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 SII - Non-clinical part of the safety specification

Active substance	
Product(s) concerned	
MAH/MAA 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.

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This module should present a summary of the important non-clinical safety findings. Where studies have "negative" findings, these should be mentioned if of relevance to the target population (e.g. negative reproductive toxicity). The topics should normally include, but do not need to be limited to:

Key Safety findings (from non- clinical studies)	**Relevance to human usage**
Toxicity including: • Single and repeat-dose toxicity, • reproductive (must be discussed if medicine might be used in women of child-bearing potential) • developmental toxicity • nephrotoxicity • hepatotoxicity • genotoxicity • carcinogenicity	
General safety pharmacology: • cardiovascular (including potential for QT interval prolongation) • nervous system • etc.	
Mechanisms for drug interactions	
Other toxicity-related information or data	

Specify whether there is a need for additional non-clinical data if the medicinal product(s) is/are to be used in special populations

SII Conclusions on non-clinical data

List of safety concerns from non-clinical data that have:

- been confirmed by clinical data
- have not been adequately refuted by clinical data
- which are of unknown significance
- or where further research needed

Safety concerns
Important identified risks (confirmed by clinical data)
Important potential risks (not refuted by clinical data or which are of unknown significance)
Missing information

These safety concerns should be carried forward to Part II Module SVIII.