Contents

Acknowledgments 3

1. Objectives 4

2. Organisation and structure 5
   2.1 Workshop presentations 5
   2.2 Break-out sessions 5
   2.3 Panel discussion 6

3. Workshop presentations 7
   3.1 Risk communication: overview of current knowledge 7
   3.2 Audit of national methods of communications. Findings about methods currently adopted by NCAs 8
   3.3 Web-portals. Outline findings about NCA websites, key aspects of the guideline and practical examples 9
   3.4 Impact assessment of current strategies on risk communication. Findings about stakeholder attitudes, needs and preferences 10
   3.5 My experience with risk communication 11
   3.6 Risk communication – good practice. Presentation of proposals for improvement 12
   3.7 Lecture ‘Communicating benefit and harm information – some insights from research’ 13

4. Breakout sessions 14
   4.1 Main ideas raised 14

5. Panel discussion 16

6. Conclusions 17
   6.1 Summary of presentations 17
   6.2 Evaluation 17
Acknowledgments

Experts participating in Work Package 6 (WP6)

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

- Ahlqvist Rastad, Jane, Medical Products Agency (MPA), Sweden
- Andric, Adriana, Agency for Medical Products and Medical Devices of Croatia, (HALMED), Croatia
- Baldelli, Ilaria, Italian Medicines Agency (AIFA), Italy
- Barrow, Paul, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom (first part of the project)
- Bouder, Frederic, Maastricht University, the Netherlands
- Coleman, Anna Marie, Health Products Regulatory Agency (HPRA), Ireland
- Cupelli, Amelia, Italian Medicines Agency (AIFA), Italy
- De Vries, Sieta, University Medical Center Groningen, the Netherlands
- Escudero, Yvette, Spanish Agency for Medicines and Medical Devices (AEMPS), Spain
- Garcia, Juan, observer from the European Medicines Agency (EMA).
- Haddad, Rita, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom (first part of the project)
- Hearn, Jess, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
- Knudsen, Yngvil, Norwegian Medicines Agency (NOMA), Norway
- Loughlin, Louise, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
- Maciá, Miguel Ángel, Spanish Agency for Medicines and Medical Devices (AEMPS), Spain
- Michan, Line (Danish Health and Medicines Authority (DKMA), Denmark)
- Montero, Dolores, Spanish Agency for Medicines and Medical Devices (AEMPS), Spain
- Mol, Peter, University Medical Center Groningen, the Netherlands.
- Rodriguez, Alfonso, Spanish Agency for Medicines and Medical Devices (AEMPS), Spain
- Samdal, Hilde, Norwegian Medicines Agency (NOMA), Norway
- Sipic, Ivana, Agency for Medical Products and Medical Devices of Croatia (HALMED), Croatia
- Van der Sar, Maartje, University Medical Center Groningen, the Netherlands
- Wennberg, Annika, Medical Products Agency (MPA), Sweden
1. Objectives

The Workshop held on Risk Communication on Medicines was envisioned to achieve three main objectives:

- Share the results from the surveys and the documents produced:
  
  - Surveys:
    
    - Survey to National Competent Authorities (NCAs) (audit of national communication methods and web-portals).
    
    - Survey to healthcare professionals (general practitioners, cardiologists, pharmacists) through learned societies in 9 Member States (MSs).
    
    - Consultation with patients and consumers through key associations.

  - Documents:
    
    - Risk Communication – Proposal for improvement.
    
    - Good Practice Guidance on national web-portals.

- Listen and learn from the workshop attendees experiences on risk communications. The attendees represented academia, healthcare professionals, patients and consumers as well as pharmacovigilance assessors and communicators experts from NCAs. All MSs were invited to send two experts, one in pharmacovigilance and one in communication.

- Gather feedback from the audience on aspects related to risk communication in general, and on the Proposals for Improvement document.
2. Organisation and structure

2.1 Workshop presentations

During the workshop the results from the three surveys relating to risk communication, provided by National Competent Authorities (NCAs), were presented together with proposals for improving current practices, on the basis of the survey results.

