



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Update on revision of RMP guidance and on pilot of new RMP template

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3rd industry stakeholder platform - operation of EU pharmacovigilance legislation



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An agency of the European Union



## Elements to be aligned during their revision

<b>GVP Module V</b>	<b>RMP template for MAHs</b>	<b>RMP summaries</b>
Comprehensive revision	Simplification based on experience and feedback so far	Fine-tuning to address the learnings from the pilot phase
Release for public consultation	First user testing by industry associations ahead of the public consultation	Feedback to be obtained from patients, health care professionals and industry



## Imminent: Piloting of the revised RMP template for MAHs

Industry associations are invited for user testing ahead of public consultation:

- It is proposed to use the template by populating an existing RMP in the new format
- The objective is testing of usability without submission of the actual RMP in the context of an assessment

Comments are proposed to be provided by end of April

- The feedback will be used to fine-tune the template ahead of the public consultation, which will be in parallel with the GVP V revision

The revised template structure will become operational only after finalisation subsequent to the public consultation



## Outlook for next steps

Piloting of the revised RMP template for MAHs – imminent

Discussion at the 4<sup>th</sup> industry stakeholder platform on the operation of EU pharmacovigilance legislation:

- Presentation on the GVP V revision
- Comments received on the revised RMP template for MAHs
- Feedback obtained on the RMP summaries

Changes to the RMP assessment process during the initial MAA evaluation – to be started in mid-2015