



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Industry Forum November 2017

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An agency of the European Union





Achievements 2017 and Plans for 2018

Introductory Cover Note

Process Modules:

- PSMF Rev2 [Mar 2017](#) [Rev3 18]
- RMP Rev2 [Mar 2017](#)
- ICSR Rev2 [Aug 2017](#) [Rev3 18]
- VI.Addl Dplcts [Aug 2017](#)
- PSUR Rev1 [Rev2 18]
- PASS Rev3 [Oct 2017](#)
- Signals Rev1 [Oct 2017](#)
- IX.Addl Stats [Oct 2017](#)
- Comms Rev1 [Oct 2017](#)
- RMM Rev2 [Mar 2017](#) [Rev3 18]

Population- or Product-Specific Considerations:

- Paediatrics * **to finalise Q1/2 18**
- Preg/breastfdg (Q1/2 2018)
- Geriatrics (Q1/2 2018)

Annex I:
DEF Rev4 [Oct 2017](#)

GVP Archive

Links to non-GVP guidance

Annex II
- Templates [Oct 2017](#)

Annex III
- Guidance prior to GVP

Annex IV
- ICH guidance

Annex V
- ABBREV Rev1 [Oct 2017](#)

Symbols:

- * Public consultation closed
- () Public consultation planned
- [] Revision to be considered