



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Questions and answers on the risk management plan (RMP) summary

In March 2014 the European Medicines Agency (EMA) began publishing summaries of risk management plans (RMP) for centrally authorised medicines. A new format for RMP summaries, introduced in March 2017, is to be used for new medicines or for updating RMP summaries for existing medicines.

What is a risk management plan?

A risk management plan (RMP) is submitted as part of the dossier that is evaluated by regulatory authorities before a medicine can be authorised. The RMP is regularly reviewed and it is updated as new information becomes available. RMPs cover a medicine's safety profile and include measures taken to prevent or minimise any harm to patients from the medicine.

All medicines have both benefits and risks; a medicine is authorised only if the benefits outweigh the risks. The RMP details the known concerns about the safety of the medicine and how they can be managed. When a medicine is first authorised, it is impossible to know everything about its safety as the medicine will have been tested in relatively few patients and for a limited duration. Some side effects are very rare, or occur only in patients with other conditions or particular genetic makeup. All medicines are carefully monitored after marketing (pharmacovigilance), so that new side effects can be detected quickly, and regulatory authorities can ensure that the benefits outweigh the risks at all times. The RMP may also outline any additional studies that have been recommended at the time of licensing to provide more information on the medicine's safety profile.

More information about RMPs can be found on the Agency's website: ema.europa.eu/Human/regulatory/Pharmacovigilance/Risk-management_plans.

Why is EMA publishing summaries of RMPs?

Publishing RMP summaries is a further step towards increased transparency and improved public access to information on medicines, as required by the European pharmacovigilance legislation¹ and

¹ Regulation (EU) No 1235/2010 and Directive 2010/84/EU.



reflected in key guiding principles of the Agency. RMP summaries complement the public-friendly information already available in the Agency's summaries of the European public assessment report (also known as EPAR summaries) and the package leaflet. They allow stakeholders, including the general public, better access to the information behind the decision-making of European regulatory authorities as they review the safety of a medicine or active substance.

What information is found in the RMP summary?

The RMP summary for centrally authorised medicines summarises the full RMP, which is a long and technical document. The RMP summary covers:

- an overview of the medicine and what it is used for
- tables summarising the important risks of the medicine and how the risks are managed;
- a summary of any safety information that is missing and needs to be collected (e.g. on the long-term use of the medicine);
- any additional measures to ensure safe use that are required as part of the licensing of the medicine;
- a list of any planned studies to provide more information on the safety of the medicine.

Are there differences between the RMP summaries of similar medicines?

An RMP is drawn up to manage a medicine's risks based on the information available for that particular medicine. While medicines with a similar active ingredient, or which belong to the same class and are used for the same condition, may have similar information in their RMPs (and therefore their summaries), there may also sometimes be important differences in their risks.

These differences may reflect differences in the information submitted by the company or in the overall balance of benefits and risks between different medicines. For example, studies may be designed differently and include different groups of patients (e.g. different age groups, ethnic population) or be of different duration. In addition, similar medicines may show different results in studies even if the studies have the same design. These differences, reflecting the data available, can lead to some differences in the medicines' risk profile and, therefore, in their RMPs.

Why doesn't every medicine have an RMP summary?

All companies now applying to European regulators for marketing authorisation must include an RMP in the dossier supplied for evaluation. For medicines that do not yet have an RMP, it is likely that one will be required with any future significant change to the marketing authorisation.

The EMA will eventually publish RMP summaries for all centrally authorised medicines.

Who writes the RMP and the RMP summary?

The RMP is drafted by the company along with other documents submitted with its application. It is then reviewed by the regulator. During the evaluation of the application for centrally authorised medicines, the RMP must be reviewed by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and approved by the Committee for Medicinal Products for Human Use (CHMP) before marketing authorisation is recommended.

The RMP summary is part of the RMP and is assessed as part of the RMP evaluation.

What does the RMP summary relate to other public information about risks?

Information about a medicine's side effects and precautions for reducing its risks is covered in the *summary of product characteristics* (for healthcare professionals) and the *package leaflet* supplied with the medicine (for patients). This contrasts with the RMP summary, which only covers important risks, some of which may call for special measures to minimise any harm.

Another resource, the *EPAR summary*, available on the EMA website, explains how the EMA assessed the benefits and risks of a medicine in order to recommend it for authorisation in the EU.

RMP summaries, available on the EMA website, tell interested readers more about how important risks of a medicine are being managed. Their content is described under the question on 'What information is found in the RMP summary?'.

While all these resources contain information about the risks with a medicine, they serve different purposes.

When are RMP summaries updated?

Over time, as the information on the safety profile of medicines increases, the RMP will be updated to reflect this new information and the RMP summaries will be updated at the same time.