

**SCOPE Joint Action**  
**Work Package 6**

**Stakeholder Event**  
**London, 21 September 2015**



# WP6 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.
- Improvement of web portals from national agencies.

# WP6.1: Topics

- 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

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

# WP6.1: T1 - Audit of national methods of communications



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## Workflow



# WP6.1: T1 - Audit of national methods of communications



## 1. NCA- 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?

# WP6.1: T1 - Audit of national methods of communications



## 2. Response Analysis

- 26 out of 27 MS responded to the survey.
- Final Report of currently used tools and channels (March 2015)

## 3. Conclusions

- Real interest in the area and a high ambition for improvement among MS.
- Risk communication systems and processes are available in the MS.
- The information and examples provided will be used for developing guidance and recommendations on good communication practice for NCAs in Europe.

# WP6.1: T1 - Audit of national methods of communications



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## 4. Recommendations

- Advantages of DHPC distribution via scientific organizations.
- Consider how stakeholders could be further alerted to important safety messages in DHPCs.
- Integration of safety communications in the prescribing and dispensing electronic tools.
- Use of multiple channels/tools and repeating information to strengthen messages.
- Development of ways to collaborate with patient organisations with the aim to strengthen communication on safety messages.
- Methodology for follow-up and impact measures.

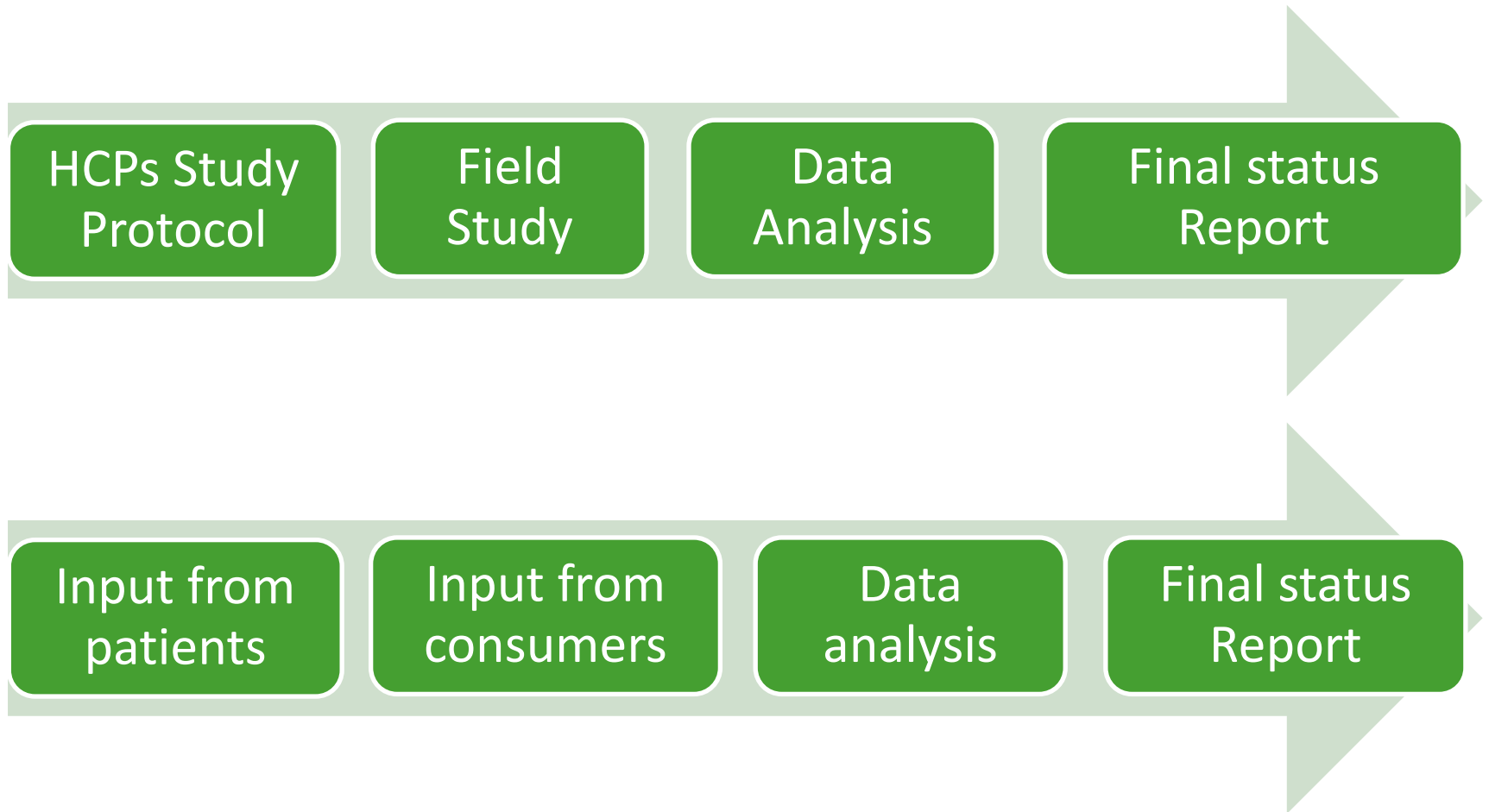
# WP6.1: T2- Impact assessment of risk communication



