



 agencia española de
medicamentos y
productos sanitarios



SCOPE Joint Action

Work Package 6 on Risk Communication

London, 8 March 2016

**Dolores Montero
Spanish Agency on Medicines
and Medical Devices**

A large, stylized green leaf graphic is positioned in the bottom right corner of the slide, partially overlapping the text area.

Scope Project



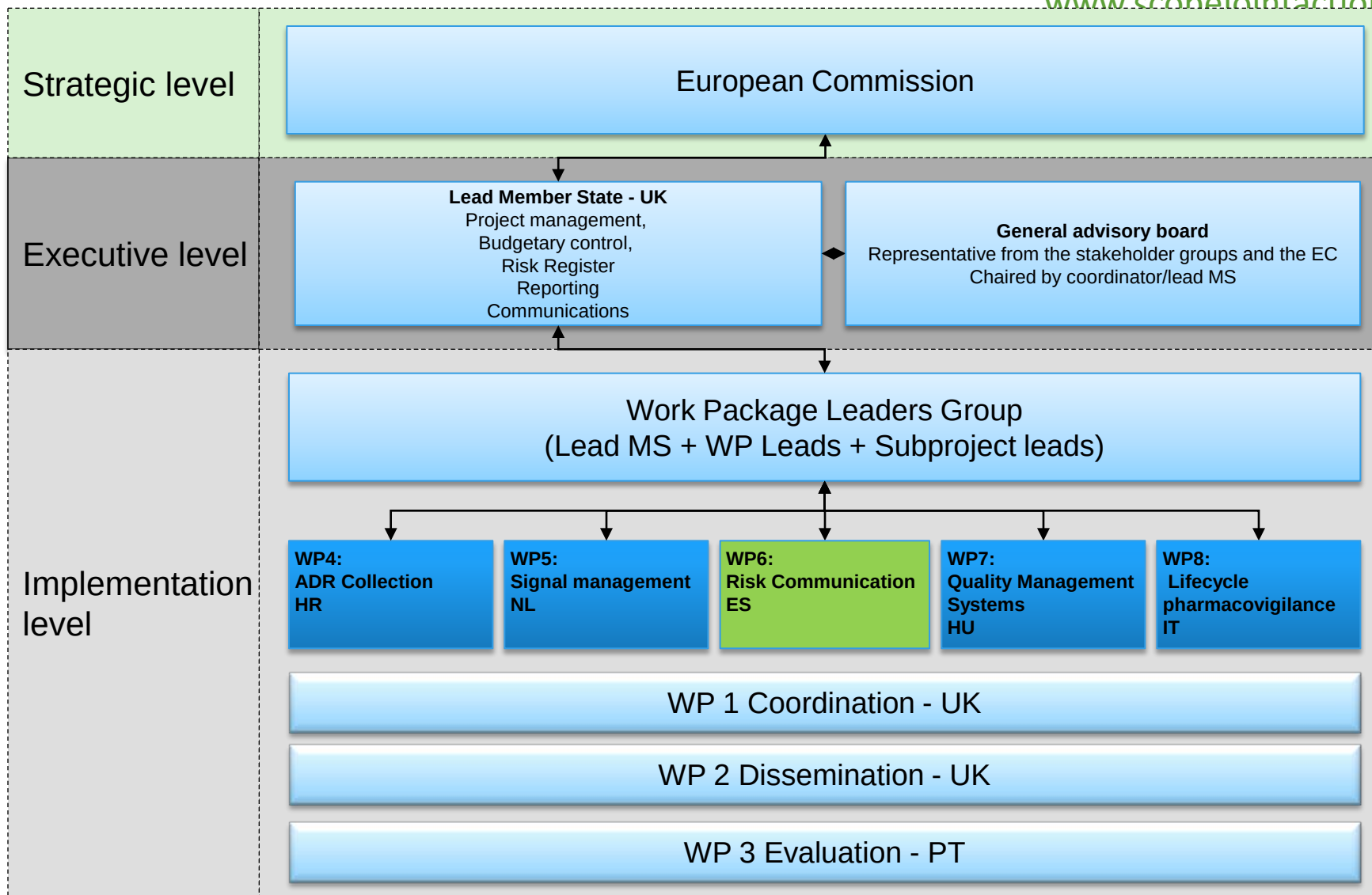
SCOPE

www.scopejointaction.eu

SCOPE co-ordination



www.scopeintaction.eu



WP6: Risk communication

How is risk currently being communicated by national agencies? Use of the website?

How are these communications perceived by healthcare professionals and patients?

Could different tools and good practices be identified?

Recommendations for websites based on review of current practices

WP6: Risk communication

How is risk currently being communicated by national agencies? Use of the website?

