Risk management plan (RMP)

1. Overview on RMP

Understand the components of an RMP and their role in addressing risks associated with a product.

What is an RMP?

An RMP is a detailed description of the risk management system that is put in place to identify, characterise, prevent, and minimise risks relating to a product.

The RMP comprises the product's:

- **Safety concerns**, which include the product's important identified risks or potential risks, and missing information
- **Proposed pharmacovigilance (PV) activities** to identify and characterise safety signals and clinically relevant risks
- **Proposed risk minimisation activities (RMA)** to reduce the probability or severity of adverse events

Routine PV activities and RMA should be conducted for all products registered in Singapore.

Additional PV activities and RMA may be necessary for products requiring extra level of monitoring or risk minimisation to ensure that their benefit-risk profiles remain acceptable for the approved indication(s). More details are provided in the tabs below.

⊕ Pharmacovigilance (PV) activities

⊕ Risk minimisation activities (RMA)

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RMP submission for product registration

Last updated: 29 Aug 2024