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## Workflow





# WP6.1: T2- Impact assessment of risk communication



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- Communicating safety information to HCPs and patients is essential for achieving the objectives of pharmacovigilance in terms of promoting and contributing to the protection of patients and public health.
- As per the GVP Module XV (guideline on good pharmacovigilance practices on safety communication), the views and expectations of patients and HCPs should be taken into account.
- A survey among HCPs was conducted focusing on process indicators relating to the effectiveness of safety communication.
- Input from patients and citizens on risk communication will also be sought

# WP6.1: T2- Impact assessment of risk communication



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## **1. Study aim**

Knowledge about attitudes, awareness, preferences and behaviour of HCPs on safety communications (both safety communications and educational materials).

## **2. Participants**

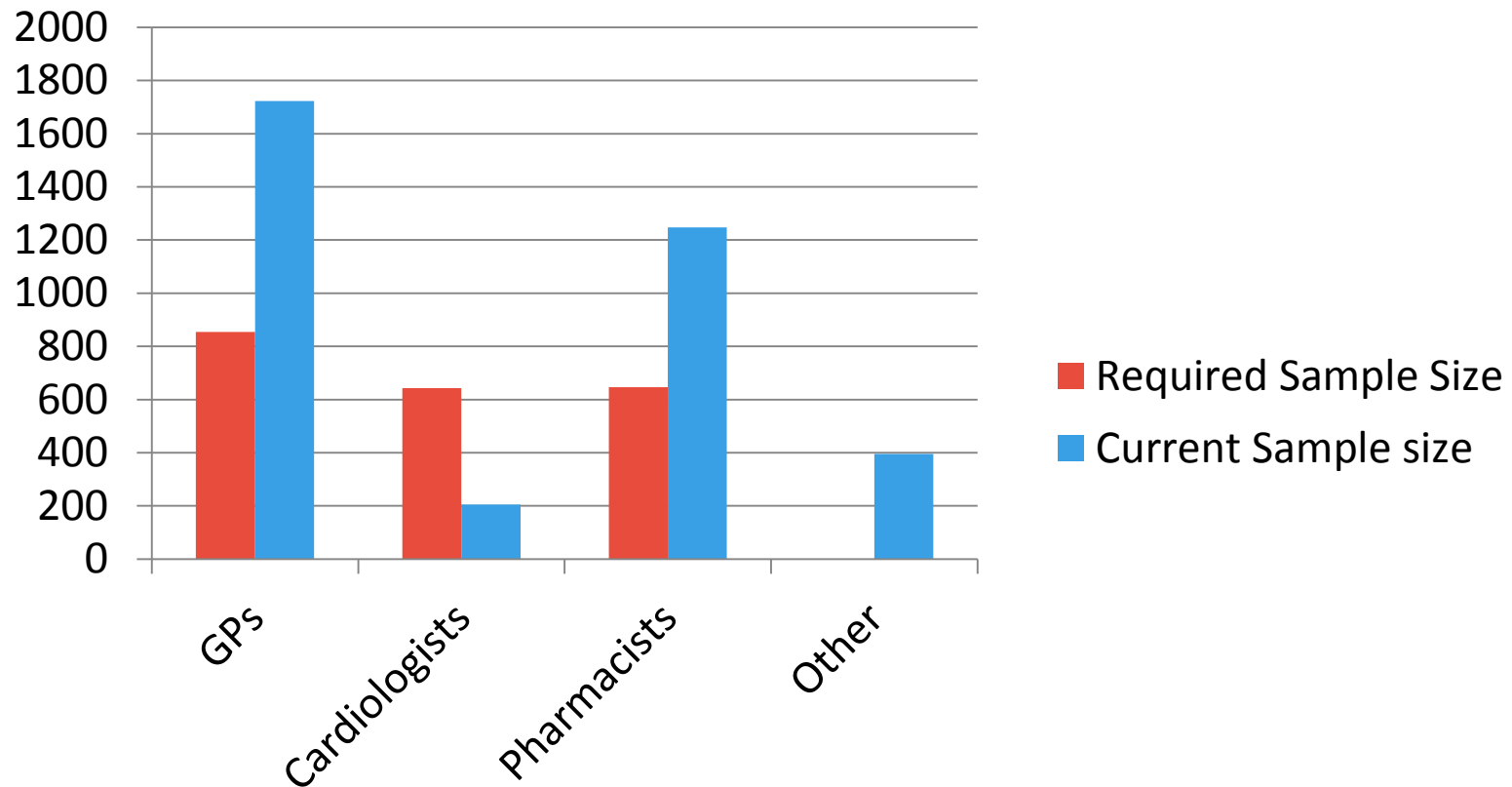
Multi-country study (IE, SE, UK, NO, DK, IT, HR, NL and ES)

