EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The new Pharmacovigilance legislation and implementation planning

Second Stakeholders meeting 17 June 2011

European Medicines Agency, London, UK

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An agency of the European Union

Agenda

1. Implementing the new legislation: Governance

   - EMA;

   - EU Network;

   - Working methodology;

   - Reporting timelines;

   - Stakeholders liaison.

2. Implementing the new legislation: Deliverables

   - Implementation phasing plan;

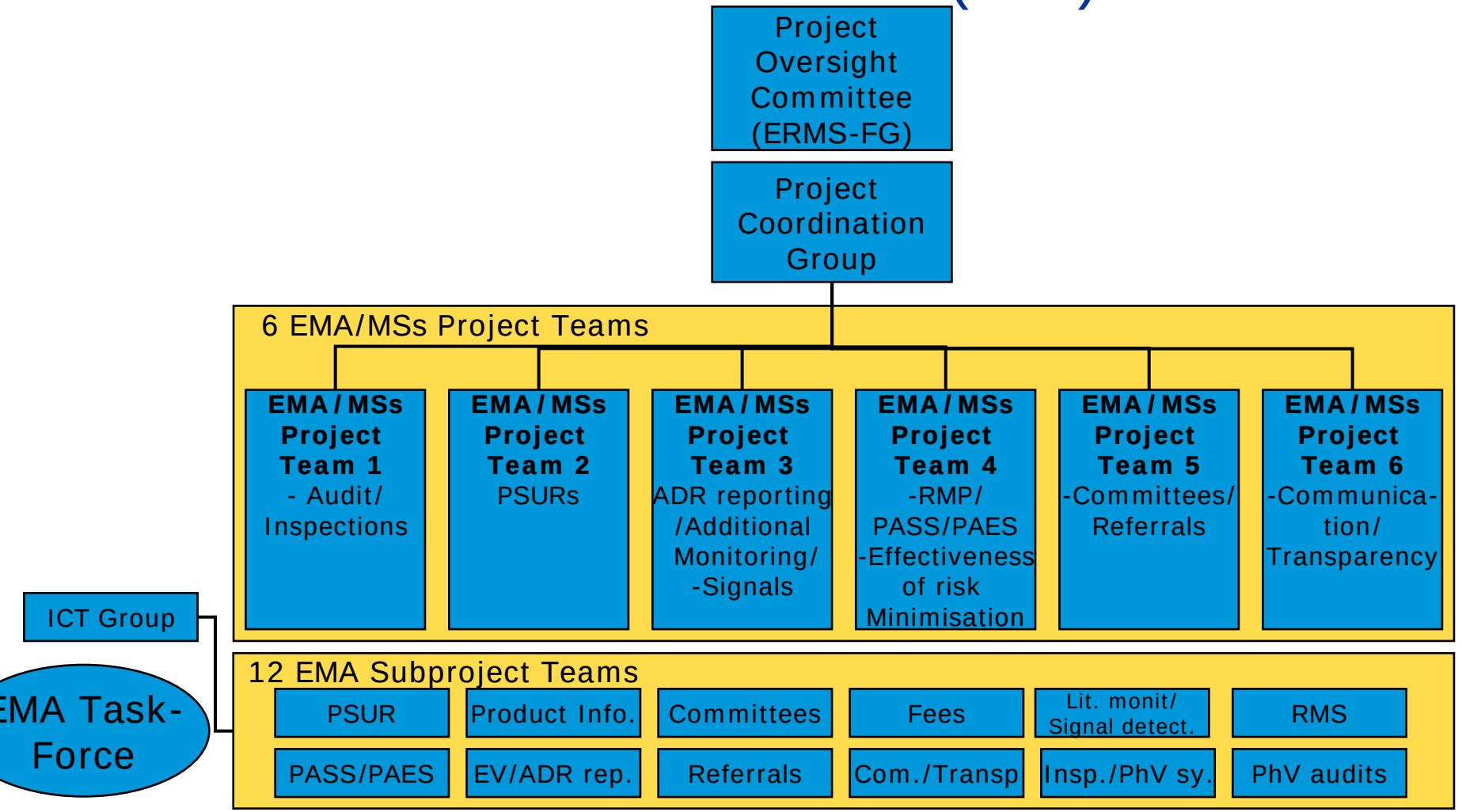
   - EMA/Member States technical contribution to EC draft Implementing Measures and Concept Papers;

