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 IV: Plans for post-authorisation efficacy studies

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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

IV.1 Applicability of efficacy to all patients in the target population

Based on the data in RMP Part II modules SIII, SIV and SV, the MAH/Applicant should very briefly discuss whether there are any gaps in knowledge about efficacy in the target population and whether there is a need for further efficacy studies post-authorisation. This should NOT include efficacy studies aimed at extending the indication.

Factors which might be relevant include:

- Applicability of the efficacy data to all patients in the target population – e.g. if 98% of patients in trials were Caucasians discuss whether efficacy is likely to be same in other races in target population
- Factors which might affect the efficacy of the product in everyday medical practice – e.g. use in general practice rather than the clinical trial hospital out-patient setting
- Long term efficacy
- Any evidence that there might be variability in benefits of treatment for sub populations.

IV.2 Tables of post-authorisation efficacy studies

The MAH/Applicant should list any post authorisation efficacy studies which are proposed by the MAH/Applicant in relation to the above and also include those studies which have been imposed by the CHMP/NCA or which are Specific Obligations. A synopsis of the protocols should be provided in Annex 8.

Table 1. Efficacy studies which are specific obligations and/or conditions of the MA

Description of study (including objectives and study number)	**Milestone(s)**	**Due Date(s)**
	1.(e.g. protocol submission)	<Enter a date>
	2.(e.g. study start)	<Enter a date>
	3.(e.g. study finish)	<Enter a date>
	4. (e.g. final report)	<Enter a date>

Table 2. Other efficacy/effectiveness studies

Description of study (including objectives and study number)	**Milestone(s)**	**Due Date(s)**
	1.(e.g. protocol submission)	<Enter a date>
	2.(e.g. study start)	<Enter a date>
	3.(e.g. study finish)	<Enter a date>
	4. (e.g. final report)	<Enter a date>

IV.3 Summary of Post authorisation efficacy development plan

This should be a complete overview of all studies (on-going, planned)

Study (type and study number)	Objectives	Efficacy uncertainties addressed	Status (planned, started)	Date for submission of interim or final reports

IV.4 Summary of completed Post authorisation efficacy studies

Study (type and study number)	Objectives	Efficacy uncertainties addressed	Status (Completed, Study report submitted)	Date of submission of final study report