Survey to all national agencies, 26 replies

Main topics:

- National internal procedures for safety communication – organisation and process
- External safety communication – communication in practice
- Communication channels and target audience
- DHPC handling/process
- General experience and good examples
- Organisation on website in terms of risk communication

Reports available at

<http://www.scopejointaction.eu/work-packages/wp6-risk-communications/>

How is risk currently being communicated by national agencies? Conclusions

- The MS have different approaches to risk communication but systems and processes are available in the majority of MS.
- Follow up of recommended actions is, if at all, only performed on a case by case basis.
- It would be effective if safety or alert messages could be directly linked to the medicinal product information in electronic prescription system and the SmPC-PIL databases
- Using multiple tools/channels and repetition of the message is considered valuable for strengthening the uptake of the information.

How is risk currently being communicated by national agencies? Conclusions

Collaboration with opinion leaders and key specialists in the relevant field as well as with patient organisations is considered as key to a successful communication

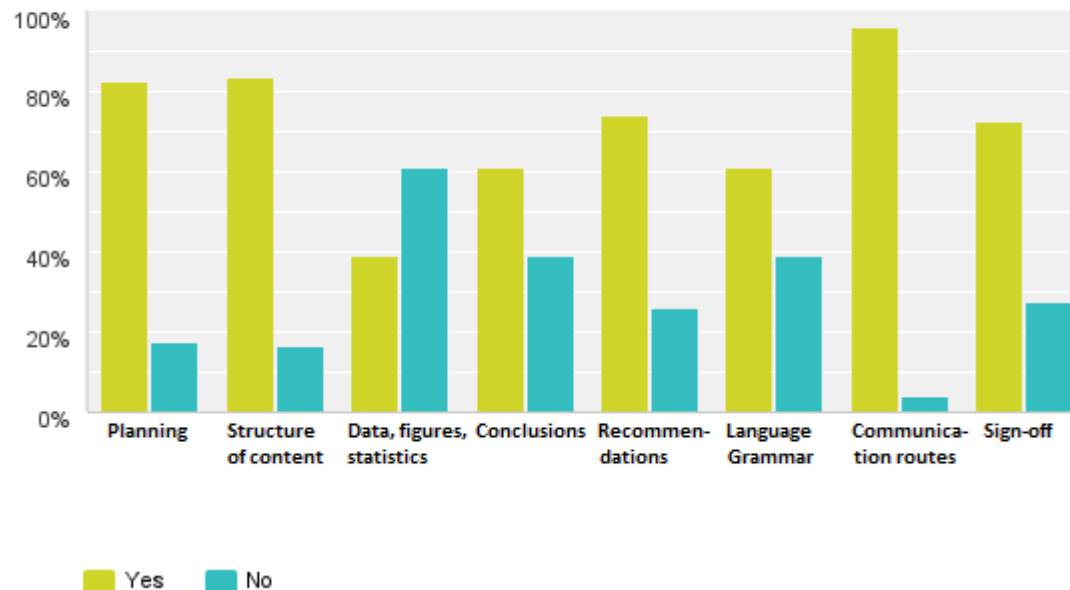
The advantages of DHPC distribution via scientific organizations could be further assessed.

How is risk currently being communicated by national agencies? Conclusions

Routines for monitoring the desired effects of the safety communications could increase the NCA's skills in developing good communication routines, and could also be a tool for raising awareness of the safety communication in the target audience.

