Strengthening Collaborations for Operating Pharmacovigilance in Europe

Work Package 6 – Risk Communication

PCWP and HCPWP Joint Meeting Workshop on Benefit Risk Communication

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Strengthening Collaborations for Operating Pharmacovigilance in Europe

- From 2013 to 2016
- Support operations of pharmacovigilance in Member States following requirements introduced by the European pharmacovigilance legislation (July 2012)
- Funded by the European Commission (CHAFEA) and with contributions of the involved Member States
- Gather information and expertise on how regulators in Member States run their responsibilities in the field of Pharmacovigilance
Overall aims of SCOPE

- Provide practical tools and guidance for NCAs to develop their pharmacovigilance obligations
- Develop and deliver guidance and training in key aspects of pharmacovigilance
- Benefit medicines safety monitoring and communications outputs
- Help to safeguard public health
Expected Outputs

• Improve reporting mechanisms for adverse drug reactions

• Implementation of shared understanding of best practice in signal management

• To identify the most appropriate practices in Risk Communication through the creation of a standardized toolkit

• To enable Member States to develop optimal quality management systems for pharmacovigilance.

• The development of a competency framework to support exemplary pharmacovigilance throughout the product lifecycle.

• To create a platform for interaction amongst European NCAs to strengthen regulatory collaboration.
SCOPE Management Structure

European commission

Lead Member State – UK Project management, Budjectary control, Risk Register Reporting Communications

Work Package Leaders Group (Lead Member State + Work Package Leads)

General Advisory Board Representative from the stakeholder groups and the EC chaires by Lead Member State

WP 4: ADR Collection HR
WP 5: Signal Management NL
WP 6: Risk Communication ES
WP 7: Quality Management Systems HU
WP 8: Lifecycle Pharmacovigilance

WP 1 Coordination- UK
WP 2 Dissemination- UK
WP 3 Evaluation- PT
WP 6- Risk Communication

• Collect information on the risk communications practice in the EU network.

• Develop a series of recommendations in the form of a communications toolbox, so that MSs could select the most appropriate tools according to needs and expectations.

• Develop a guide for the media on scientific risk communication.

• Particular focus on web portals.
WP 6 Participants

- Croatia
- Denmark
- Ireland
- Italy
- The Netherlands
- Norway
- Spain (Leader)
- Sweden
- United Kingdom
WP 6-Risk Communication
Lead: ES

• Topic 1- National Competent Authorities methods for risk communication. Leader: SE

• Topic 2- Impact assessment on risk communication. Leader: IE

• Topic 3- Toolkit for improving practices. Leader: IT

• Topic 4- Web Portals. Leader: UK
1. **MS- Survey**:
   - communication channels and tools used
   - frequency and timelines of communications
   - engagement levels with stakeholders
   - cascade systems and professional networks for dissemination of information
   - Impact assessment
   - What worked well? Problems? Ideas?
Topic 1- Audit of national methods of communications

Leader: SE    Active participants: DK, IT, HR, NO, ES, NL, IE, UK

Workflow

- Preparation: MS-Survey
- Launch: MS- Survey
- Assessment: survey responses
- Final status: Report
Study protocol

• On knowledge, attitudes and preferences of target audiences towards different tools and channels for safety communication, relevance of communications and impact on their practices

Field study- in WP participating MS (DK, IE, IT, ES, HR, NO, SE, UK, NL)

Analysis of the study results

Prospective case studies

• To examine performance in practice of a number of communications for high profile drug safety issues from healthcare professional and, if feasible, patient perspective
Topic 2 - Impact Assessment of risk communication

Lead: IE  Active Participants: ES, NL, NO, SE

Workflow

- Literature Review
- Study Protocol
- Field Study
- Analysis of results
- Prospective case studies
Topic 3- Toolkit for improving practices on risk communication

Analysis of outputs from Topics 1 and 2:
• ways of communication, preferences from HCP, impact in clinical practice

Development of a toolkit
• What are the options that best worked and in which environment

Training session tailored to audiences

Workshop
• Involvement of interested parties (NCA, healthcare professionals, citizens, media)
Topic 3- Best Practice

Lead: IT  Active Participants: DK, NL, SE, ES, IE, HR  Additional experts involved

Workflow

- Analysis of outputs of topics 2 and 3
- Development of a toolkit on safety communications
- Training Workshop
1. **Work from Outputs of other Topics in WP**
   - To scope needs and design of webportal

2. **Development of guidance**
   - For internal preparation of safety information for publication on web portal
   - For coordination of information presentation within the EU network

3. **Deliver and launch**
**Topic 4- Webportals**

**Lead: UK**  Active participants: ES, NO, SE  ICT Subcontractor needed

**Workflow**

- Preparatio
n Survey
- Launch Survey
- Outputs of other Topics
- Development of guidance
- Deliver and launch
Overall aims of WP 6

• To define best practice in Risk Communications through the creation of a standardised toolkit

• To create a forum for interaction amongst European National Competent Authorities to strengthen regulatory collaboration
For more information

- http://www.scopejointaction.eu
Thank you!

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