## **3. Target audience**

Primary healthcare physicians, cardiologists and pharmacists (the latter in some MS)

# WP6.1: T2- Impact assessment of risk communication

- Survey preliminary results (31 August 2015)





# WP6.1: T2- Impact assessment of risk communication



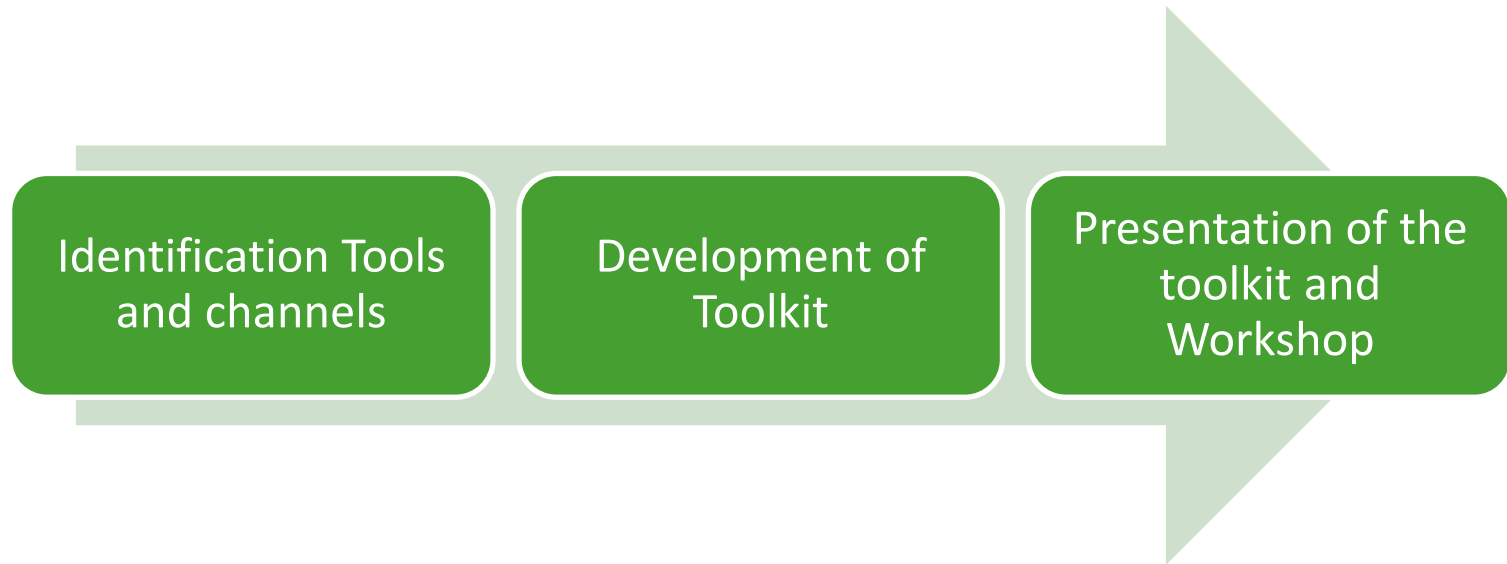
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- The results of the survey (HCPs) and the **Results** of the patients/consumers consultations will be used to evaluate the effectiveness of current safety communication tools.  

- The evaluation will lead to **Recommendations** for safety communication strategies.  

- The Recommendations can be used by national competent authorities to **Improve** their safety communication strategies.

# WP6.1: T3- Best Practice

## Workflow



# WP6.1: T3- Best Practice

- Based on the data extracted from the three surveys conducted within WP6:
  - T.1 - Methodologies that are currently used by NCAs for the dissemination of safety information.
  - T.2 - Effectiveness of different risk communication methods and the stakeholder (HCPs, Patients/Consumers) needs and preferences.
  - T.4 - Current status of NCA's webportal and identification of weak areas.

## **Objectives:**

- Focuses on optimize current risk communication methods and improve implementation of any necessary actions into clinical practice.
- Strategies to fulfill legislation requirements at national level among the MSs.
- The practical experience reported by NCAs can be broadly used for knowledge exchange and for identifying useful tools and methods for MSs communications.

