

# State of the art in Safety Communication

## Outputs from SCOPE – how to implement in practice

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The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional

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I am not receiving any compensation

# Presentation on behalf of WP6 Team



# SCOPE 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 and make proposals for improvement**
- 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



# WP6- Risk communication What has been done?

- How are we doing on risk communication? Two surveys to NCAs:
  - risk communications
  - websites/portals
- What is the perception from HCPs?
  - One survey to HCPs (primary care/cardiologists/pharmacists)
- What are the views from patients/consumers?
  - One consultation to patients and consumers through organisations (BEUEC, EURORDIS, EUPATI)
- How can we improve?
  - Webportal Good Practice Guide
  - “Risk Communication Proposal for improvement” document
- Workshop on Risk Communications on Medicines (Madrid, June 2016)



# SCOPE Work Package 6 Structure

Overall coordination: AEMPS

1. Audit of National Methods of Communications. *Lead by MPA*  
Findings about Risk Communications methods currently adopted by NCAs.
2. Impact Assessment of Risk Communication. *Lead by HPRA*  
Findings about stakeholder attitudes, needs and preferences in relation to risk communication strategies currently in place
3. Good Practice. *Lead by AIFA*  
Risk Communication – Proposal for improvement document
4. Webportals. *Lead by MHRA*  
Outline findings about MS websites, key aspects on the guideline and practical examples



# Audit of National Methods of Communication (26 NCAs )

## CONTENT

Procedures for safety communication – organization and process

External safety communication – communication in practice

Communication channels and target audience

DHPCs - handling/process

General experience and good examples



# Audit of National Methods of Communication (26 NCAs )

## CONCLUSIONS

High ambition to improve

Multiple tools/channels to strengthen information uptake

Integrate safety communications in prescribing and dispensing electronic tools or in product information national databases

Collaboration with key experts in relevant fields (tailor message to national situation)

Routines for monitoring the impact of safety communications should be developed





# HCPs survey- Medicines Safety Communications and their effectiveness

Aim: explore the attitudes, knowledge, preferences and behaviours of HCPs in Europe, regarding methods to communicate safety issues of medicines.

## Target population

- General practitioners (GPs)
- Cardiologists
- Pharmacists (except ES, SE)
- *Other responders (HCPs active in clinical practice)*



# Methods

## Online survey in 9 Member States (35 Q)

### CONTENT

DHPCs

NCA communications

Educational materials

Awareness of specific safety issues  
(same examples, national layouts)

General preferences (e.g. channel,  
source)

