EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Pharmacovigilance Practices (GVP)

3rd Stakeholders Meeting on the new pharmacovigilance legislation

Presented by: Priya Bahri (EMA) and Patricia Moore (MHRA)

Scope

- Self-standing guidance on pharmacovigilance processes
- Compliance with legal tasks and responsibilities
- Addressed to EU marketing authorisation holders, competent authorities in Member States and Agency
- Participation of patients and healthcare professionals
- Replaces Volume 9A in the future

GVP development process

- Governance structure
- EMA-Member States Project Teams
- Consideration to stakeholder expectations (experience, PCWP, HCPWG, non-EU regulators, conferences, publications…)
- Internal consultations (PhVWP, PhVIWG, CHMP, CMD(h), PCWP…)
- Public consultation

GVP development status

- Ongoing
- 2 waves
- 1st wave to be released for public consultation early 2012 → final in mid-2012
- 2nd wave to be released for public consultation later in 2012 → final as of end 2012

GVP structure by modules - 1st wave

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

X Signals

GVP structure by modules – 2nd wave

- Audits
- Inspections
- Additional monitoring
- Public participation
- Communication
- Continuous phv and regulatory action
- Referrals / Union procedures
- Effectiveness of risk minimisation
- Incident management

GVP annexes and considerations

- Annex for definitions
- Annex for ICH guidelines
- Considerations: chapters for product- and population-specific guidelines

Structure within modules

A – Introduction

B – Structures and processes

C – Operation of the EU network

Transparency in GVP

- Committed to transparency in pharmacovigilance
- Process-specific transparency provisions in each GVP Module
- E.g. assessment reports, committee outcomes, RMP summaries
- Web portal

Public participation in GVP

- Dedicated GVP Module
- Public hearings
- Patient and healthcare professionals as PRAC Members and ad hoc experts
- Input from PCWP (patients working party) and HCPWG (healthcare professionals working group) on e.g. risk minimisation and communication
- Adverse reaction reporting

Prepare for 1st wave public consultation

February ….. March 2012