Governance – EMA (1/5)

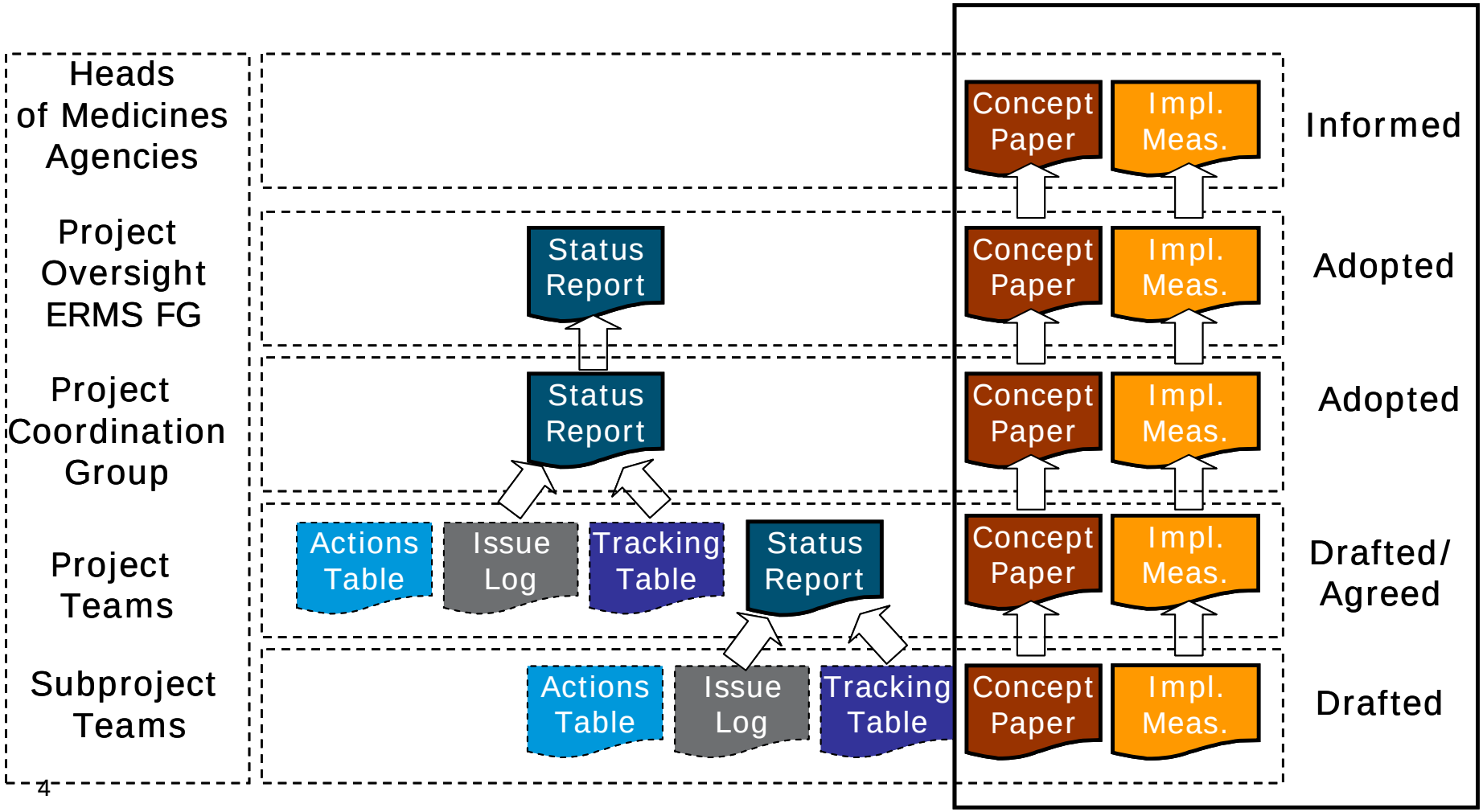
- EMA Project 00305: Cross-Agency Task Force
  - Established Jan 2010
  - Monthly meetings