# WP6.1: T3- Best Practice

## 1. Toolkit

The toolkit on risk communication is intended for EU NCAs

- The three surveys, performed to collect information on current methods of risk communication at national level, will be the bases for the Risk Communication toolkit.
- The toolkit will provide useful framework that can be adapted to local situations.

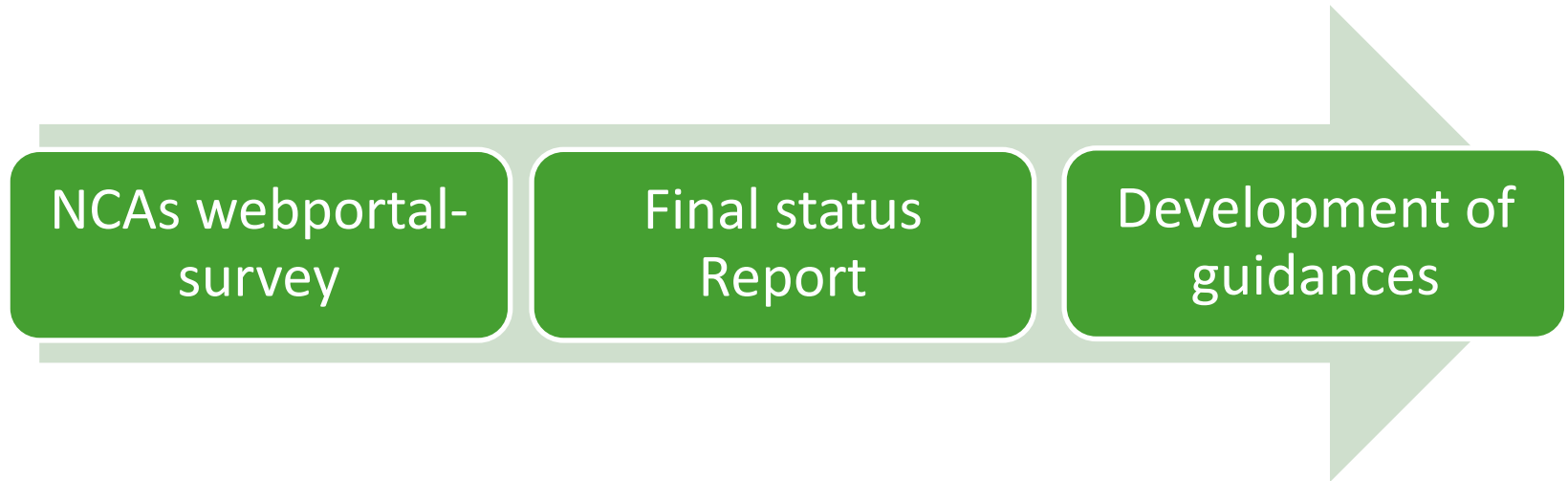
## 2. Workshop

*Objectives:*

- Review current practice in Risk Communication among the EU NCAs as emerging from the surveys.
- Present the toolkit.

# WP6.1: T4- Webportals

## Workflow





# WP6.1: T4- Webportals

- Focuses on web-portals to provide safety information and risk communications about medicines.
  - Provide practical guidance on meeting the requirements for complying with the legislative requirements
- 1. NCA- Survey**
- Identify the range of practice across EU member states.
  - Direct next steps and recommendations for delivery of guidance on national provision of web-portals.
  - Support member states to meet the requirements set out in the EU pharmacovigilance legislation.

# WP6.1: T4- Webportals

## 2. Response Analysis

- 25 out of 27 MS responded to the survey.
- Final Report of currently used tools and channels (May 2015).

## 3. Recommendations

- Structuring information, how to tailor information for specific audiences.
- Making information accessible.
- Monitoring usage/feedback, obtaining user evaluation and using this to inform and enhance web-portals.

## WP6.2: Overall aims

- 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.

# WP6.3: Deliverables

WP 6 Risk Communications	Deliverables
Topic 1- Audit of national methods of communications	National Competent Authorities methods for Risk Communication Report
Topic 2- Impact assessment	Impact of Risk Communications Report
Topic 3- Best Practice	<ul style="list-style-type: none"><li>- Risk communications toolkit</li><li>- Workshop</li></ul>
Topic 4- Webportals	Webportal best practice guide

## WP6.3: Planned work

- Analyze the results of the study on the impact and effectiveness of risk communications from HCPs point of view.
- Input from patients and citizens on Risk Communications.
- Develop a Webportals publication Guide.
- Develop Risk Communication toolkit for the NCAs.
- Organize 2016 Risk Communication Workshop.

# WP6 Participants

- Wennberg, Annika (MPA)
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- Alonso Lebrero, José Luis (AEMPS)
- Escudero Fernández, Yvette (AEMPS)

**Thank you!**