Demographics

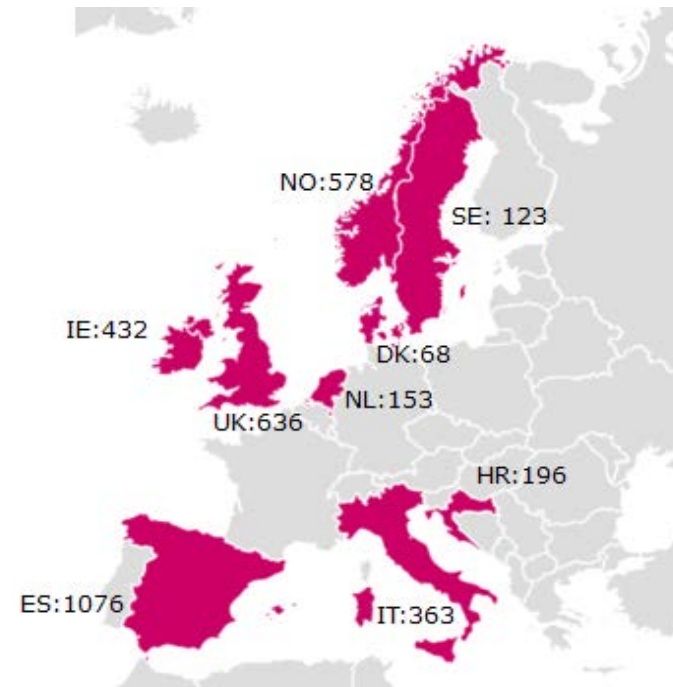


# Some Results

3625 respondents

- 1766 GPs
- 222 cardiologists
- 1300 pharmacists
- 337 other

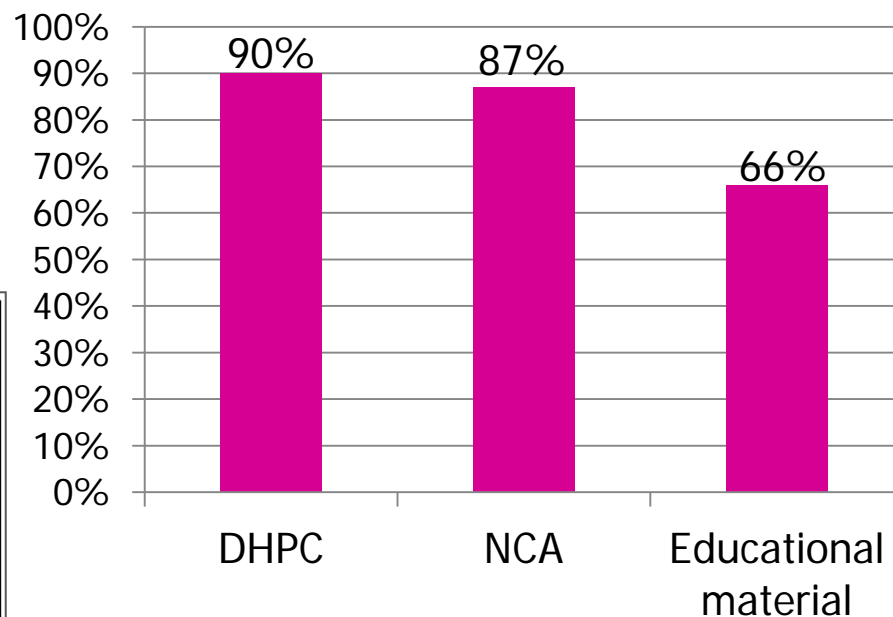
	N (%)
Female	2215 (61)
Primary employment setting	
Community-based	2570 (70)
Hospital-based	857 (24)
Other	244 (6)
Age	
<35 year	625 (17)
35 – 45 year	964 (27)
46 – 55 year	1071 (30)
>55 year	964 (27)
Accreditation	
<5 years	370 (10)
5 – 20 years	1394 (38)
>20 years	1859 (51)



# Familiarity

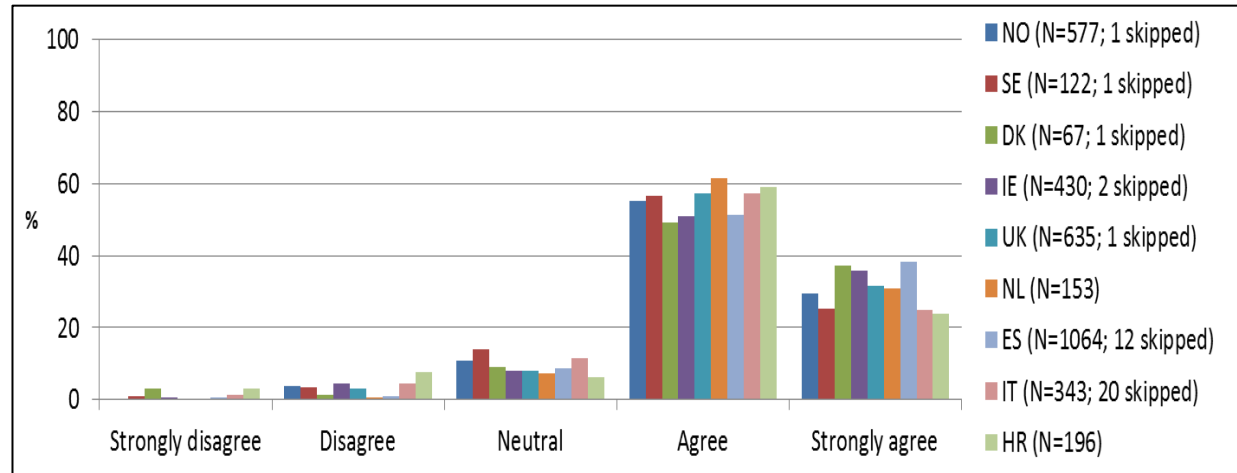
Yes, I have received this type of information and I sometimes read it

