP refers to, including authorisation numbers

- if applicable, overview of additional risk minimisation measures from approved EU RMP which will be implemented in Montenegro, stating related safety risks for which additional risk minimisation measured need to be conducted
- information on whether the documents that are part of additional risk minimization measures that will be implemented in Montenegro, are approved or pending approval in ALIMS and HALMED. **In the event that mentioned documents pend approval, it is necessary to state the date of submission to ALIMS/HALMED. Once the material has been approved by ALIMS/HALMED, the marketing authorisation holder shall with no delay inform CInMED on it and also deliver the plan for conducting additional risk minimisation measures in Montenegro. CInMED recommends that marketing authorisation holder in Montenegro distributes those materials that were first to obtain the approval.**
- if EU RMP envisages distribution of educational materials and etc., to healthcare professionals, it is necessary to submit the proposal of the communication plan, stating health institutions/ healthcare professionals to whom the material will be distributed, manner of communication and date of communication
- if EU RMP envisages additional risk minimisation measures (eg. educational material) it is necessary to submit the statement on compliance of the material that is delivered to healthcare professionals in Montenegro to educational material approved in the EU, or by ALIMS or HALMED. **Educational material in Serbian or Croatian approved by ALIMS, i.e. HALMED may be distributed in Montenegro with corrected data referring to local regulatory authority and marketing authorization holder.** If educational materials are delivered to healthcare professionals personally, or by the post, it is necessary to put a label designed by CInMED on the front of the envelope. The label is available here.
- **prepared educational material to be distributed to healthcare professionals/patients in Montenegro shall be submitted to CInMED for approval only in the case when approved educational materials in one of the languages in official use in Montenegro are not available.**
- if EU RMP that envisages additional risk minimisation measures that do not differ to previously submitted version of RMP is submitted, the cover letter should also contain all the information on safety risks, additional conducted risk minimization measures and educational materials in use, noting that there is no difference with the previously submitted version of the RMP. If differences compared to the previous version exist, they should be clearly listed in the cover letter, along with a plan for their implementation

*** Additional note: If RMP is submitted for the medicine which is not on the market (and will not be any time soon), additional risk minimization measures in terms of education of healthcare professionals and distribution of education materials, need to be implemented prior to placing the medicine onto the market. In this case, the communication plan may be submitted subsequently, i.e. not at the same time as the the RMP, along with an appropriate information on it in the cover letter. The communication plan may be updated in accordance with new information on healthcare professionals who prescribe/dispense/administer medicines, with an obligation that the marketing**

authorisation holder submit an updated version to CInMED in the form of additional documentation for the appropriate RMP.

Following the completion of the implementation of additional risk minimisation measures in line with the communication plan, the marketing authorisation holder shall inform CInMED on it (via e-mail).

On this occasion, marketing authorisation holder is obliged to submit the educational materials that have been distributed in Montenegro, in PDF format, via e-mail.