The other aspect addressed by Work Package 6 (WP6) related to guidance on web-portals (Web-portals Good Practice Guidance) and was based on a survey to NCAs and some case studies. The Guidance shows the strengths and weaknesses of the NCAs websites in respect of communication on the safety of medicines and gives some suggestions for improvement.

Furthermore, two representatives from academia participated as speakers in the Workshop sharing research results on Risk Communications:

- Professor Frederic Bouder (Risk Communication – Overview on current knowledge)
- Professor Theo Raynor (Communicating benefit and harm information – some insights from research).

Two collaborators in the project, a patient representative (François Houyez) and a healthcare professional (Dr. Roar Dyrkor), shared their experience on risk communication with the audience.

2.2 Break-out sessions

In order to get feedback from the attendees, the workshop audience was divided into four groups for the breakout sessions; pharmacovigilance assessors and communicator experts from NCAs, patients and consumers representatives and healthcare professionals representatives were distributed evenly among the groups. The discussions were supported by pre-specified questions developed by the SCOPE (WP6) team, and covered important aspects from the surveys that were considered needing further input. A facilitator from WP6 was appointed for each breakout session. The conclusions gathered from the breakout groups were presented in the plenary by one spokesperson nominated by each group during the second day of the workshop. The main contents for discussion in each of the four groups were:

- Public participation in risk communication and general processes and procedures.
- Communications on emerging safety issues including NCA websites.
- Dissemination of messages to target audience.
- Supplementary materials as additional risk minimisation tool (educational materials).
2.3 Panel discussion

To broaden the perspective even further, a panel discussion took place with a few representatives from NCAs other than those participating in WP6 as well as experts from supranational organisations (European Medicines Agency (EMA) and World Health Organization (WHO) – Uppsala Monitoring Centre), and representatives from consumer/patient and healthcare professional organisations. Specific questions for discussion were developed in advance.
3. Workshop presentations

3.1 Risk communication: overview of current knowledge

Professor Frederic Bouder gave a presentation which focused on:

- The meaning of risk communication along the years
- The changing nature of risk communication on the 21st century
- How to improve risk communication

During the presentation Professor Bouder discussed key risk communication concepts such as risk perception drivers, the importance of trust and the two-way communication model. He also introduced the evolution of risk communication practices, including moving towards a more transparent risk communication environment where stakeholders and the media play an active role. Also national differences, risk communication impact and context-specific communications were addressed.

At the end of the presentation some key aspects were highlighted:

- Patients perceive all risks differently depending on several factors.
- Trust-building and two-way communication requires good skills to respond to the public and the media.
- Proactive communication is important.
- Healthcare professionals (HCPs) are the crucial link between regulators and patients.
- Context, e.g. country specific and therapeutic sensitive issues impact on risk communications practices.
3.2 Audit of national methods of communications. Findings about methods currently adopted by NCAs

Based on the survey carried out during 2014, a status report on current risk/safety communication methodologies at NCAs, including experience on methods and impact, was developed by WP6. The survey methodology and the conclusions included in the report were presented.

The main topics covered by the survey were:

- Procedures for safety communication – organisation and process
- External safety communication – communication in practice
- Communication channels and target audience
- Direct Healthcare Professional Communications (DHCPs) – handling/process
- General experience and good examples

From the survey it could be extracted that even though the NCAs have different approaches to risk communication, systems and processes are available in the majority of NCAs.

The main conclusions could be summarised as follow:

- Audit of national methods – high response rate to the survey (26 NCAs),
- In general, there is a high ambition to improve
- NCAs use multiple tools/channels to strengthen information uptake
- Some MSs are integrating safety communications in prescribing and dispensing electronic tools or in product information databases
- Collaboration with opinion leaders and key scientists in relevant fields enables understanding of needs and is essential to successful communication of safety messages
- The lack of routines for monitoring the desired effects of safety communication suggest that methodology for follow-up and impact measures should be developed.
3.3 Web-portals. Outline findings about NCA websites, key aspects of the guideline and practical examples

In parallel with the National Methods of Communication survey, a questionnaire about the NCAs websites was also carried out by WP6. During the workshop the Web-portals Good Practice Guide, based on the questionnaire results analysis and some case studies, was presented.

