EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good pharmacovigilance practices for the European Union (EU-GVP)

7th Industry Stakeholder Platform on the
Operation of the EU Pharmacovigilance Legislation

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Introductory Cover Note

Process **M**odules:
- PhV systems [*]?
- PSMF [*]?
- Inspections [*]?
- Audits
- RMP *
- ICSR [*]
- PSUR [*]
- PASS *(✓)
- Signals [*]
- Addition. Monitoring
- Communications *(✓)
- RMM [*]?

Population- or Product-Specific Considerations:
- Vaccines
- Biologicals (✓)
- Preg/Breastfdg. Women []
- Geriatric population []

Annex I: Definitions

Annex II: Templates

Annex III: Guidance prior to GVP

Annex IV: ICH Guidance

Annex V: Abbreviations

Links to non-GVP guidance

GVP Archive

Legal basis: Article 108a of Directive 2001/83/EC

Web path: www.ema.europa.eu > Human regulatory > Pharmacovigilance > Good pharmacovigilance practices

Symbols:
- (✓) Under finalisation
- [] Planned
- [*] Rev. planned
- * Rev. under public consultation
- *(✓) Rev. under finalisation