CInMED
Institute for Medicines and Medical Devices of Montenegro

INSTRUCTION ON THE MANNER OF SUBMITTING THE SUMMARY OF PSMF

According to the Law on Medicines (Official Gazette of Montenegro, No. 14/26), *Pharmacovigilance System Master File (PSMF)* is a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products.

Marketing authorization holder is obliged to submit an **integral PSMF (EU or global - for medicnes that are not authorised in the EU) and a local integral PSMF, at the request of CInMED**, within 7 days from the date of receipt of the request.

Submitting of Summary of PSMF

Each application for marketing authorization, as well as application for renewal of marketing authorization, shall be accompanied by the **EU Summary PSMF**, prepared in accordance with the *Guideline on good pharmacovigilance practices (GVP) - Module II*. With regards to medicines that are not authorized in the EU, a marketing authorization holder is required to submit the Summary of Global PSMF.

Additionally, each application for marketing authorization, as well as application for renewal of marketing authorization shall be accompanied by the **Summary of local PSMF** containing the following information:

- Contact details of the person responsible for pharmacovigilance;
- Contact details of the back-up responsible person for pharmacovigilance, in case that he/she is appointed;
- Statement that a marketing authorization holder has the system necessary to fulfill duties in the area of pharmacovigilance that are defined by the Law on medicines (Official Gazette of Montenegro, No. 14/26);
- Version, approval date and the location where local PSMF to which the submitted summary refers is kept.