The structure of the guidance was shared:

- Content and structuring information
- Making information accessible
- Monitoring user feedback
- Steps going forward

At the end of the presentation the conclusions of the guidance were summarised in three points:

- The NCAs need to adapt to suit the needs of their target audiences
- User testing is therefore an important part of maintaining a useful website
- The guidance document can be useful for authorities wishing to optimise their website

Some recommendations on which information that should be provided and how to organise the information were given during the presentation (i.e. structure the information, use engaging information, the importance of a national central repository, web-design and new channels). Furthermore the quality control steps were highlighted during the presentation.
3.4 Impact assessment of current strategies on risk communication. Findings about stakeholder attitudes, needs and preferences

Two WP6 representatives explained the HCP survey, followed by the Patients and Consumers Consultation presentation. The aim of the HCP survey was presented along with the methodology used, the results and finally the conclusions achieved. During the presentation some key aspects from the HCP survey were shared with the audience:

- Trust in the sender, applicability for daily practice and the severity of a safety issue are the main reasons for reading and subsequently taking action in response to safety communications.
- NCAs as well as professional bodies are considered to be the most trustworthy senders of safety information.
- Measures to increase awareness about the availability and objectives of educational materials are needed because, based on the questionnaire results, the educational materials are the less known tool.
- Safety communications should be clearly distinguished from promotional materials as industry and public press were considered less trustworthy senders.
- The distributor channels should be based on national preferences. Some differences between countries were highlighted, mostly on the desire for hardcopy material, frequency of reminders, extent of the information provided.

The patient and consumer consultation report was presented. The consultation was targeted to patients and consumers throughout Europe and the aide-memoire used was distributed through European associations. Main conclusions were:

- HCPs are the most trusted source of information on medicines.
- Face to face discussion with the HCPs is the preferred channel for receiving information.
- Familiarity with educational materials is low.
- Educational materials should be used as a tool to increase understanding of safety information between patient and healthcare professionals.
- Targeted safety information was preferred when possible. There is potential for collaboration with patient organisations in this regard.
- Understanding of the regulatory system and how it works needs to be improved among patients and consumers.
- Transparency is important and will enhance trust.
3.5 My experience with risk communication

Healthcare professional representative: (Roar Dyrkorn, NO)

Dr. Dyrkorn shared his experience and explained how Academic Detailing (AD) was performed in Norway, highlighting its strengths and weaknesses. During the presentation AD was defined as a one-to-one interactive communication with a practicing doctor which takes about 20 minutes during office hours discussing a therapeutic guideline (for example Better use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)). The method AD is widely used in Australia, Canada and USA. The general practitioner gets a therapeutic update in their own offices during office hours and do not have to travel to attend; the method has proven efficacy for practice change towards knowledge based treatments.

The two main conclusions of this activity were pointed as follow:

- The method AD is based on trust and reliable relationships in one-to-one interactive communication. Between the general practitioner and the visiting clinical facilitator
- The doctors to be visited must always be confident that the message delivered is evidence based, independent and for the best for their patients.

Patient representative: François Houyèz (EURORDIS)

Insight on risk communication from the perspective of patients and consumers was provided.

Mr. Houyèz discussed activities that could be deeper explored and where the patients could be involved. Also the social media and the development of a new app for adverse drug reaction reporting were mentioned.

