EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Risk Management Plan guidance and templates - Feedback from the public consultation

8th industry stakeholder platform - operation of EU pharmacovigilance legislation

Presented by Emil Cochino on 1 July 2016
Scientific and Regulatory Management Department

# Comments received

32 sets of comments on the GVP Module V

- Average 11 pages
- Upper values: 29, 36, 49 or 54 pages

14 sets of comments on the RMP Template

- Average 5 pages

Senders: MAHs, industry associations, education associations, individuals, consultancy companies, national pharmaceutical associations, CRO associations, NCAs, national healthcare system representatives

# Types of comments

1. Answering the 4 questions asked; Yes/No +/- expanded position
2. Overall concerns and position statements
3. Flat out accusations that the guidance weakens public health, increases the MAH stranglehold on PhV, and does not improve transparency
4. Support for network's efforts so far and encouragement
5. Typographical and editorial comments (minor <-> follow RMP structure <-> fundamental changes in the template of the GVP)
6. Rewording of paragraphs, to improve readability / English
7. Examples and further guidance to expand the proposed text
8. Removal of duplication

# Types of comments (continued)

9. Adding references to other sections of the document, or reusing text
10. Questions on the meaning of text for consultation / requests for clarification
11. Flags for sections that could be misread / applied inconsistently - with helpful proposals for clarity
12. Disagreement with new proposals and concepts. i.e. text in previous version of GVP V was better / should have not been removed
13. Consistency between GVP V and the Template
14. Move guidance text to template or from template to guidance
15. No comments at all

# Frequently raised topics or strong objections

- Risk definitions - mostly supportive comments but room for improvement
- Clarity on ADR ≠ Risk ≠ Important risk (also correspondence with 4.8)
- Avoid using equivalent terms related to risks – could create confusion
- QPPV signature / oversight
- PM updates of SII-SIV rarely needed
- include triggers for SIII-SV update (with next warranted RMP update?)
- SVI should retain risk identification discussion
- Risks that are not important: why in the RMP and why SVII section

# Frequently raised topics or strong objections (continued)

- structure of SVII discussion on risks that are not considered important
- Reconsider SVII requirements for generics, clarify for biosimilars, include new MA application for old substances / other legal routes
- Better guidance on missing information and potential risks in off-label use
- More guidance on/objection to removing a safety concern or stopping an additional risk minimisation activity
- Ensure consistency with upcoming GVP PIII (pregnancy and breast-feeding)
- Expand PASS categories guidance
- Clarity on RMP Annex 1: CAP/NAP
- The purpose of Annex 3a - protocols submitted for review with the RMP

# Frequently raised topics or strong objections (continued)

- Proposal to remove annex 4 (specific adverse event follow-up form)
- eCTD hyperlinks: not available for all products, documents not in same sequence
- NCAs as facilitators in sharing content of RMP / educational material
- NCAs to inform generic products of changes in originator RMP and the other way
- Guidance on work-sharing and mutual recognition for RMP assessment
- More guidance on procedural aspects
- The need for clear implementation plan and transitional arrangements for GVP V and especially for the RMP template

# RMP Template specific comments/topics

- **Make sure template is consistent with GVP V text**
- Support for reduction in duplication with other sections of the dossier / eCTD links
- Modular RMP or not?
- SII-SVI: clarify requirement for applications with no access to original trial data
- Rethink SVII.1.2. and SVII.2.2. (risks not important)
- Examples for impact on B/R balance considerations when describing an important risk
- Effectiveness studies for vaccines – PASS? Consequence on RMP classification?
- Define milestone requirements for studies

# RMP Template specific comments/topics (continued)

- New definitions for types of routine risk minimisation measures – expand
- Effectiveness also for routine risk minimisation activities?
- Template should be more flexible (not focused on initial MA application)
- Efficacy section removed – RMP not a B/R document?
- SVII structure when the product has no important risks or missing information
- Annex I – should anything be included in the RMP PDF?
- Annex II: for completed studies better to include link to final CSR(instead of protocol)
- Detailed guidance on educational materials -> GVP V or XVI

# Next steps

Finalise review of comments

Make proposals for text update

Consult drafting group & conduct second drafting workshop (PRAC/CMDh/CHMP)

Define implementation plan and transitional arrangements

Consult relevant committees and working groups, and other stakeholders

Publish

Train assessors, organize info-days, tutorials, awareness sessions…

# Thank you for your attention

## Further information

emil.cochino@ema.europa.eu

**European Medicines Agency**
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

Follow us on **@EMA_News**