EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 November 2012
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Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU part I: Product(s) Overview

Active substance(s) (INN or common name):	
Pharmaco-therapeutic group (ATC Code):	
Name of Marketing Authorisation Holder or Applicant:	
Number of medicinal products to which this RMP refers:	Choose one of the following: • 1 • 2 • 3 • 4 • 5 • 6
Product(s) concerned (brand name(s)):	

Data lock point for this RMP	<Enter a date>	Version number	<Enter a version no>
Date of final sign off	<Enter a date>		

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Administrative information on the RMP

Part	**Module / annex**	**Date last updated for submission (sign off date)**	***Version number of RMP when last submitted / or Not Applicable**
PART II Safety Specification	SI Epidemiology of the indication and target population(s)	<Enter a date>	
	SII Non-clinical part of the safety specification	<Enter a date>	
	SIII Clinical trial exposure	<Enter a date>	
	SIV Populations not studied in clinical trials	<Enter a date>	
	SV Post-authorisation experience	<Enter a date>	
	SVI Additional EU requirements for the safety specification	<Enter a date>	
	SVII Identified and potential risks	<Enter a date>	
	SVIII Summary of the safety concerns	<Enter a date>	
PART III Pharmacovigilance Plan		<Enter a date>	
PART IV Plan for post-authorisation efficacy studies		<Enter a date>	
PART V Risk Minimisation Measures		<Enter a date>	
PART VI Summary of RMP		<Enter a date>	
PART VII Annexes	ANNEX 2 Current or proposed SmPC/PIL	<Enter a date>	

Part	Module / annex	Date last updated for submission (sign off date)	*Version number of RMP when last submitted / or Not Applicable
	ANNEX 3 Worldwide marketing status by country	<Enter a date>	
	ANNEX 4 Synopsis of clinical trial programme	<Enter a date>	
	ANNEX 5 Synopsis of pharmacoepidemiological study programme	<Enter a date>	
	ANNEX 6 Protocols for proposed and on-going studies in Part III	<Enter a date>	
	ANNEX 7 Specific adverse event follow-up forms	<Enter a date>	
	ANNEX 8 Protocols for studies in Part IV	<Enter a date>	
	ANNEX 9 Synopsis of newly available study reports in Parts III-IV	<Enter a date>	
	ANNEX 10 Details of proposed additional risk minimisation activities	<Enter a date>	
	ANNEX 11 Mock up examples	<Enter a date>	
	ANNEX 12 Other supporting data	<Enter a date>	

** A new RMP version number should be assigned each time any Parts/modules are updated*

Some modules of the RMP may be omitted (for eligible types of products see GVP V table V.2) if the RMP relates only to products falling into these categories. In these circumstances leave the date field blank and write "Not applicable" or "NA" in the version field

QPPV name ……

QPPV signature ……

Contact person for this RMP ……

E-mail address or telephone

number of contact person ……

There can only ever by ONE agreed RMP for a product or products. Wherever possible there should only be one additional submitted RMP version under evaluation. To facilitate this, MAHs are reminded that where possible "routine" updates of a RMP should NOT be submitted when there is already a version of a RMP being evaluated as part of an on-going procedure. A cover letter should be submitted instead stating that there is no change to the RMP version xx dated yy submitted as part of procedure.

Where a procedure would normally require the submission of an updated RMP as part of the dossier, but there is already another version under evaluation because of another procedure, it is also possible to submit a letter as stated above.

In some circumstances there may be a need to submit a third RMP which is a different version from both the agreed RMP and a second RMP version currently undergoing evaluation e.g. if new safety concerns have been recently identified or if a new indication requires different risk minimisation measures. In this case different versions of a RMP will be simultaneously under evaluation. The purpose of this section is to provide oversight.

Overview of versions:

Version number of last agreed RMP:

Version number	<Enter a version no>
Agreed within	<Indicate procedure>

Current RMP versions under evaluation:

RMP Version number	Submitted on	Submitted within
<Insert number>	<Enter a date>	<indicate procedure number>
… etc.		

For each product in the RMP

Invented name(s) in the European Economic Area (EEA)	
Authorisation procedure	<indicate procedure>
Brief description of the product including: • chemical class • summary of mode of action • important information about its composition (e.g. origin of active substance of biological, relevant adjuvants or residues for vaccines	
Indication(s) in the EEA Current (if applicable)	
Proposed (if applicable)	
Posology and route of administration in the EEA Current (if applicable)	
Proposed (if applicable)	
Pharmaceutical form(s) and strengths Current (if applicable)	
Proposed (if applicable)	

Country and date of first authorisation worldwide	<Enter a country> <Enter a date>
Country and date of first launch worldwide	<Enter a country> <Enter a date>
Country and date of first authorisation in the EEA	<Enter a country> <Enter a date>

Is the product subject to additional monitoring in the EU? Yes ☐ No ☐