EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Pharmacovigilance Practices (GVP)

PCWP November 2012

Presented by: Priya Bahri © EMA

What and Why

- Set of pharmacovigilance guidelines
- EU-wide implementation of legislation
- Consistency with international guidance
- Common work practices between EU regulators

→ Worksharing between organisations

→ Cooperation

→ Quality management

Scope

- Self-standing guidance on pharmacovigilance processes with legal basis
- 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

- EMA-Member States governance structure
- Consideration to stakeholder expectations (experience, PCWP, HCPWG, non-EU regulators, conferences, publications…)
- Internal consultations with committes and working parties
- Public consultation

GVP chapters

- Modules on pharmacovigilance processes (M)

- Product- and Population-Specific Considerations (P)

GVP Modules – final

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 – ongoing

III Audits FINAL IN DECEMBER

IV Inspections FINAL IN DECEMBER

X Additional monitoring FINAL IN Q1 or Q2 2013

XI Public participation Public consultation in Q2 2013

XII Continuous phv, benefit-risk evaluation, communication planning and decision-making for regulatory action Public consultation in Q1 2013

XIII Incident management (tbc)

XIV International collaboration (tbc) Public consultation in Q2 2013

XV Safety communication FINAL IN JAN 2013

XVI Risk minimisation measures Public consultation in Q1 2013

Structure within Modules

A – Introduction

B – Structures and processes

C – Operation of the EU network

GVP Considerations for product- and population-specific pharmacovigilance

- Biological medicinal products … 2013…
- Vaccines Public consultation in Jan 2013
- Pregnancy … 2013…
- Elderly …
- ……

GVP updates and maintenance

- For Modules / Considerations as needed and prioritised

- In a joint Agency-Member States process

GVP Annexes

- Annex for definitions
- Annex for templates
- Annex for ICH guidelines
- Annex for other relevant guidelines

Transparency in GVP

- Committed to transparency in phv
- Process-specific transparency provisions in each GVP Module in C-part
- E.g. assessment reports, committee outcomes, RMP summaries
- European Medicines Web-portal

GVP Webpage on 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

Need for further advice

Pharmacovigilance helpdesk:

p-pv-helpdesk@ema.europa.eu

GVP

Questions?