EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Vigilance Practice Modules I-IV
PV quality assurance and control

Fergus Sweeney, PhD,
European Medicines Agency
Head, Compliance and Inspections

EU 28: Science, Medicines, Health
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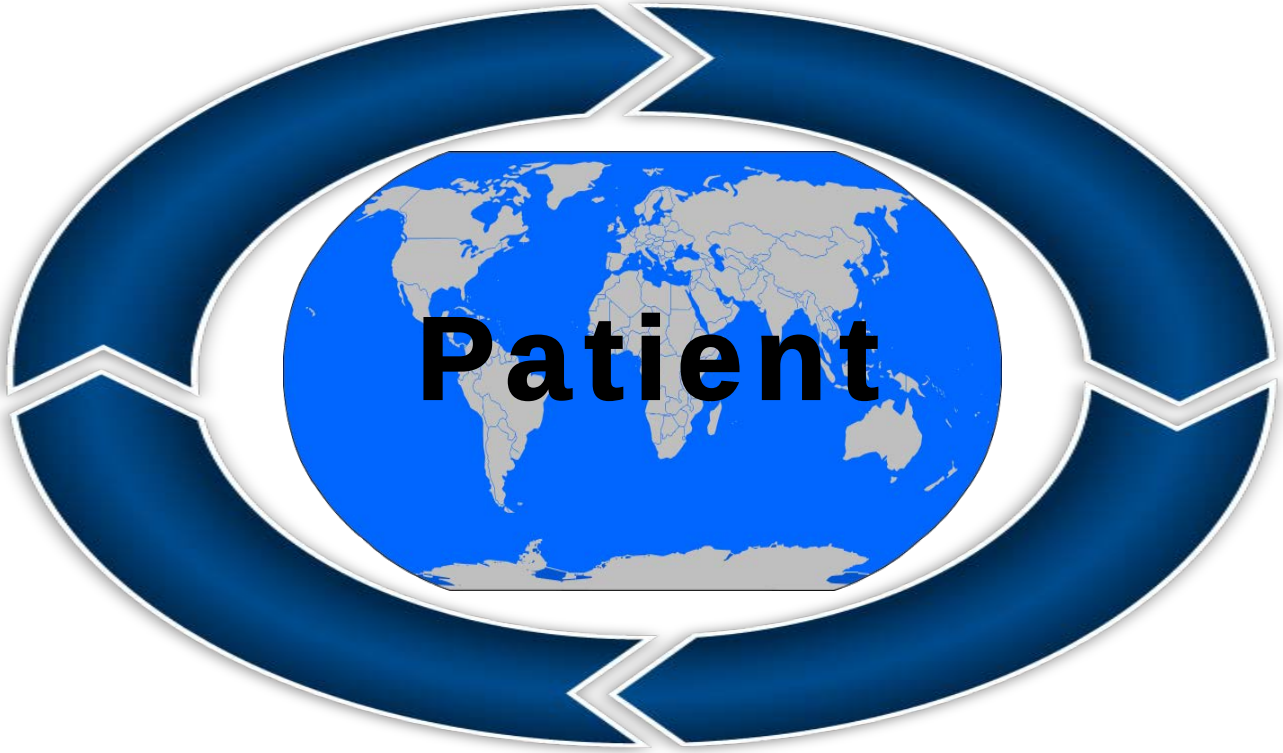
Pharmacovigilance – risk benefit monitoring cycle

