EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New Pharmacovigilance Legislation and Implementing Measures – Minimum Requirements for Quality Systems (MAH, EMA, NCA), minimum requirements for Pharmacovigilance System Master File

Stakeholder Meeting, 17 June 2011,
EMA, London.

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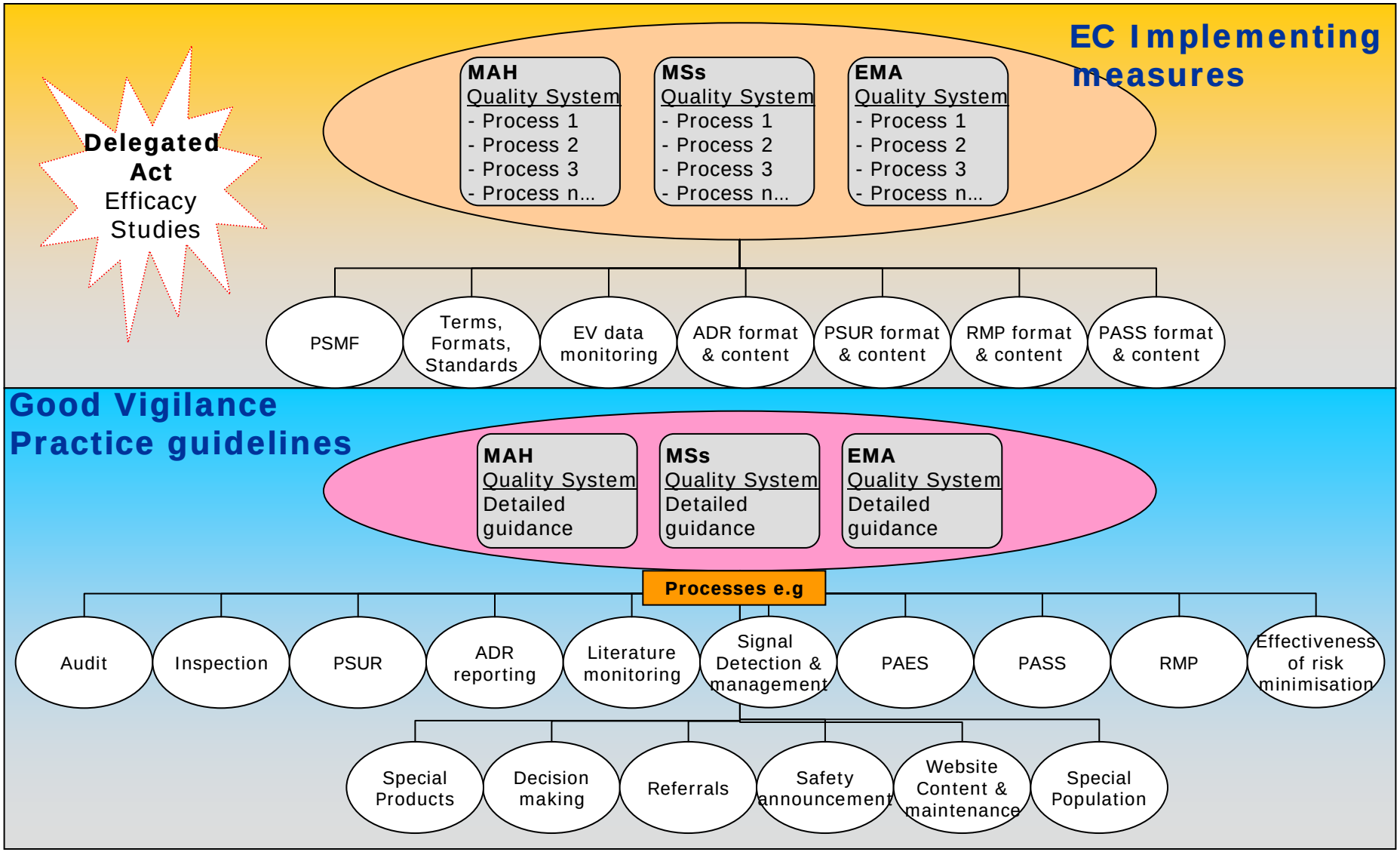
Pharmacovigilance – risk benefit monitoring cycle

