



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Patient Health Protection

## Guidance on format of the risk management plan (RMP) in the EU part II: Module SVIII - Summary of the safety concerns

|                                          |  |
|------------------------------------------|--|
| Active substance                         |  |
| Product(s) concerned<br>(brand name(s)): |  |
| MAH/Applicant name                       |  |

Data lock point for this module

<Enter a date>

Version number of RMP when this module was last updated

<Enter a version no>

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices:  
Risk Management Systems.



A summary should be provided of the safety concerns identified in previous Modules (SII, SIV, SVI, and SVII) of part II. A safety concern may be an:

- important identified risk;
- important potential risk; or
- Missing information.

For RMPs covering multiple products where there may be significant differences in the important identified and important potential risks for different products, similar to the presentation of risks in RMP module SVII, it may be appropriate to subdivide the summary of safety concerns under specific headings with the relevant identified and potential risks under each heading. Headings which could be considered include:

- safety concerns relating to the active substance;
- safety concerns related to a specific formulation or route of administration;
- safety concerns relating to the target population;
- risks associated with switch to non-prescription status.

Division of safety concerns by headings should only be considered when the risks clearly do not apply to some products and inclusion as a single list could cause confusion.

**Table 1.** Summary of safety concerns

| Summary of safety concerns |          |
|----------------------------|----------|
| Important identified risks | < > List |
| Important potential risks  | < > List |
| Missing information        | < > List |