Observe – Report – Monitor – Analyse – Evaluate - Act



Patient – Health Care professional – MAH – Regulator

Pharmacovigilance

Patient

Patient

Healthcare professional

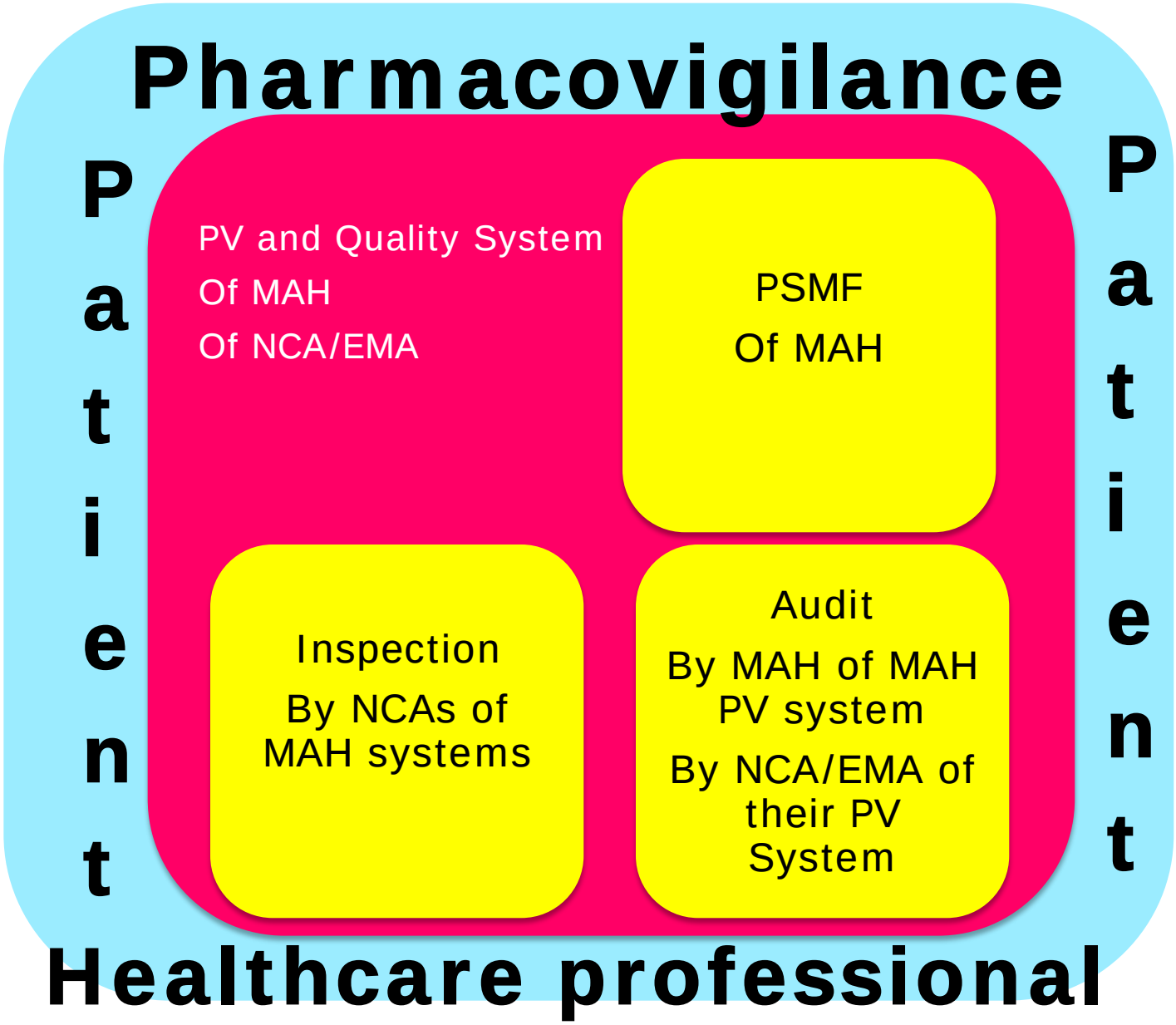
Pharmacovigilance

Patient

PV and Quality System
Of MAH
Of NCA/EMA

Patient

Healthcare professional


Pharmacovigilance
Patient
Patient
PV and Quality System
Of MAH
Of NCA/EMA
PSMF
Of MAH
Inspection
By NCAs of MAH systems
Audit
By MAH of MAH PV system
By NCA/EMA of their PV System
Healthcare professional

Pharmacovigilance All GVPs

Patient

PV and Quality System
Of MAH
Of NCA/EMA
GVP I

PSMF
Of MAH
GVP II

Inspection
By NCAs of MAH systems
GVP III

Audit
By MAH of MAH PV system
By NCA/EMA of their PV System
GVP IV

Patient

Healthcare professional

GVP I
Pharmacovigilance system and its quality system

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 2012
EMA/541760/2011

Guideline on good pharmacovigilance practices (GVP)

