EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Pharmacovigilance Practices (GVP)

PRAC,
Project Team PhV Systems-QS-Inspections-Audits,
PCG, PCWP/HCPWG September 2012

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GVP Modules – 1st wave: FINAL June 2012

I PhV Systems and their Quality Systems

II PhV System Master File

V Risk Management Systems

VI Individual Case Safety Reports

VII Periodic Safety Update Reports

VIII Post-Authorisation Safety Studies

IX Signals

GVP Modules – 2nd wave: ONGOING

III Audits PUBLIC CONSULTATION UNTIL 21 SEP 2012

IV Inspections PUBLIC CONSULTATION CLOSED, TT FOR FINALISATION AWAITED

X Additional monitoring PUBLIC CONSULTATION CLOSED, TT FOR FINALISATION AWAITED

XI Public participation **DRAFTING ONGOING**

XII Continuous phv, benefit-risk evaluation, communication planning and decision-making for regulatory action **DRAFTING ONGOING**

XV Safety communication PUBLIC CONSULTATION UNTIL 21 SEP 2012

XVI Risk minimisation measures **DRAFTING ONGOING**

GVP Modules – 2nd wave: TBC

XIII Incident management (tbc)

XIV International collaboration (tbc)

Guidance on referrals

- Not in GVP

Instead in:

- Notice to Applicants and

- EMA-HMA Procedural Advice

Under lead of Regulatory Affairs Sector

GVP Considerations for product- and population-specific pharmacovigilance

- Biological medicinal products
- Vaccines **REV DRAFTING ONGOING**
- Pregnancy **PCG AGREED FOR REV/NEW**
- Children
- Elderly
- ……

GVP Annexes

- Annex for definitions **1st WAVE FINAL, REV ONGOING**
- Annex for templates **TO BE EXTRACTED FROM MODULES APPENDICES ISSUE 2013**
- ANNEX for list of other guidelines **ISSUE PHV: 2012, NON-PHV: 2013**
- Annex for ICH guidelines **ISSUE 2013**

GVP Webpage

EMA website: go to

Home >

Regulatory >

Human medicines >

Pharmacovigilance >

Good pharmacovigilance practices

Link:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c