- Initial mandate:
  - Assess in detail the impact of the new legislative proposal on the European Medicines Agency activities or operations
  - Deliver on time the measures necessary to implement the new legislation

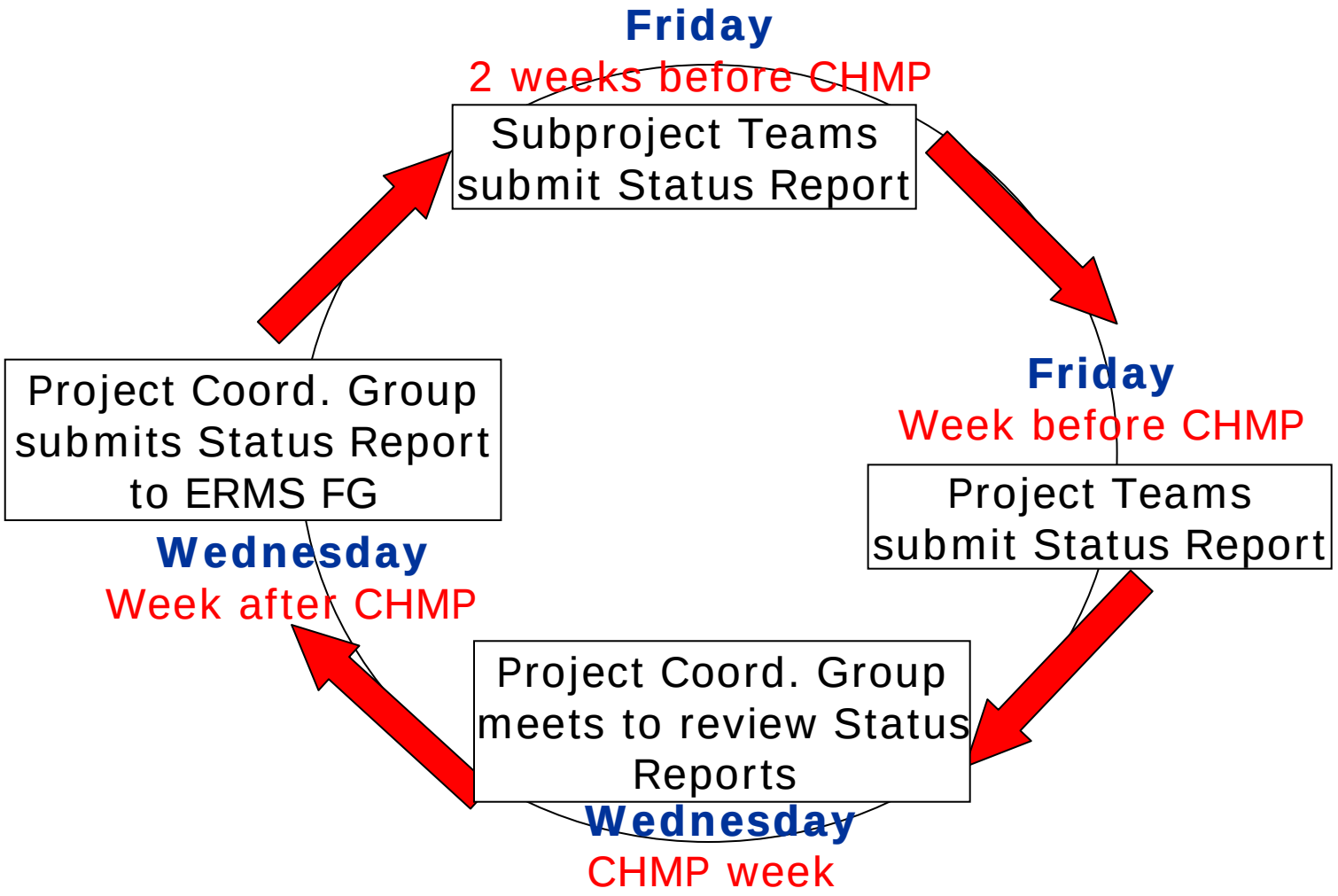
1. Governance – EU Network (2/5)



