EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

RMP template

4th industry stakeholder platform - operation of EU pharmacovigilance legislation

Risk Management Plan (RMP) activities updates session

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RMP template for Industry

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!

RMP template for Industry

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.

RMP template for Industry

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.

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Main changes following comments received:

• Simplify, avoid duplication of sections/table - with the aim to improve RMP updates in post-authorisation 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 monitoring*

– 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 effectiveness of the risk minimisation program*	*Educational materials*

RMP template for Industry

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;
  - Initial MAA: provide draft key messages of additional RMM such as educational materials for review.

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