Module I – Pharmacovigilance systems and their quality systems

Draft finalised by the Agency in collaboration with Member States and submitted to ERMS FG	19 January 2012
Draft agreed by ERMS FG	24 January 2012
Draft adopted by Executive Director	20 February 2012
Released for consultation	21 February 2012
End of consultation (deadline for comments)	18 April 2012
Revised draft finalised by the Agency in collaboration with Member States	20 June 2012
Revised draft agreed by ERMS FG	21 June 2012
Revised draft adopted by Executive Director as final	22 June 2012
Date for coming into effect	2 July 2012

Pharmacovigilance (phv) system

A system used by an organisation

- to fulfil its legal tasks and responsibilities in relation to pharmacovigilance and
- designed to monitor the safety of authorised medicinal products and
- detect any change to their risk-benefit balance

Guidance for the establishment and maintenance of quality assured pharmacovigilance systems:

- Marketing authorisation holders
- Competent Authorities of Member States
- European Medicines Agency

Describes general application of quality management to pharmacovigilance systems and requirements specific to the operation of the EU network

Take home message:

Quality system is to assure the integrity of the pharmacovigilance system and is an integral part of the pharmacovigilance system

Produce visibly good pharmacovigilance

- Public health
- Overall confidence
- Public trust

GVP II
Pharmacovigilance System
Master File

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 April 2013
EMA/816573/2011 Rev 1*

Guideline on good pharmacovigilance practices (GVP)

Module II – Pharmacovigilance system master file (Rev 1)

Draft of first version finalised by the Agency in collaboration with Member States	19 January 2012
Draft agreed by ERMS FG	24 January 2012
Draft adopted by Executive Director	20 February 2012
Released for consultation	21 February 2012
End of consultation (deadline for comments)	18 April 2012
Revised draft of first version finalised by the Agency in collaboration with Member States	20 June 2012
Revised draft agreed by ERMS FG	21 June 2012
Revised draft adopted by Executive Director as final	22 June 2012
Date for coming into effect	2 July 2012
Draft Revision 1* finalised by the Agency in collaboration with Member States	21 February 2013
Draft Revision 1 agreed by ERMS FG	8 March 2013
Draft Revision 1 adopted by Executive Director as final	9 April 2013
Date for coming into effect of Revision 1	12 April 2013

Pharmacovigilance System Master File PSMF

One MAH = one or more medicinal products = one PV System = one PSMF = one QPPV

One PSMF = one location in EU = declared in Art 57 database and in summary of pharmacovigilance in the dossier

- A uniform information set describing the pharmacovigilance system is available to the QPPV and for the purposes of audit. Tool for MAH and QPPV to oversee and manage PV system.
- Held and maintained by the MAH (not in dossier)
- To be made available immediately on request to authorities - A practical reference for inspection and assessment. Oversight based on periodic inspection.

Module II – PSMF, Information contained in the PSMF

- QPPV details
- Products
- Organisational structure
- Sources of safety data
- Computerised systems and databases
- Processing of safety data
- PV system performance
- Quality System
- Annexes (lists)

GVP IV
Pharmacovigilance Audit

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2012
EMA/228028/2012

Guideline on good pharmacovigilance practices (GVP)

Module IV – Pharmacovigilance audits

Draft finalised by the Agency in collaboration with Member States and submitted to ERMS FG	12 July 2012
Draft agreed by ERMS FG	20 July 2012
Draft adopted by Executive Director	25 July 2012
Start of public consultation	26 July 2012
End of consultation (deadline for comments)	21 September 2012
Revised draft finalised by the Agency in collaboration with Member States	5 December 2012
Revised draft agreed by ERMS FG	6 December 2012
Revised draft adopted by Executive Director as final	12 December 2012
Date for coming into effect	13 December 2012

TASKS AHEAD

EMA and NCA and HMA' is to **put in place an audit teams** which adopt a strategic mind-set to respond to risk and ready **to deliver audit reports in line with the legislative requirements**

FIRST AUDIT reports of the pharmacovigilance system audit **needs to be ready** (EMA- IV Q.2013, NCA's-21 September 2013).

