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

INSTRUCTION ON THE MANNER OF SUBMITTING PERIODIC SAFETY UPDATE REPORT

When submitting post-authorisation documentation on safety of a medicine (*Periodic Safety Update Report - PSUR/PBRER*) to the Office of CInMED, please ensure that the instructions listed below are followed, so it could be received and filed in an appropriate manner:

1. Post-authorisation PSUR/PBRER shall be submitted to the **Pharmacovigilance Department** (it should be stated in the cover letter that is along with PSUR/PBRER submitted to CInMED)
2. Marketing authorisation holder shall follow the frequency of submission of PSUR/PBRER defined by the **EURD list.** At the request of CInMED, marketing authorisation holder shall submit PSUR beyond the EURD frequency of submission of PSUR/PBRER
3. **PSUR, PBRER,** 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 depending on whether it is a PBRER (Periodic Benefit Risk Evaluation Ratio), PSUR (Periodic Safety Update Report), or other appropriate document pertaining to post-marketing safety of a medicine;
4. If marketing authorisation holder submits documents on post-marketing safety **for several different medicines** (different INN) documents referring to one INN should be on a separate CD, with separate cover letter
5. **Cover letter** submitted to the Pharmacovigilance Department together with PSUR/PBRER should include the following information:
   - **subject**: post-authorisation PSUR/PBRER
   - all medicines **(brand name, strength, pharmaceutical form, packaging)** that PSUR/PBRER refers to should be stated in a cover letter, including **authorisation numbers**
   - **period of time** that PSUR refers to, IBD (international birth date, if known), DLP (data lock point for the next PSUR, if known)
   - whether **changes in company reference safety information** (*CCDS – Company Core Data Sheet*) occured in the period of time that PSUR/PBRER refers to
6. Cover letter must be **signed by person responsible for pharmacovigilance** of marketing authorisation holder of a medicine in Montenegro, or in case of his/her unavailability, by a back-up responsible person, if the information on the appointment of a back-up is submitted to the Institute.