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Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU part II: Module SVI - Additional EU requirements for the safety specification

Active substance	
Product(s) concerned (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.

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SVI.1 Potential for harm from overdose

Discuss the potential for harm from overdose – either intentional or accidental. Give special attention to medicinal products where there is increased risk of harm – either where there is a narrow therapeutic margin or potential for major dose-related toxicity, and/or where there is a high risk of intentional overdose in the treated population. Where harm from overdose has occurred during clinical trials, this should be explicitly mentioned. Where appropriate, overdose should be included as a safety concern in RMP Module SVIII

SVI.2 Potential for transmission of infectious agents

The applicant/marketing authorisation holder should discuss the potential for the transmission of an infectious agent. This may be because of the nature of the manufacturing process or the materials involved. For vaccines, any potential for the transmission of live virus should be discussed. For advanced therapy medicinal products, a cross reference to RMP modules SVII (ATMP) may be made.

SVI.3 Potential for misuse for illegal purposes

Discuss the potential for use as a recreational drug or facilitating assault etc. If appropriate discuss the means of limiting this in the risk minimisation plan.

SVI.4 Potential for medication errors

If necessary, this section may be completed separately for each product.

SVI.4.1 Description of medication errors during the clinical trial programme

Product name(s)				
Description of error	Number of occurrences	Analysis of cause	Steps taken to prevent	Comment

SVI.4.2 Preventive measures for the final product(s) being marketed

Discuss how the following errors have been prevented in the design of the product, packaging, labelling etc.

- Prevention of error due to wrong medication
- Prevention of error due to wrong dose (strength, form, concentration)
- Prevention of error due to wrong route of administration

SVI.4.3 Effect of device failure

For products where a device is an integral part of the administration of the product.

SVI.4.4 Reports of medication errors with the marketed product(s)

Product name(s)				
Description of error	Number of occurrences	Analysis of cause	Steps taken to prevent	Comment

Where multiple strengths, posologies or concentrations are available, or where different products have different formulations, reconstitution differences etc., consideration should be given to including "medication error" as a safety concern.

SVI.5 Potential for off-label use

The potential for off-label use should be discussed. This is particularly relevant where a medicinal product has an indication restricted to a subset of the population within a disease area or there are situations where the medicinal product must not be given for safety reasons. The potential for use in other disease areas should also be considered where this is likely.

SVI.6 Specific paediatric issues

SVI.6.1 Issues identified in paediatric investigation plans

Any issues identified in paediatric investigation plans should be detailed and the relevance to the indications covered by this RMP discussed. Include details of how paediatric investigation plan recommendations have been considered. Cross reference may be made to other RMP Modules.

Product Name and PIP <Number>		
Issue (safety or long term efficacy)	Background	Relevance to indications covered in this RMP and how, if appropriate, it will be addressed.

SVI.6.2 Potential for paediatric off-label use

If the disease or disorder which is being treated or prevented is found in the paediatric population, and the product is not authorised in all paediatric age groups, the potential for off-label paediatric use in the non-authorised age groups should be discussed. If there are limited

treatment options it should not be assumed that clinicians will adhere to the labelled indication so it is important that potential paediatric issues are discussed and consideration given for their inclusion as a safety concern. Any actual use should be discussed and cross reference to other relevant RMP sections provided.

SVI.7 Conclusions

Safety concerns from this module (to be carried through to Part II Module SVIII)	
Safety concern	Comment