SCOPE Work Package 6
Risk Communication

National Strategy for Implementation of Recommendations on Risk Communication: Key Actions

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Contents

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1. Introduction

After the Risk Communications on Medicines Workshop was held in June 2016, all suggestions provided by the audience were compiled in an evaluation report. One of the recommendations from the audience was to summarise the suggestions for improvement document in a bullet point format to accompany the other Work Package 6 (WP6) documents. Creation of a more strategy focused document was suggested.

Based on the results gathered from the survey and the comments received from the workshop, a summary of key actions was developed.

The purpose of this document is to guide National Competent Authorities (NCAs) in the process of implementing the recommendations from SCOPE WP6. The level of complexity and the resources needed differ for the various key actions suggested.

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2. Actions

2.1 Develop a national strategic plan on risk communication

This plan should be based on the following general principles:

a) The ultimate aim should be raising the role of the NCA as a trusted source of safety messages on medicines.

b) Priorities and strategies on risk communication should be tailored according to the current situation in the NCA; risk communication main objectives, resources and feasibility of potential new actions.

c) Ensure the coordination of the safety communications at the European Union (EU) level.

Each NCA should consider these factors and implement first, the actions with higher impact on patient safety and possibly less complex outcomes, to put in place nationally. Demands and impacts are highly dependent on the situation in each Member State (MS), as well as on how developed the NCA is in terms of risk communications.

2.2 Build a communication team

a) Ensure adequate resources.

b) Appoint a person to coordinate.

c) Organise a multidisciplinary team where possible and/or provide the possibility of engaging external experts (a network available for consultation at short notice).

d) Assess training needs of the team and prepare a training plan considering internal and external resources.

2.3 Organisation and dissemination of safety communications

Adapted to the national context, considering the following aspects:

a) Prioritise relevance in terms of healthcare, urgency (patient harm, frequency, disease patterns, extent of use of a given drug, etc.) and impact on clinical practice.

Ensure appropriate content and language is used depending on the target audience:

i)   Plain language, optimise design/layout, onion layers concept (key messages — more detailed information — full info on source of evidence)

ii) User testing of the key messages

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b) Consider available tools and channels and explore other strategies to amplify the message:

    i) Learned societies (or other trusted national bodies) for dissemination of the risk communications

    ii) Point of care alerts adapted to be displayed in electronic prescription systems

    iii) Periodic bulletins

    iv) NCA's official social media account(s)

2.4 Assign roles and responsibilities to the communication team members

a) According to the communication tools (bulletins, communications targeted to healthcare professionals (HCPs) and/or patients/consumers, press releases, safety messages on prescribing/dispensing systems, etc.)

b) According to the different phases of the communication process: elaboration, approval, internal activities coordination, active dissemination, web publication of communication materials, impact assessment, answer to external and internal queries, etc.)

If possible, a "communication manual" should be developed, including all the processes and procedures, roles and responsibilities. This document could be consulted by staff and would contribute to achieve structured and systematic workflow.

2.5 Build relations with target audiences

Engage with national representatives of the different target audiences (HCPs, patients/consumers organisations, and other national bodies such as learned societies) to enable two-way communications, particularly for getting feedback on the best dissemination channels, and for message understanding and amplification.

2.6 Review of national website

Review content and structure and obtain user feedback in line with the recommendations from the Web-portals Good Practice Guide developed by SCOPE WP6.

2.7 Enhance the role of NCAs as a source of communication materials

In particular:

a) Consider publication of additional communication materials on the NCA website (i.e. educational materials, direct healthcare professional communications (DHCPs) and other communications)

b) Consider pro-active communications from NCAs, with the involvement of learned societies

2.8 Review procedures for national handling of educational materials

Presented by Marketing Authorisation Holders (MAHs), in particular:

a) Ensure that a procedure is in place to properly assess purpose, content and dissemination of individual documents

b) Consider targeted awareness campaign on the aim of the educational materials

2.9 Organise a proactive system to evaluate the impact/effectiveness of risk communication processes and outcomes

Including the following:

a) Measurement of compliance. The recommendations that impact on clinical practice could be measured (including educational materials)

b) Introduce the principles of continuous improvement (cycle of learning and improving)

c) Explore available data sources, particularly access to prescribing and dispensing data, and other data from national systems that provide information about the use of medicines (quantitative and qualitative)

2.10 Promote awareness and training of healthcare professionals

On medicines regulation and risk communication at pre and postgraduate levels.