<b>Range DHPCs</b>	
Country	77% NO – 97% IE
Profession	85% other – 94% GPs
<b>Range NCA</b>	
Country	28% NL – 96% ES
Profession	74% cardiologists – 91% other
<b>Range Educational material</b>	
Country	60% ES – 79% IE
Profession	45% other – 74% pharmacists

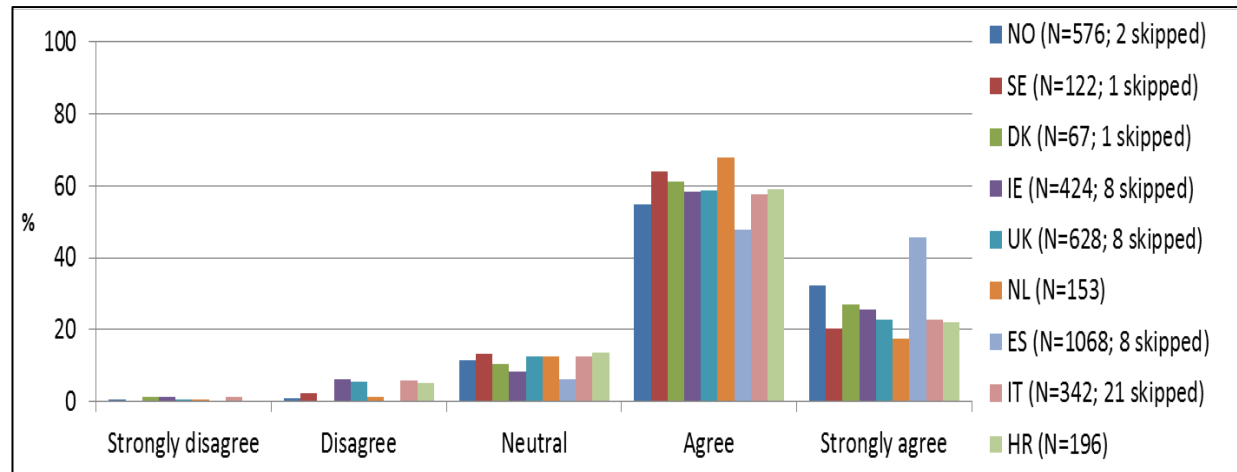


# Sender

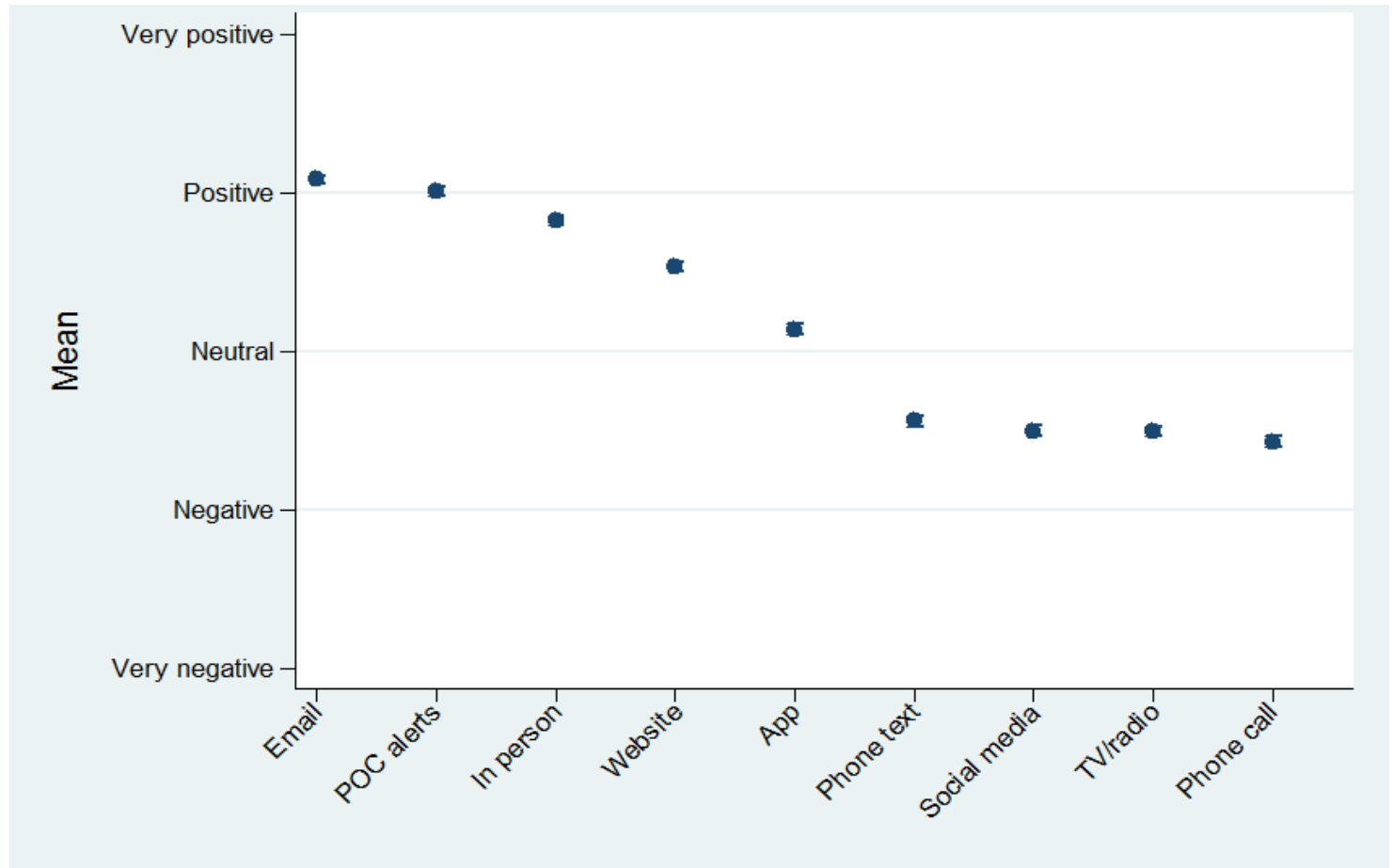
I only read the safety information if, I trust the sender



I only take action in response to a safety warning if, I trust the sender



# Alternative channels



# Some recommendations

- Promote role of trusted sender (eg. NCA, professional body)
- Increase awareness of educational material, clear distinction from promotional materials
- GPs considered useful reminders of messages
- Format and alternative channels for distribution to be based on national preferences
- Integrate communication in electronic prescribing tools (point of care alerts)