1. Governance – working methodology (3/5)



1. Governance – Reporting timelines (4/5)



1. Governance - Stakeholders liaison and consultation (5/5)

- Stakeholders meetings involving EMA, Member States, EC, Industry, Patients and Healthcare Professionals representatives:
  - 15th April 2011 (positive feedback)
  - 17th June 2011
  - More later in the year.....
- Formal public consultations by EC and EMA

2. What will be delivered?(1/6)

Hierarchy of rules

- **Regulation** (EC) 1235/2010
  - **Directive** 2010/84/EC

EC Implementing Measures

= Commission regulation

(Reg. Art. 87a and Dir.Art.108

- **Policies**
- **Operations**
- **ICT**

Deliverables

EMA/MSs Technical contribution

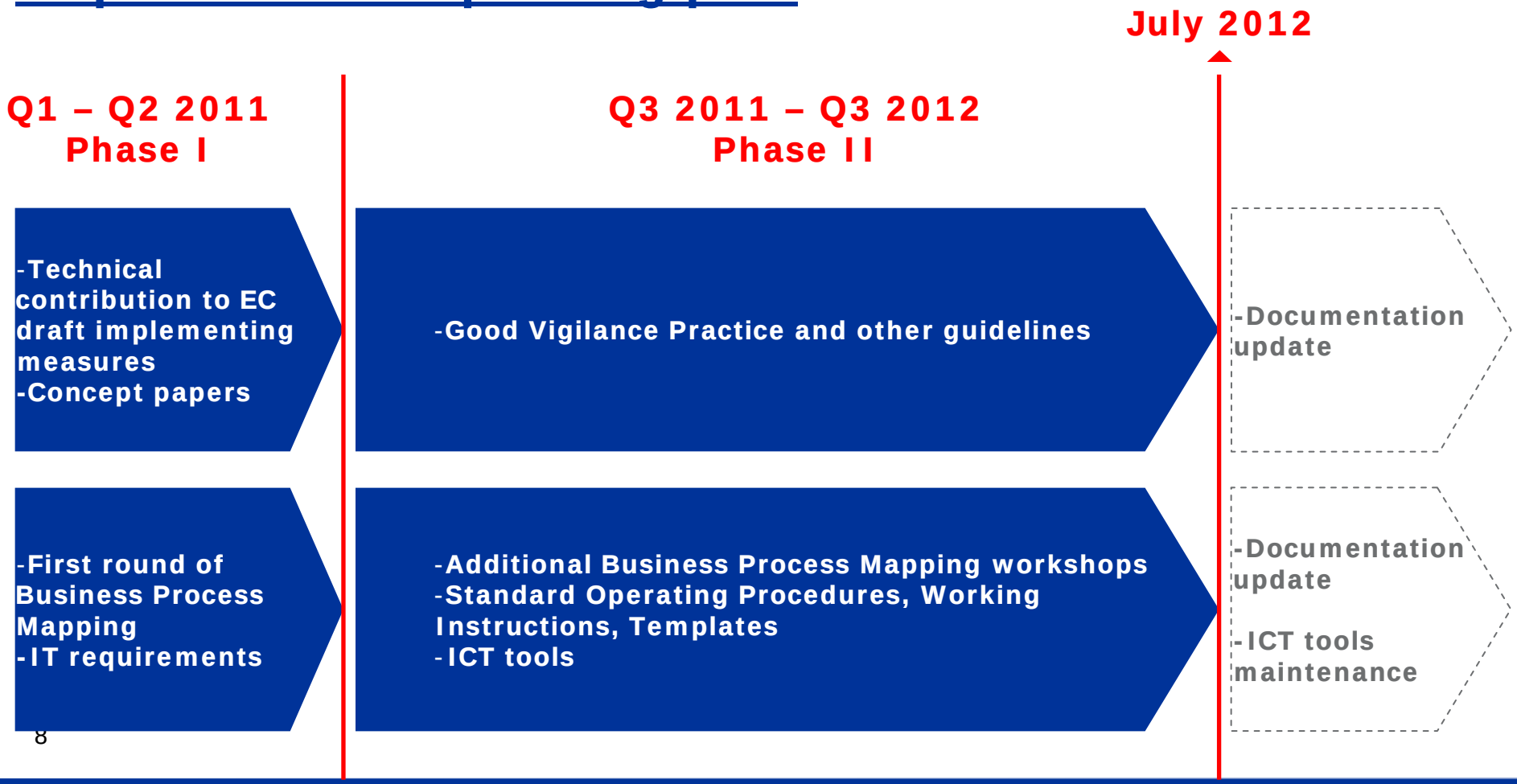
Concept Papers → Guidelines

Process Mapping → SOP/WIN/Templates

IT requirements → IT tools

2. What will be delivered? (2/6)

Implementation phasing plan



2. What will be delivered? (3/6)

EMA/Member States technical contribution to EC implementing measures

Reg. (EC) 1235/2010 Art. 87a and Dir. 2010/84/EC Art. 108

(a) The content and maintenance of the pharmacovigilance system master file kept by the MAH;

(b) The minimum requirements for the quality system for the performance of pharmacovigilance activities by the **Agency, the NCAs and MAH;**

(c) The use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;

2. What will be delivered? (4/6)

EMA/Member States technical contribution to EC implementing measures

Reg. (EC) 1235/2010 Art. 87a and Dir. 2010/84/EC Art. 108

(d) The minimum requirements for the monitoring of data included in the EV database to determine whether there are new risks or whether risks have changed;

(e) The format and content of electronic transmission of suspected adverse reactions by MSs and MAHs;

