

RMP template

4th industry stakeholder platform - operation of EU pharmacovigilance legislation

Risk Management Plan (RMP) activities updates session



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Pilot testing with stakeholders which took place in 23rd March 2015:

- Stakeholders involved: EGA, EFPIA, AESGP, EUCOPE nominated Member;
- Objective to get feedback on the structure and data presentation, specifically on:
 - ☐ Clarity of the structure
 - Focus and conciseness
 - ☐ Completeness for all necessary data elements
 - Avoidance of redundancies
- Comments were received on 4th May 2015 thank you!

Overview of main comments received:

- Simplification of the RMP template to avoid duplication, unnecessary RMP updates;
- Clarification on requirements for specific application types (e.g. generics, fixe dose combination requirements, etc..);
- Clarifications on RMP version numbers and RMP parallel submissions;
- Template allowing removal of safety concerns when appropriate.

Main changes following comments received:

• Re-focus RMP: PhVg planning tool to address key safety concerns;

- Focus on the scientific arguments which lead to the identification of the safety concerns in view of defining risk minimisation measures and post-authorisations studies:
 - For initial MA: Part II modules should focus on the rationale for the identification of safety concerns;
 - In post-authorisation: Part II modules should be updated whenever there is a change (even deletion)
 of the safety concerns;
 - Follow GVP module V definitions on important and identified risks and missing information.

Main changes following comments received:

- Simplify, avoid duplication of sections/table with the aim to improve RMP updates in postauthorisation procedures (reduce unnecessary RMP updates):
 - Routine risk minimisation measures by safety concern (one table)

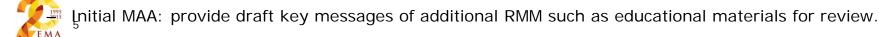
Safety concern	Routine risk minimisation activities	
Hepatotoxicity	Please refer to SmPC section 4.2 and 4.4. where guidance is provided on liver test monitor	ring

- Summary table of additional PhV activities and risk minimisation measures by safety concern.

Safety concern	Additional Pharmacovigilance activities	Additional risk minimisation measures
Hepatoxicity	Post-authorisation study to investigate the	Educational materials
	effectiveness of the risk minimisation	
	program	

Main changes following comments received:

- Section by section guidance on content requirements depending on MAA type (e.g. generics, fixed does combination, etc...):
 - Example: for generics where a RMP is available for the reference medicinal product, Part Modules
 SI to SVII can be omitted.
- Provide improved guidance on post-authorisation studies:
 - Improved guidance on categorisation of studies, wording of studies descriptions, submission dates.
- Simplification of Annexes:
 - To facilitate submission of PASS protocols -dedicated Annex for protocols submitted for assessment;
 - Provide links to Clinical study reports of approved protocols;



RMP summary

- Template to be revised format and structure simplification:
 - Main elements should be: Summary of safety concerns + Summary of risk minimisation measures + Planned post-authorisation development plan;
 - Up-to date "living" document.
- Process simplification
 - Aim to finalise it at time of CHMP opinion.
- Target audience, based on pilot refocus towards a professional audience summary not to be in plain language:
 - i.e. Generics could refer to the originator's RMP summary (when available) for their initial MA submission.
- Under consideration to have a 'section' for patients (in lay language)

Next steps

Update in parallel as GVP module V – follow same timelines:

- PRAC, CHMP and CMDh endorsement
- Public consultation planned for autumn 2015
- Receive Industry and other stakeholders' feedback