SCOPE Work Package 6
Risk Communication

Introductory Document

2016

SCOPE

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Contents

Summary

Work Package 6 Objectives

This work package has developed a document for risk communication, highlighting areas of good practice and proposing areas for improvement in medicines risk communication. In addition, a guidance document for optimising the presentation of web-based safety information has been created.

WP6 Deliverables

Guidance documents

- Risk Communication – Proposals for Improvement
- Good Practice Guide – Web-based Safety Information

Survey reports

- Audit of National Methods of Communication
- Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness
- Patients and Consumers Consultation Report
- Web-portals

Background

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action been created to support operations of pharmacovigilance in Europe following requirements introduced by the European pharmacovigilance legislation that came into effect in June 2012. SCOPE will develop and deliver guidance, training in key aspects of pharmacovigilance, and tools and templates to support good practice. Through this approach, SCOPE aims to support consistent, sustainable, approaches to pharmacovigilance operations in the EU medicines regulatory network.

Work package 6

The activities of the SCOPE Joint Action have been divided into project work packages.

Work package 6 (WP6) has focused on how risks associated with the use of medicines are communicated, including the presentation of such information by national agencies. As part of this work, experts from the national agencies of Croatia, Denmark, Ireland, Italy, the Netherlands, Norway, Spain, Sweden and the United Kingdom have participated. WP6 has also benefited from advice given by a communications expert from Maastricht University and an observer from the European Medicines Agency (EMA), together with support from the University Medical Center at Groningen.

As a starting point the legal obligations of national agencies were reviewed. The revised legislation on pharmacovigilance for human medicinal products in the EU that came into force in June 2012 includes a number of provisions to strengthen safety communication and its coordination (Articles 102 and 106a of Directive 2010/84/EU amending Directive 2001/83/EC).

The legislation also states that Member States (MSs) are required to create and maintain a web-portal (website), linked to the proposed European medicines web-portal for making a minimum amount of information on medicines publicly available (Article 102d and 106 of Directive 2010/84/EU amending Directive 2001/83/EC), in order to increase the level of transparency in pharmacovigilance processes and outcomes.

To optimise current risk communication methods and to improve implementation processes, the SCOPE WP6 team gathered insights into how national medicines agencies are currently performing such communications. Through surveys, information regarding the communication of safety messages, the perception of current practices and the preferences of healthcare professionals, patients and consumers was collected.

WP6 topics

The collective efforts of WP6 were coordinated by the Spanish regulatory agency (Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)), and delivered through 4 topics:

- Topic 1: Audit of national methods of communications by the competent authorities. Leader: Sweden
- Topic 2: Impact assessment of Risk Communication. Leader: Ireland
- Topic 3: Best practices. Leader: Italy
- Topic 4: Web-portals. Leader: United Kingdom

Surveys

Audit of national methods of communication' survey

Regarding the 'Audit of national methods of communication', a survey was launched in July 2014 to 27 National Competent Authorities (NCAs) collaborating in SCOPE. The survey was available for completion until November 2014, with 26 Member States answering the questionnaire. Gaining knowledge on the current practices across Europe was the main objective of the questionnaire, in addition to identifying promising strategies, plans and tools for safety communication. The assessment of the collected responses was collated to create an official WP6 Topic 1 - Audit of National methods of communications by the competent authorities survey report, which was published on the SCOPE website in 2015.

NCAs' web-portals survey

In parallel, between July 2014 and October 2014, a second survey was sent out to NCAs on the topic of NCAs' web-portals, and how this method of communication presents safety information and risk communications about medicines. 25 NCAs responded to the questionnaire, and from these responses a second survey report (WP6 Topic 4 – Web-portals) was created and published on the SCOPE website. The information collected was also used to create guidance and to document areas of good practice, proposing recommendations and examples for improving the presentation of web-based safety information.

Healthcare professionals survey

With the aim of gathering understanding and preferences from clinical professionals, a third survey was issued, this time directed at healthcare professionals in 9 participating countries. Information on their behaviour, knowledge and preferences in relation to risk communication methods was collated and presented in a report (WP6 – Healthcare Professional Survey: Medicines safety communications and their effectiveness). Furthermore, the views of patients and consumers were gathered via the distribution of an 'aide-memoire' to patient and consumer organisations. This was facilitated via collaboration with European associations (EUPATI (European Patients' Academy on Therapeutic Innovation) and BEUC (The European Consumer Organisation)) and the conclusions from this consultation were summarised in a fourth survey report (Patients and Consumers Consultation Report).

Risk Communication – Proposals for Improvement

Based on the collective responses to the surveys to NCAs and to Healthcare professionals, and the patient and consumers aide-memoire, a document entitled "Risk Communication – Proposals for Improvement" was developed. This document includes recommendations that could be used and adapted to the available communication resources and organisation of National Competent Authorities.

The WP6 documents

The WP6 documents are delivered as follows:

- 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
- Good Practice Guide – Web-based Safety Information
  - Annex 1: SCOPE Web-portals survey report
  - Annex 2: Sources of advice and guidance
  - Annex 3: Further examples of NCA user testing surveys and results
  - Annex 4: Examples of MS communication strategies

Participating experts

Experts participating in this work are listed below (in alphabetical order):

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