21 June 2023

Instructions for the submission of Summaries of risk management plans

Summaries of risk management plans (RMP Part VI: Summary of the risk management plan) are required to be submitted for medicinal products authorised by national, mutual recognition and decentralised procedures. Fimea publishes on its website the English versions of the summaries of the approved RMPs prepared by the Marketing authorisation holder. For centrally authorised products, the RMP summaries are published on the European Medicines Agency's website.

After the implementation of the revision of Good pharmacovigilance Practices (GVP) Module V – Risk Management systems https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf the submission of Finnish and Swedish translations of the RMP summaries are not required.

The approved English version of the RMP summary shall be submitted within 60 days from the granting of the marketing authorisation. If the RMP document is presented using a variation application, or if the variation application affects the summary of the RMP document, the RMP summary shall be submitted within 60 days from the approval of the variation.

The RMP summaries shall be submitted as PDF-documents by email to turva@fimea.fi.