# Patient and Consumer Consultation

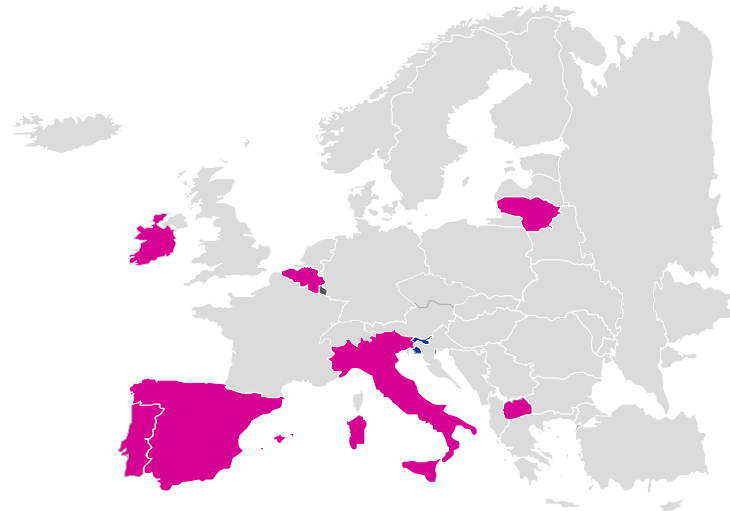
## Methods

### Aide Memoir Distribution

- BEUC (The European Consumer Organisation)
- EURORDIS (The European Organisation for Rare Diseases)
- EUPATI National Platforms (ENPs)

11 patient/consumer orgs contributed, representing 7 MSs:

- Belgium
- Spain
- Portugal
- Ireland
- Italy (IT)
- Lithuania (LT)
- Macedonia (MK)





# Trusted sources of medicines information

- Doctors, followed by pharmacists and other Health Care Professionals.
- Patient Organisations (depending on disease, area and country)
- Face-to-face discussion with the HCP is the preferred channel
- Scarce use of NCA websites



# Communications about specific safety reviews

- Communicated at the start of the review
- Transparency will enhance trust
- Target communications (collaboration with patient organisations)

## Educational materials

- Low familiarity with educational materials and unawareness of NCA approval
- Concise information and user-friendly language to be encouraged



# Good Practice- Proposal for improvement

## CONTENT

Processes and Procedures

Message preparation

Tools and channels for  
safety communications

Dissemination

Impact evaluation



# Good Practice- Proposal for improvement

## SOME RECOMMENDATIONS for NCAs

Multidisciplinary team, provision of training

Engage external experts when feasible

Need to re-focus educational materials

Two-way exchange with HCPs and patients/consumers

Communication tailored on the receiver(s)

Enhance NCA role (most trusted sender)

Dissemination via learned societies, point-of-care alerts and other possible amplifiers

Measure the impact of the process for continuous improvement



# Webportals – Survey (25 NCAs)

## SURVEY CONTENT

Languages

Information – content

Information - Presentation

Target audience

Accesible formats

Raising awareness of safety information

## SURVEY CONCLUSIONS

Significant diversity and practice

Lack of clarity on webportal concept

Value of providing guidance and examples:

-Review of a number of websites, identifying good practices, user friendliness and user feedback



# Webportals- Guidance

## Content

- Important considerations when developing websites
- Overview of challenges during web development
- Content and structure of the information
- How to improve accesibility
- Tips to organize the information
- Quality control
- Monitoring user feedback
- Steps forward



# Risk Communication on Medicines Workshop

- National Competent Authorities 70 pax
- Health Care Professionals 15 pax
- Patients and Consumers 9 pax
- UMC
- Lareb 2 pax
- EMA 2 pax
- EAMI 1 pax
- Academia 3 pax

**103  
pax**



# Workshop - Some ideas for reflection

- Create a European forum involving NCAS and Academia representatives for a consistent strategy on risk communication.
- Elaborate further on the identified factors influencing a good communication
- Build on practical approaches and advices for implementation within the EU network
- Develop suggestions about the way to make progress after SCOPE project finalisation





Want to know more? [www.scopejointaction.eu](http://www.scopejointaction.eu)

1. Risk Communication – Proposals for Improvement

- Annex 1: WP6 Survey Report – Audit of National Methods of Communications
- Annex 2: WP6 Survey Report – Patients and Consumers Consultation
- Annex 3: WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness
- Annex 4: Risk Communications on Medicines Workshop Report

2. Good Practice Guide – Web-based Safety Information

- Annex 1: SCOPE Web-portals survey report



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