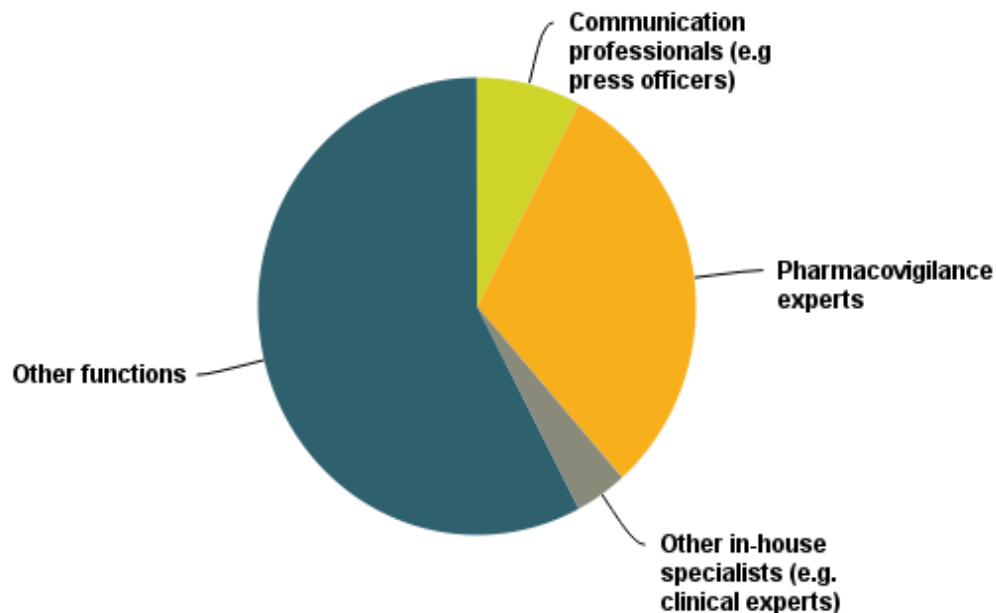
Some results

Items included in quality systems/SOPs/internal guidelines



Some results

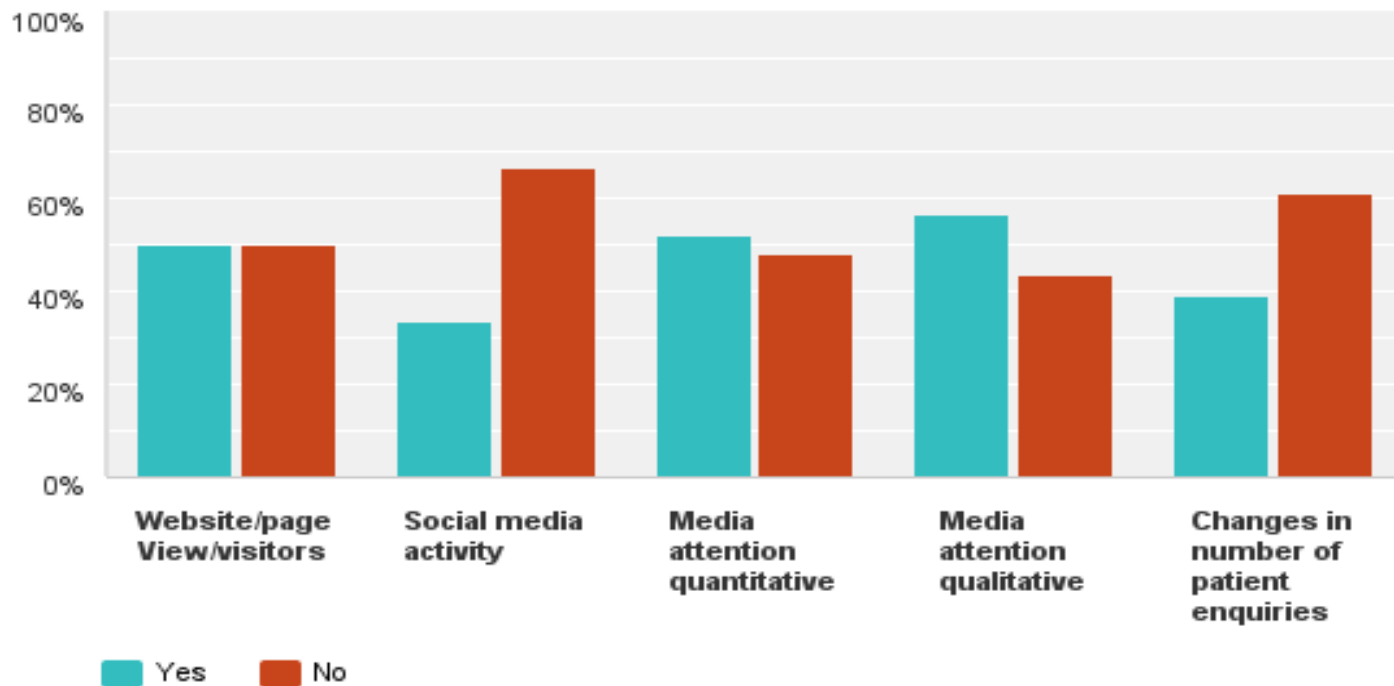
Functions involved in safety communications



Some results.- Communication in practice – national diffusion of EMA communications



Some results. Follow up of safety communication



How such communications are perceived by healthcare professionals and patients?

HCPs survey in 9 Member States (DK, NO, ES, HR,
IE, IT, NL, UK, SE):

GPs, cardiologists (pharmacists)

3,625 replies received and being analysed

Input from patients/citizens: collaboration from
BEUC and EUPATI being analysed

Could different tools and good practices be identified?

- Set of practical tools.
- Suggestions to manage Risk Communications: decisional flow and implementation.
- Based on:
 - How NCAs are currently communicating.
 - HCPs, patients and consumers input
 - Effectiveness of different communication methods.

Recommendations for websites based on review of current practices

WP6: Risk communication

When results will be ready? June 2016

- A **workshop** will be held **on 16-17 June in Madrid**, results presented with the aim to enhance the toolkit and good practices
- Attendance of NCA, WHO, EMA, academia, HCP and patients involved...**but open to anyone interested in the field and eager to provide input!!**

Thank you!

