

Update on Good Pharmacovigilance Practices (EU-GVP)

Industry Stakeholder Platform – Operation of EU Pharmacovigilance

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Updates on ongoing work

Priority 1 first lane:

- GVP Module XVI Rev 3 on risk minimisation measures (RMM), Addendum II on RMM evaluation and GVP Annex I Rev 5 on definitions
 - Aiming at publication in March/April 2024
 - ✤ Almost 700 comments from the public consultation and evolving field
 - ✤ Clarifications needed



Updates on ongoing work

Priority 1 second lane:

• GVP Module XVI Addendum III on pregnancy prevention programmes

- ✤ Aiming at publication in Q4 2024/Q1 2025
- Almost 400 comments from the public consultation and evolving field; to re-start after GVP M XVI rev 3 has been finalised
- Change needed?

GVP Chapter P III on pregnancy and breastfeeding

- Aiming at publication in 2024
- Almost 400 pages of comments from the public consultation and evolving field

• Reflection Paper on digital support to RMM and their evaluation

- ✤ Aiming at public consultation launch in Q1/2 2025
- Two multistakeholder meetings and written contributions
- Draft table of contents, agreed terminology and draft text; drafting ongoing for next meeting to be scheduled
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Updates on ongoing work

Priority 2:

• GVP Module VIII Rev 4 on post-authorisation safety studies

- Aiming at launch for public consultation in March/April 2024
- Areas of revision: feasibility assessment; implementation of ICH-M14; definitions of Regulation (EU) No 536/2014)

Priority 3:

• GVP Module V Rev 3 on risk management system



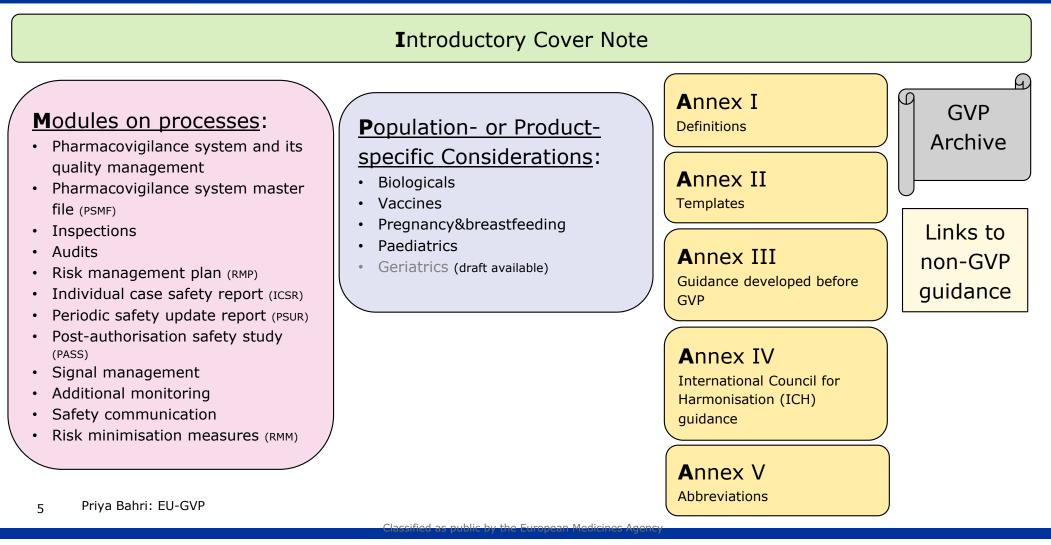
Planned work

- Careful planning of required updates and revisions necessary given foreseen revised Directive, Regulation and Implementing Regulation
- Planning started within EMA and at PRAC level, and in collaboration with PhVIWG
- Few GVP modules/chapters may possibly be revised and go for public consultation in 2025 and finalisation together with legal changes
- GVP modules/chapters will be updated with legal changes once final legislation available and together with ICH changes and other established changes (e.g. DHPC publication policy) without public consultation
- Some GVP modules/chapters may be further revised after the legal change updates
- In Q1/2 we will have an online launch event for Module XVI rev 3

4 Priya Bahri: EU-GVP

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Thank you

Further information

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