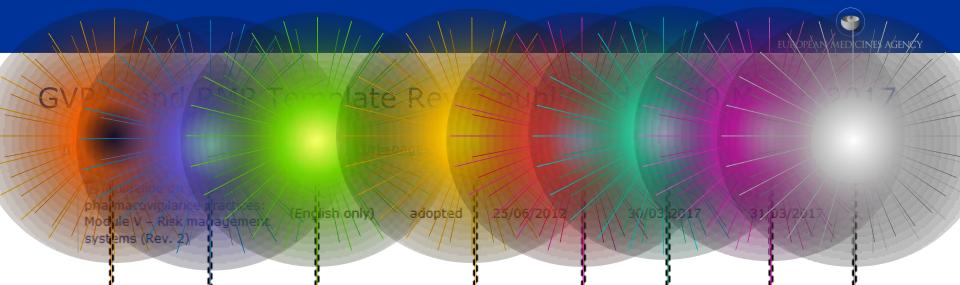


GVP V and RMP Template Rev 2 – Update on implementation

11th industry stakeholder platform, 02 June 2017

Núria Semis-Costa and Emil Cochino Scientific and Regulatory Management Department





http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp&micl=WC0b01ac(158067a113)

Guidance on the format of the risk management plan (English only) adopted 80/03/2017 31/03/2017 (RMP) in the EU - in integrated format (Rev. 2) Guidance on format of the risk-management plan in the 08/11/2012 21/08/2013 22/08/2013 (English only) adopted European Union - in integrated format (Rev. 1)

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Transitional arrangements

Rev 1 Template RMPs accepted:

- 6 months from publication i.e. 30 September 2017:
 - Initial MA applications
 - D121 responses
- 12 months for all other submissions, i.e. 31 March 2018:
 - D181 responses
 - D91 responses for initial MA applications with accelerated assessment
 - All post-authorisation submissions

After these dates there will be no exceptions: RMP using Rev 1 -> outstanding issue: to update the RMP

Consider using early the Rev 2 of the RMP Template (e.g. long or parallel procedures)

GVP V and RMP Template Rev 2 - Update on implementation

Further guidance in preparation

- Pre-submission and post-authorisation procedural guidance (PAG & PSG) to be updated
 - Including more guidance on RMP submission and assessment in parallel procedures
- RMP Q&A on scientific/content
 - Including frequently asked questions from applicants
 - Including lessons learned from monitoring the RMP submission quality (active project)
- EMA internal training is ongoing
 - Contact your Risk Management Specialist for product-related queries
- Training of PRAC and CHMP assessors planned

Assessment report templates to be updated

- include additional guidance based on last 5 years of experience
- RMP assessment process improvements under discussion
- reflect Rev 2 of the RMP Template
- update the EPAR publication process and templates

Restart of RMP summaries publishing

- Pilot phase ended last year, recommendations included in the updated Rev 2 RMP Template
- Summary uses only data available and assessed in the RMP
- Not in lay language
- Prepared by the applicant and approved with the RMP assessment
- Ready at the time of the Opinion
- RMP summaries for RMP using Rev2 Template will be published for all procedures: initial applications and post-authorisation updates
- In time, all active products will have public RMP Summaries



Future interaction with Industry

- EMA will organise trainings for the Industry or participate in existing fora (subject to resource availability)
 - Next: DIA Workshop on Benefit-Risk Strategy Prague 15 and 16 June
 - Other events are being planned
- Contact
 - AskEMA form
 - Contact details also on next page

Any questions?

Further information

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