EC shall make public a report on the performance :
-EMA-by 2 January 2014
-NCA's -21 July 2015

MAHs must have an audit programme for all new products Authorised since July 2012 and for all existing products At the time of implementation of the PSMF and no later Than July 2015

GVP III
Pharmacovigilance Inspection

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2012
EMA/119871/2012

Guideline on good pharmacovigilance practices (GVP)

Module III – Pharmacovigilance inspections

Draft finalised by the Agency in collaboration with Member States and submitted to ERMS FG	25 May 2012
Draft agreed by ERMS FG	30 May 2012
Draft adopted by Executive Director	22 June 2012
Start of public consultation	27 June 2012
End of consultation (deadline for comments)	24 August 2012
Revised draft in collaboration with Member States	23 November 2012
Revised draft agreed by ERMS FG	6 December 2012
Revised draft adopted by Executive Director as final	12 December 2012
Date for coming into effect	13 December 2012

GVP Module III – Pharmacovigilance inspections

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GVP Module III – Pharmacovigilance inspections

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PhV Inspectors Working Group

PhV Inspectors Working Group

- PhV IWG formed in 2008
- Meets Quarterly at the Agency
- Human and Veterinary medicinal products
- Delegates from 30 EU/EEA member states – agencies responsible for inspection H + V
- Pre-accession - Croatia,
- Observers from Bosnia-Herzegovina, FYRM, Kosovo, Serbia, Turkey and Switzerland.

PhV Inspectors Working Group

Objectives

- Harmonisation through practice
- Shared experience, discussion, conclusion
- Policy/guidelines/SOPs development
- Network of contact between inspectors
- Joint inspections on most Centralised inspections

Section on the Agency's website – work programme and annual report from the group: http://www.ema.europa.eu/Inspections/PhVInspmtg.html

Human medicines
- Pre-authorisation
- Post-opinion
- Post-authorisation
- Product information
- Scientific advice and protocol assistance
- Scientific guidelines
- Innovation Task Force
- Regulatory and procedural guidance
- SME office
- Paediatric medicine
- Orphan designation
- Herbal products
- Referral procedures
- Article 58 applications
- Compassionate use
- Pharmacovigilance
- Advanced therapies

Inspections
- GCP compliance
- GLP compliance
- GMP/GDP compliance

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Pharmacovigilance Inspectors Working Group

Email Print Help Share

The Sector draws on the expertise of member states' inspectorates for the fulfilment of many of its PhV inspections related tasks. This is primarily achieved through the PhV IWG, made up of inspectors involved in PhV inspections related to human and veterinary products, respectively.

The PhV IWG focuses on harmonisation and co-ordination of PhV related activities at Community level. The Group activities are outlined in its work plan.

It is involved in the preparation of new and revised guidance and community procedures relating to inspection and PhV. The Sector chairs and provides secretarial support to the PhV IWG. Members provide the expertise for the fulfilment of the group tasks and play a key role in the development of collaborative projects both within the community and externally.

The PhV IWG meets on a regular basis four times a year at the European Medicines Agency with representatives of the PhV inspectorates of the European Economic Area Member States dealing with human and veterinary medicinal products, respectively, and also observers from candidate countries and Switzerland.

They support the co-ordination of the provision of PhV inspection related advice and provide a link with other groups such as CHMP, CVMP, and PhVWP (H+V). These links include joint meetings with pharmacovigilance assessors and contributions to training of both inspectors and assessors. A PhV IWG / PhVWP subgroup assists in the development of detailed proposals on procedures and guidance. The Mandate of the PhV Inspectors Working Group describes the group's role and activities in more detail. The Human and Veterinary PhV inspection policies developed by this group provide additional information on the legal framework to the inspections, the objectives, the inspection programmes, the different types of inspections, the composition of the inspection team, the focus and preparation of the scope of the inspection and finally about the selection of the sites to be inspected.

The PhV Inspectors maintain a dialogue with GCP and GMP Inspectors on areas of common interest

Send all queries regarding this content to: gcp@ema.europa.eu.

Documents of Interest

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Document(s)	Language	Status	First published	Last updated	Effective Date
Work plan for the Pharmacovigilance Inspectors Working Group for 2013	(English only)	adopted	14/03/2013		

EUROPEAN MEDICINES AGENCY

A partnership approach

Vigilance

Harmonisation

Information sharing and analysis

Planning, conduct and follow-up

Coherent and responsive systems

EMA NCAs Inspectors Assessors

MAH

Healthcare Professional

All working to serve and protect Patients

Thank you