



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Good Pharmacovigilance Practices (EU-GVP)

EMA Industry Stakeholder Platform Meeting
15 November 2024





Updates on completed work

- **GVP Module XVI Rev 3 on risk minimisation measures (RMM) and Addendum II on RMM evaluation**
- **GVP Annex I Rev 5 on definitions**
 - ❖ Published on 5 August 2024
 - ❖ Public launch event on 11 September 2024
 - ❖ Application ongoing



Updates on ongoing priority work

- **GVP Module XVI Addendum I on RMM for teratogenic medicines**
 - ❖ Aiming at publication in Q2/3 2025
 - ❖ Almost 400 comments from the public consultation; evolving field
 - ❖ Analysis of general comments and PRAC discussion in May 2024 in the light of recent PRAC experiences: changes in the guidance needed; 3 author team meetings held Jul-Nov 2024; PRAC discussion on changes at PRAC Dec 2024
 - ❖ Meeting with commenting stakeholder planned as part of the finalisation in Q2 2025
- **GVP Chapter P III on pregnancy and breastfeeding**
 - ❖ Aiming at publication in Q1/2 2025
 - ❖ Finalisation by author team ongoing for PRAC adoption and subsequent steps
- **Reflection Paper on digital support to RMM and their evaluation**
 - ❖ Aiming at public consultation launch in 2025/Q1 2026
 - ❖ Two multistakeholder meetings and written contributions in 2022-2023
 - ❖ Draft table of contents and terminology agreed; draft text collated; drafting ongoing for next meeting to be scheduled



Updates on other ongoing work (subject to “prioritised work first”)

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

- ❖ Aiming at launch for public consultation in Q1 2025, but only after amended Implementing Regulation has been published
- ❖ PRAC review completed, editor review ongoing for PRAC adoption and subsequent steps
- ❖ Areas of revision: feasibility assessment; implementation of ICH-M14 (final rev in GVP); definitions of Reg (EU) No 536/2014; amended Implementing Regulation

• **GVP Module V Rev 3 on risk management systems**

- ❖ Aiming at launch for public consultation in 2025 (together with revised RMP template which is not part of GVP)
- ❖ Will incorporate and replace the GL on Safety and Efficacy of ATMPs, considering recent public consultation comments
- ❖ Author team meetings ongoing

• **GVP Chapter P I Rev 1 on vaccines**

- ❖ Aiming at launch for public consultation in 2025/Q1 2026
- ❖ Author team established for start in Jan 2025; preparatory work ongoing
- ❖ Areas of revision: data monitoring tools, data analysis methods, COV19-lessons learnt, alignment with international guidance



Updates on further work planned at EMA, PRAC and PhVIWG, priority when amended Implementing Regulation published

- GVP Module IX rev 2 on signals: aim to publish in close time proximity to when respective legal articles enter into force in 2025; no public consultation
- GVP M I, II, III, IV, VI, VII: aim to publish in close time proximity to when respective legal articles enter into force in 2025; no public consultation



Updates on further work planned at EMA, PRAC and PhVIWG

- Careful planning of required updates given foreseen revised Directive and Regulation
- Some GVP modules/chapters may be further revised and go for public consultation together with legal changes implemented
- Some GVP modules/chapters may be further revised and go for public consultation after the legal change updates
- Revisions with ICH changes (e.g. ICH-E2D(R1)) and other established changes (e.g. EMA DHPC publication policy) will be implemented without public consultation

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

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

Contact me at priya.bahri@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000