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Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU part II: Module SV - Post-authorisation experience

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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The purpose of this RMP module is to provide information on the number of patients exposed post authorisation; how the medicinal product has been used in practice and labelled and off-label use including use in the special populations mentioned in RMP module SIV. It should also include brief information on the number of patients included in completed or ongoing observational studies conducted either to elucidate a safety issue or for drug utilisation purposes. It is appreciated that detailed data may not be available. These tables provide guidance on how the data might be provided when available. Details of significant actions taken to update information on the safety of the medicinal product should also be provided in this module.

SV.1 Action taken by regulatory authorities and/or marketing authorisation holders for safety reasons

List any significant regulatory action (including those initiated by the MAH in any market in relation to a safety concern. Significant regulatory action would include a restriction to the approved indication, a new contra-indication, a new or strengthened warning in section 4.4 of the SPC (or equivalent) or any action to suspend or revoke a marketing authorisation.

The list should be cumulative but newly taken action (since last update to the module) should be presented separately first, as well as being in the cumulative list. Roll-out in multiple countries of a new safety statement initiated by the MAH can be presented as one action (but list all countries and range of dates e.g. March-September 2011.) Comments may be added if the regulatory action is not applicable to certain products/formulations as authorised in the EU.

Table 1. Detailed description of action taken since last update to this module

Safety issue	
Background to issue	
Evidence source	
Action taken	
Countries affected	
Date(s) of action	

Table 2. Cumulative list

Safety concern 1			
Country(ies)	Action taken	Comment	Date(s)

Safety concern 2 etc.			
Country(ies)	Action taken	Comment	Date(s)

SV.2 Non-study post-authorisation exposure

Where possible, data on patients exposed post marketing should be provided based on market research. When the number of persons is calculated on the basis of sales data, details and justification should be provided of the measure used to calculate exposure. Tables should be provided for each indication and route of administration where possible.

SV.2.1 Method used to calculate exposure

If different methods have been used to calculate exposure for some tables, this section should be repeated before the relevant table(s).

SV.2.2 Exposure

By age group and gender				
Indication				
Age Group	Persons		Exposure (e.g. packs or person years)	
	M	F	M	F
Age group 1				
Age group 2				
Etc.				

By indication		
	Persons	Exposure (e.g. packs or person years)
Indication 1		
Indication 2		
Etc.		

By route of administration		
	Persons	Exposure (e.g. packs or person years)
Oral		
intravenous		
Etc.		

By dose		
Indication		
	Persons	Exposure (e.g. packs or person years)
Dose level 1		
Dose level 2		
Etc.		

By country		
Indication		
	Persons	Exposure (e.g. packs or person years)
EU		
Non-EU		

If possible, EU use should be broken down into country or sales area. Note the categories provided, are suggestions only and other relevant variables can be used e.g. oral versus i.e., duration of treatment etc.

SV.3 Post-authorisation use in populations not studied in clinical trials

Where there are data on post-authorisation use in the special populations identified in RMP module SIV as having no or limited exposure in clinical trials, estimation of the numbers exposed and the method of calculation should be provided whether or not the usage is on- or off-label. Comment on any differences in benefit or risk seen between the special population and the target population as a whole.

Paediatric use		
Estimated use	Number	Comment on any variation in benefit or risk from overall target population
• Pre-term new-borns • Neonates (birth to 27 days) • Infants and toddlers (1 month to 23 months) • Children (2 years to e.g. 11 years) • Adolescents (e.g. 12 years to 18 years)		
Data source		
Method of calculation		

Elderly use		
Estimated use	Number	Comment on any variation in benefit or risk from overall target population
• 65 – 74 years • 75 – 84 years • 85+ years		
Data source		
Method of calculation		

Pregnant or breast feeding women		
Estimated use	Number	Comment on any variation in benefit or risk from overall target population
• Pregnant • Breast feeding		
Data source		
Method of calculation		

Hepatic impairment		
Estimated use	Number	Comment on any variation in benefit or risk from overall target population
• Mild • Moderate • Severe		
Data source		
Method of calculation		

Renal impairment		
Estimated use	Number	Comment on any variation in benefit or risk from overall target population
• Mild • Moderate • Severe		
Data source		
Method of calculation		

Other use (specify)		
Estimated use	Number	Comment on any variation in benefit or risk from overall target population
• Specify category • Specify category • Specify category		
Data source		
Method of calculation		

SV.4 Post-authorisation off-label use

Post marketing, updates to the safety specification, should include information on EU off-label use; i.e. the intentional use, for a medical purpose, which is not in accordance with the authorised product information for a medicinal product. Off-label use includes use in non-authorised paediatric age categories.

EU off-label use			
Off label category	Country	Source of information	Comment
<E.g. Use in dysmenorrhoea (non-authorised indication)>	<E.g. Italy>	<E.g.Poseidon: Drug utilisation study using Emilia Romagna NHS drug prescription in general practice, Italy>	<E.g. Epidemiological study in electronic health care records found 15 women (1.7%) prescribed painoprofen for dysmenorrhoea out of total of 975 users>

SV.5 Epidemiological study exposure

Marketing authorisation holders should provide a listing of epidemiological studies which are, or have been, conducted to elucidate safety or efficacy issues, study drug utilisation or measure effectiveness of risk minimisation measures. This listing should include studies undertaken by the marketing authorisation holder itself or funded by them via a grant, whether specific or unconditional. Studies undertaken by a marketing partner, or where the MAH has been sent the results by a third party, should also be included.

Study title and study type (e.g. cohort or case/control)	**Objectives**	**Population studied (data source and country)**	**Duration (study period)**	**Number of persons (in each group or of cases and controls) and person time (if appropriate)**	**Comment**
<E.g. Poseidon (cross sectional DUS)>	<E.g. Investigate utilisation of painoprofen in General Practice in Italy>	<E.g. Emilia Romagna NHS drug prescription in general practice, Italy>	<E.g. 3 month time window>	<E.g. 975 users from study population of 3.5M>	<E.g. Study report in annex 5>
Study 2 etc.					