EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Risk management plans

Table of contents

Companies are required submit a risk-management plan (RMP) to the European Medicines Agency (EMA) when applying for a marketing authorisation. To help applicants, guidance is available on how to submit RMPs.

RMPs include information on:

- a medicine's safety profile;
- how its risks will be prevented or minimised in patients;
- plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine;
- measuring the effectiveness of risk-minimisation measures.

In the European Union (EU), companies must **submit an RMP** to the Agency at the time of application for a marketing authorisation. For medicines that do not have an RMP, one may be required with any application involving a significant change to the marketing authorisation.

In addition, for nationally authorised medicinal products, any national competent authority (NCA) in the EU can request an RMP whenever there is a concern about a risk affecting the **benefit-risk** balance of a medicine.

RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. Companies need to submit an **updated RMP**:

- at the request of EMA or an NCA;
- whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimisation milestone being reached.

When justified by risk, the competent authority can also specify a date for submission c next RMP as a condition of the marketing authorisation in exceptional cases.

RMPs can only be submitted at the same time as the periodic safety update report (PSUR) if the change in the RMP comes as a consequence of the PSUR.

For more information, see:

- Module V – Risk-management systems on Good pharmacovigilance practices
- Practical questions and answers to support the implementation of the variations guidelines

Guidance on RMP format

Guidance on the format for RMPs is available in a single document. This is available in PDF and in Word formats below.

Guidance on the format of the risk management plan (RMP) in the EU - in integrated format (Rev. 2.0.1) (PDF/492.64 KB)

Adopted

First published: 30/03/2017
Last updated: 30/11/2018
Legal effective date: 31/03/2017
EMA/164014/2018 Rev. 2.0.1

Guidance on the format of the risk management plan (RMP) in the EU - in integrated format (Rev. 2.0.1) (DOC/564.5 KB)

Adopted

First published: 30/03/2017
Last updated: 30/11/2018
Legal effective date: 31/03/2017
EMA/164014/2018 Rev. 2.0.1

Risk management plans for COVID-19 vaccines

Marketing authorisation applicants for COVID-19 vaccines should follow EMA's guidance on preparing RMPs for COVID-19 vaccines, together with the guidance in this section and Good pharmacovigilance practices, which apply to all medicines.

The guidance reflects special **safety monitoring** measures for COVID-19 vaccines by providing considerations and requirements for several sections of the RMP.

EMA publishes the full body of the RMP (plus Annex 4) for all authorised COVID-19 vaccines, in line with its exceptional transparency measures for COVID-19 medicines.

Consideration on core requirements for RMPs of COVID-19 vaccines (PDF/339.77 KB)

First published: 13/11/2020

Last updated: 01/09/2022
EMA/PRAC/73244/2022

For more information, see:

- Guidance for medicine developers and other stakeholders on COVID-19
- COVID-19 vaccines: development, evaluation, approval and monitoring

Publication of RMPs and their summaries (updated)

Update: From 20 October 2023, EMA is publishing **RMPs** (main body and annexes 4 and 6) for all centrally authorised products:

- initial evaluations;
- RMP updates.

EMA no longer publishes **RMP summaries** from the same date.

The aim is to **increase transparency** of the safety review process for all centrally authorised products.

The RMP or RMP summary is available on each medicine page. Alternatively, a historical list of all RMP summaries is available.

For further information on RMPs and on the anonymisation of personal data (PD) and assessment of commercially confidential information (CCI) during the preparation of RMPs, see:

Guidance on the anonymisation of protected personal data and assessment of commercially confidential information during the preparation of RMPs (main body and annexes 4 and 6) (PDF/167.22 KB)

First published: 04/11/2022
EMA/781194/2021

Template: Declaration for the risk management plan (RMP) publication (DOCX/17.73 KB) (updated)

First published: 28/08/2023
Last updated: 29/09/2023

Post-authorisation guidance

Guidance is available for marketing authorisation holders of centrally authorised medicines on the procedural and regulatory aspects to the RMP lifecycle during the post authorisation phase:

- Risk management plans (RMP) in post-authorisation phase: questions and answers

Superseded templates

Guidance on the format of the risk management plan (RMP) in the EU - in integrated format (Rev. 2) (PDF/539.09 KB)

First published: 30/03/2017
Last updated: 17/01/2019
EMA/PRAC/613102/2015 Rev.2 accompanying GVP Module V Rev.2

Guidance on format of the risk-management plan in the European Union – in integrated format (Rev. 1) (PDF/314.42 KB)

Adopted

First published: 08/11/2012
Last updated: 21/08/2013
Legal effective date: 22/08/2013
EMA/465932/2013

Guidance on format of the risk-management plan in the European Union for generics (Rev. 1) (PDF/230.41 KB)

Adopted

First published: 08/11/2012
Last updated: 21/08/2013
Legal effective date: 22/08/2013
EMA/465933/2013

Template for European Union risk-management plan (superseded) (PDF/190.06 KB)

First published: 27/09/2006
Last updated: 27/09/2006
EMEA/192632/2006

Related content

- Good pharmacovigilance practices
- Guidance for medicine developers and other stakeholders on COVID-19

Topics

- Regulatory and procedural guidance
- Pharmacovigilance

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