Observe – Report – Monitor – Analyse – Evaluate - Act

Patient – Health Care provider – MAH – Regulator

Structure of implementing measures and Good Vigilance Practice: 'GVP'



Implementing Measures
Minimum Requirements for
Quality Systems
of
MAH, NCA, EMA

Directive 2010/84/EU

“ The pharmacovigilance activities provided for in this Directive require that uniform conditions be established as concerns the contents and maintenance of the pharmacovigilance system master file, as well as the minimum requirements for the quality system for the performance of pharmacovigilance activities by the national competent authorities and marketing authorisation holders, …”

and

“.. the Agency…” Regulation (EU) No 1235/2010

Pharmacovigilance and Quality System…

Pharmacovigilance system is defined in Regulation, Directive and GVP

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

Implementing measures set out minimum requirements,

i.e. key obligations of the MAH, NCA, EMA for the implementation of the quality system

Guidelines /GVP/ will set out the details

How can a quality system help us?

- to produce visibly good pharmacovigilance

→ Public health
→ Overall confidence
→ Public trust

MAH Quality System

Implementing Measure implementing Article 108(b) of Directive 2010/84/EU amending Directive 2001/83/EC as regards the minimum requirements for the quality system for the performance of pharmacovigilance activities by marketing authorisation holders

Draft technical contribution for the European Commission

Quality system - the organisational structure, responsibilities, procedures, processes and resources for managing quality

Quality system adequate and effective for the purpose of operating its pharmacovigilance system

Involvement of management and personnel

Ensure compliance with the legal requirements laid down in Directive 2001/83/EC and Regulation (EC) No 726/2004, as amended.

Systematic approach to quality and the implementation and maintenance of the quality system for pharmacovigilance

Expectations for quality of the pharmacovigilance system and its measurement.

Structures, processes, tasks and responsibilities.

Monitoring the establishment and effectiveness of the structures and processes.

Correction and improvement of processes.

Implementation of corrective and preventive actions.

Delegation of tasks to third parties – quality system of the third party should be equivalent.

Regular management review of the system.

QPPV involvement and sufficient authority.

Reporting of non-compliance, documentation of deviations.

Adequate, trained and qualified staff. Initial and ongoing training.

Documentation of the structure, processes and performance.

Record management.

Record retention.

Traceability of investigations and decisions.

Audit plans and reports.

Regular audit of the pharmacovigilance system and its quality system.

Guidance in GVP

Implementing Measure implementing Article 87a of Regulation (EC) No 726/2004 and Article 108 of Directive 2001/83/EC as regards to the content and maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder

Technical contribution for the European Commission

Description of pharmacovigilance system and its quality system, but not product specific details.

Reference for inspection and assessment if requested.

Inspection can be of all aspects of system and products and at any location where PV activities take place – inside or outside EU.

One pharmacovigilance system = one separate pharmacovigilance system master file = one location in one EU member state = one QPPV = one or more products of the MAHs.

Same PSMF and location for all products using the PV system.

Provisions where several MAH use same system and same PVSMF and QPPV.

Accessible to all MAHs using the system and to authorities supervising them or in whose territories products are marketed.

QPPV access and authority to promote, maintain and improve.

PSMF documents PV system and demonstrates compliance of system with requirements

Lists products to which the system described applies, reference to any other systems of the MAH if applicable, route of authorisation of each product, presence on the market and indication of special monitoring measures

Information about QPPV – job description, qualifications etc, contact details, backup arrangements and national contacts if present.

Organisational structure and sites of PV activities, including third parties.

Location, functionality and responsibility for computer systems.

Contracts and agreements for key activities.

Description of the key processes, data handling and records of the pharmacovigilance system

Description of the quality system.

Description of record keeping and archiving.

Permanently and readily available, indexed to ensure all documentation is readily available.

Notification of significant changes.

Transfer of responsibility for system content and maintenance.

Guidance in GVP

Thank you – questions – suggestions