(f) The format and content of electronic PSURs and RMPs;

(g) The format of protocols, abstracts and final study reports of the PASS;

2. What will be delivered? (5/6)

Several Concept Papers under preparation

- Pharmacovigilance audits
- Coordination of safety announcements
- EU medicines Web-portal
- Products under additional monitoring
- Public hearings
- Transparency
- Etc,….

2. What will be delivered? (6/6)

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

EC Implementing measures

'May' Efficacy Studies

MAH
Quality System
- Task 1
- Task 2
- Task 3
- Task n…

MSs
Quality System
- Task 1
- Task 2
- Task 3
- Task n…

EMA
Quality System
- Task 1
- Task 2
- Task 3
- Task n…

PSMF | Terms, Formats, Standards | EV data monitoring | ADR format & content | PSUR format & content | RMP format & content | PASS format & content

Good Vigilance Practice guidelines

MAH
Quality System
Detailed guidance

MSs
Quality System
Detailed guidance

EMA
Quality System
Detailed guidance

Processes e.g

Audit | Inspection | PSUR | ADR reporting | Literature monitoring | Signal Detection & management | PAES | PASS | RMP | Effectiveness of risk minimisation

Special Products | Decision making | Referrals | Safety announcement | Website Content & maintenance | Special Population

Any questions?

List of abbreviations

ERMS-FG: European Risk Management Strategy – Facilitation Group

PSUR: Periodic Safety Update Report

ADR: Adverse Drug Reaction

RMP/S: Risk Management Plan/System

EV: EudraVigilance

PAE/SS: Post-Authorisation Efficacy/Safety Studies

SOP: Standard Operating Procedure

WIN: Working Instruction

ICT: Information and Communication Technology

EMA: European Medicines Agency

MSs: Member States