Some remarks of Mr. Houyèz are listed below:

- Initiatives for collaboration between pharmacovigilance experts and patients are of high value. Such collaboration will facilitate patient reporting of suspected adverse drug reactions and support initiatives to reduce health products risks.
- Some pharmacovigilance activities where patients could be involved were suggested, such as:
  - Graphic visualisation of benefit/risks
  - ‘Talking points’ for HCPs
  - Contact person for pharmacovigilance in patients’ organisations and a directory
  - Focus groups/interviews to see if patients understood the safety information and act accordingly, and if not, then to understand why this is the case.
- Areas to be explored include, among others, social media, web-portals and public hearings.
- The safety messages impact on patients should be explored under the pharmacovigilance activities.
3.6 Risk communication – good practice. Presentation of proposals for improvement

The main recommendations derived from Work Package 6 surveys were included in a document called Risk Communication – Proposal for improvement; involving

- Processes and procedures
- Message preparation
- Tools and channels for safety communications
- Dissemination
- Impact evaluation.

The document is a practical guidance on certain aspects of risk communication that could be adapted to the local situations of the NCAs. Some of the recommendations are listed below.

- Use multidisciplinary teamwork.
- Media training should be provided.
- Engage external experts if possible.
- Ensure two-way communication with HCPs and patients/consumers.
- Tailor the communication to the receiver(s).
- Enhance trust in the sender.
- Use learned societies and trusted bodies as amplifiers of the risk communications.
- Measure the impact of the communication process for continuous improvement.
3.7 Lecture ‘Communicating benefit and harm information – some insights from research’

Professor Theo Raynor gave a presentation and shared with the audience some interesting research results that could impact on communicating benefit and harm information to lay people.

Communicating with lay people is important, and in this regard, some topics were highlighted:

- Use simplistic language – for example ‘safety monitoring of medicines’ instead of ‘pharmacovigilance’.
- User testing – getting the right language needs the input of ‘real people’ to test the information.
- Simplifying the writing – make the text conversational; test this by reading it out loud and ensuring it sounds natural.
- The importance of adding a summary in the safety communications – sometimes called a ‘key information section’, which highlights the key points at the beginning of a document.

Based on his research, the patients’ views about risk communication were shared, notably that patients value a balance of both benefit and harm information. Furthermore, it was explained that the information provided about medicines is currently focused on harm data, but patients would also like to receive information about a medicines’ benefit.

During the presentation, Professor Theo Raynor explained that most patients would like to know about any possible side-effects from the medicines they are taking; furthermore they would like to receive written information to support spoken information of medicines (not to replace it). Also, the medicines information should be contextualised within wider information about the patient’s illness. In addition, he highlighted the different perceptions about the purpose of medicines information – HCPs believe it is to educate patients to make the right decision but Professor Raynor noted that ‘an informed patient is not necessarily an obedient patient’.

Based on these ideas at the end of the presentation, Professor Theo Raynor indicated some recommendations:

- Different profiles of patients (“expert” patients and “real” patients) have separate but equally important roles in information development
- The importance of user testing before the safety message is distributed
- Use of plain language
- Use of simple pictures and graphs – but they must be tested first
- Design and layout are as important for readability as the words used
- Medicines ‘benefit’ information is often missing
- Involve experts in writing for lay people, when preparing risk communication activities
4. Breakout sessions

Each group discussed one of the following topics:

- Public participation in risk communication and general processes and procedures
- Communications on emerging safety issues including NCA websites
- Dissemination of messages to target audience
- Supplementary materials as additional risk minimisation tool i.e.: educational materials

4.1 Main ideas raised

The importance of the 'Risk Communication – Proposal for Improvement' document and its usefulness was highlighted by all the groups. Although the topics discussed in each breakout session were different, some recommendations or suggestions were highlighted in all groups.

- Monitoring and evaluating the results are crucial in order to adjust individual processes. When safety messages are disseminated, some follow-up activities could be considered in connection with this. In this regard, impact indicators could be used.
- The importance of the national adaptation of the communications was reinforced. NCAs should consider how the communications will affect their citizens.
- Define the objective of the safety message. Whether the message is to increase transparency (i.e.: regulatory processes explanation) or for an action (i.e.: medicine suspension), this could help communication experts during drafting. The language and the format should be adapted to the purpose of the document.
- A coherent message is important.
- Investment in effective transparency is needed. Information like ‘how regulators work’ and ‘what they do’ should be known by the audience, and an informative campaign could be considered. In addition this awareness campaign would reinforce the knowledge of NCAs as a source of safety knowledge.
- The recommendations from the 'Risk Communication – Proposal for improvement' document could be organised in a more chronological order to clarify for the readers which activities should be done before and after issuing communication. In addition, the recommendations for urgent and not so urgent procedures could be differentiated.
- Communication channels. ‘New’ communication channels should be explored, for example point of care alerts would have a significant impact on safety messaging, improving public health. Also the face to face discussion was supported as the best environment for patients and healthcare professionals.
Educational materials

