Safeguarding public health

# Joint Action on Pharmacovigilance

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# Agenda

- Background
- Actions to date
- Proposed deliverables
- Success criteria
- Break-out objectives
- Agree next steps

# Joint Action on Pharmacovigilance (2013 – 2016)

***Objectives***

*Under "Improve citizens' health security" objective*

*Facilitating collaboration among the Member States for the effective operation of the pharmacovigilance system in the EU*

# Aim

*Support Member States to find solutions for organising and running their pharmacovigilance system in the context of the new pharmacovigilance legislation in the EU*

**Financing**

*Exceptional utility co-financing - 70% EU funding*

# Stages of Activities

# Actions to date

- Proposals from EC 24/10/12
- Discussion at i-PRAC in Paphos
- Further discussions in margins of PRAC
- Preparatory paper developed by ES with others
- Needs assessment questionnaire issued 28/11/12
- Responses received from:
  FR, SI, ES, BE, NO, BG, IT, FI, HU, EE, LT, LV, SE, HR

# Results so far

| | Giver | Receiver |
|---|---|---|
| **WP1** | FR, HR, IT, LV, ES | BE, ES, BG, CY, HU, LT |
| **WP2** | HR, ES, SE | BE, IT, ES, CY, HU |
| **WP3** | | BE, HV, IT, CY |
| **WP4** | SE | BE, HV, IT, BG, CY |
| **WP5** | CY | BE, IT, CY, LT |
| **WP6** | | BE, HV, IT, BG, CY, HU |

# Work packages

| WP1 – ADR Collection | WP2 – Risk management | WP3 – QMS | WP4 – Signal Methodologies | WP5 PV Insp | WP6 – Prospective vigilance. |
|---|---|---|---|---|---|
| • ADR reporting system<br>• Patient reporting<br>• Biol traceability<br>• Webform<br>• MAH reporting<br>• EudraVigilance | • Benefit risk assessment<br>• Processes to vary, suspend etc<br>• Comms – portal, bulletin | • Record management<br>• Training plans<br>• SOPs<br>• Audit | • ADR analysis<br>• Risk management planning for certain ADRs<br>• Data exchange | • Pre-Inspections<br>• Report writing<br>• PV System Summaries<br>• CAPA assessment | • Benefit risk through lifecycle<br>• Epidemiology<br>• PASS<br>• PSURs<br>• PAES |

# Success Criteria/Deliverables

Work Package 1 – ADR Reporting

Success

- Public and HCP engagement with national reporting system
- Increased reporting by x%
- High quality reports received

Deliverables

- Consistent information campaigns to raise awareness
- Patient reporting initiated across EEA
- Effective web form
- High quality feedback to reporters
- National database meets ICSR & IDMP standards

# Success Criteria/Deliverables

Work Package 2 – Risk Communications

Success

- High quality communications reach all stakeholders
- Best Practice established across member states
- What, when and how is consistent
- Impact of communications measured

Deliverables

- Consistent, timely publications
- E-bulletins
- Web-Portals for every NCA
- Suite of benefit and risk communications established

# Success Criteria/Deliverables

Work Package 3 – Quality Management System

Success

- Increased efficiency and management
- Quality management support better PV without additional burden
- PV activities optimised
- Accreditation – e.g. ISO9001

Deliverables

- Audits performed
- Clear SOPs
- Core SOPs for all, same titles
- Performance indicators established
- EC acceptance

# Success Criteria/Deliverables

Work Package 4 – Signal methodologies

Success

- Public health prioritised at MS level
- Enhanced signal detection at NCA level
- Engagement with patient safety organisations

Deliverables

- Harmonised approach
- Methods for detection of errors for timely intervention
- Audit and tracking built in
- Training for assessors
- Simplified procedures (resource pressures)

# Success Criteria/Deliverables

Work Package 5
Success

- Systematic work sharing/collaboration
- Transparent, predictable regulatory action from consistent CAPA assessment

Deliverables

- Improved management of inspection reports through repository
- Transparent, predictable regulatory action from consistent CAPA assessment
- Appropriate sanctions for non compliance recommended
- Training for inspectors

# Success Criteria/Deliverables

Work Package 6

- Appropriate PRAC work sharing established – Referrals, RMPs, PSURs, PASS etc
- Evaluation of outcomes, follow up action
- Cost effective risk minimisation
- Proactive B/R evaluations

Deliverables

- Full understanding of process work flow matched by skills
- Assessor training
- Access to and use of other data sources for use of Epi in assessment process
- Monitoring of impact at NCA level

# Suggestions Raised

BE – Referrals, understanding procedures as to when they are mandatory = WP6

IT – PV in clinical trials. National CT databases linked to Ethics committees = Out of scope?

ES – Potential to merge Signals and ADRs = Too big?

SE – Specific proposals on Comms = WP2

SE – Database of searchable SmPC information = ?

SE – Understanding transparency requirements = WP2

# Break-out Objectives

1. Where are the GAPs?

2. Inclusion criteria, agree scope of project
- Should this be Joint Action or is it already covered elsewhere?
- Does it need to be done before Joint Action starts?
- If so is there a 2nd stage for Joint Action?

3. Prioritise activities
- What needs to be done first? Where are the quick wins?

4. Work Package Leads
- What skills are needed? What resource is needed?

5. Collaborators
- What experts should be involved (sub-contractors)? Other national bodies that need to be included?

# Break-out Objectives

Possible project names

- PERFORM
  - Pharmacovigilance in Europe Realising Operations in Risk Management
- NETWORK
  - National & European Transition to Worksharing Operations for Risk Knowledge
- SCORE
  - Strategies for Collaboration to Organise & Run pharmacovigilance in Europe
- SCOPE
  - Strategies for Collaboration to Operate Pharmacovigilance in Europe

# Next Steps

- Over the next two months we need to agree

  - Scope & Priorities
  - Deliverables
  - Work package leads
  - Dissemination approach & lead
  - Evaluation approach & lead
  - Budget costs
  - Project name

All needs to be in place before next workshop 18th Feb