EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Good Pharmacovigilance Practices (EU-GVP)

Industry Stakeholder Platform – Operation of EU Pharmacovigilance

22 November 2023

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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

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

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Introductory Cover Note

Modules on processes:

- Pharmacovigilance system and its quality management
- Pharmacovigilance system master file (PSMF)
- Inspections
- Audits
- Risk management plan (RMP)
- Individual case safety report (ICSR)
- Periodic safety update report (PSUR)
- Post-authorisation safety study (PASS)
- Signal management
- Additional monitoring
- Safety communication
- Risk minimisation measures (RMM)

Population- or Product-specific Considerations:

- Biologicals
- Vaccines
- Pregnancy&breastfeeding
- Paediatrics
- Geriatrics (draft available)

Annex I
Definitions

Annex II
Templates

Annex III
Guidance developed before GVP

Annex IV
International Council for Harmonisation (ICH) guidance

Annex V
Abbreviations

GVP Archive

Links to non-GVP guidance

Thank you

Further information

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