Although there was a group devoted to discuss educational materials, all the breakout session groups debated it. Some of the main ideas extracted are listed below:

- The educational materials should be seen as complementary to the Summary of Product Characteristic (SPC) and Patient Information Leaflet (PIL) and cannot replace the importance of a one-to-one discussion with the prescribing doctor.

- Common criteria on when these materials are needed are of importance. In this regard it was highlighted that too many formats for too many medicines will be counterproductive.

- Engagement of patients and HCP representatives in the development of educational materials could lead to more awareness and trust.

- The aim for these materials is not well understood by HCPs and patients; information about the objective and format of the educational materials is needed.

- The design, promotion and distribution of educational materials should be a priority in order to assure that the safety messages are received, understood and impact on the daily practice. In this regard, the distribution through key stakeholders / channels should be considered.

- Highlight the importance of educational materials to pharmacists and nurses – a secondary audience that could play an important supporting role.

- The importance of further work in the area of educational materials was highlighted; also measure the effectiveness impact was mentioned as a useful source of information.
5. Panel discussion

The panellists discussed the results of the surveys and the recommendations on how the impact/effectiveness of safety communications could be improved and if there were something from the breakout sessions that they considered particularly important. Their experience with educational materials was also discussed.

The most interesting reflections from the panel are listed below:

- The project has reflected the complexity of the risk communication processes.
- Monitoring the effectiveness of the risk communication is crucial and should be less passive and more proactive.
- Safety information should be communicated in a simpler way and should be more accessible. The ‘onion layer’ format could be helpful in the improvement process.
- Patients and consumers should be better involved in the risk communication process. Engagement with representatives of the different target audiences is crucial, providing their feedback on the best dissemination channels.
- The importance of a trusted sender is reinforced.
- The differences between countries and target audience should be considered in the risk communication decision process.
- Different means of communication should be used.
- Two-way communication is important but NCAs should consider resource implications.
- Putting into practice the risk communication key aspects proposed by SCOPE will be a challenge.
- Healthcare professionals should be educated about risk communication and medicines regulation at university and afterwards.
- A national action plan about educational materials is needed (evaluation, dissemination, etc.).

Overall, the panellists considered that the ‘Risk Communication – Proposal for improvement’ document was a very complete document and could be of interest for other organisations, also outside Europe.
6. Conclusions

6.1 Summary of presentations

Dr. June Raine summarised the workshop presentations given and reflected on how risk communication could move forward in the near future.

Some of the ideas are listed below:

- NCAs to use the two deliverables ‘Risk Communication – Proposals for Improvement’ and ‘Web-portals Good Practice Guide’ as toolkits for their daily work evolution.
- More research about risk communication (i.e. how to best represent quantification of the risks, formal testing, methodologies for evaluation of impact, etc.) is needed.
- Establish a multidisciplinary “network” to maintain the risk communication improvement strategy in NCAs.
- Evidence-based use of risk communication practices and tools.
- Maximise opportunities of new technology, mechanisms and media.
- Work with patients, consumers, healthcare professionals and academia.
- Deliver measurable public health benefit.

6.2 Evaluation

The post-workshop evaluation of attendees highlighted the following:

- The importance of follow-up activities.
- The need for a European forum involving NCAs and academia representatives to develop a consistent strategy for risk communication.
- How to identify important factors influencing a good communication could be further elaborated.
- Some practical approaches and advice could be identified for implementation in the network.
- Consider ways to make progress after the SCOPE project will be finished.