EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Industry Stakeholder Forum March 2018

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Plans for 2018/9

Introductory Cover Note

Process **M**odules:

PSMF Rev2 Mar 17 [Rev3 2019]
RMP Rev2 Mar 17
ICSR Rev2 Aug 17 [Rev3 2019]
VI.AddI Dplcts Aug 17
PSUR Rev1 [Rev2 2019]
PASS Rev3 Oct 17
Signals Rev1 Oct 17
IX.AddI Stats Oct 17
Comms Rev1 Oct 17
RMM Rev2 Mar 17 [Rev3 2018]

Population- or Product-Specific Considerations:

Paediatrics * Final Q2 2018
Preg/breastfdg [Q4 2018]
Geriatrics [Q2 2018]

Annex I:

DEF Rev4 Oct 17

Annex II

- Templates Oct 17

Annex III

- Guidance prior to GVP

Annex IV

- ICH guidance

Annex V

- ABBREV Rev1 Oct 17

GVP Archive

Links to non-GVP guidance

Symbols:
* Public consultation closed
[] Public consultation planned