SCOPE Work Package 6
Risk Communication

Proposals for Improvement

2016

SCOPE

SCOPE Work Package 6 Risk Communication – Proposals for Improvement

Contents

Acknowledgments

Authors

1. Preface

1.1 Purpose of the document

This document is intended to provide practical guidance on selected aspects of risk communication. We refer to it as "Proposals for improvement" as it is not intended to be didactic or to represent "best practice", but instead to give positive reflections and advice based on national competent authorities, healthcare professionals and citizens' experience, which could be considered for implementation by Member States. This document is not a replacement of Good Pharmacovigilance Practice (GVP) modules, but can provide a useful framework that could be adapted to local contexts and can be scaled up or down, depending on current situations.

1.2 Definitions and abbreviations

Terminology	Description
DHPC	Direct Healthcare Professional Communication
EMA	European Medicines Agency
EU NTC	EU Network Training Centre
FDA	Food and Drug Administration
GP	General Practitioner
GVP	Good Pharmacovigilance Practice
HCP	Healthcare Professional
HMA	Heads of Medicines Agencies
MS	Member State
NCA	National Competent Authority
PRAC	Pharmacovigilance Risk Assessment Committee
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
WHO	World Health Organization

2. Introduction

Communicating safety information to patients and healthcare professionals (HCPs) is essential for achieving the objectives of pharmacovigilance in terms of promoting the rational, safe and effective use of medicines, preventing harm from adverse reactions and contributing to the protection of patients and public health.

The most recent legislation on pharmacovigilance (1) states, in Directive 2010/84/EU amending Directive 2001/83/EC, the requirements for National Competent Authorities (NCAs):

> **Article 102**: *The MSs shall ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-site and through other means of publicly available information as necessary.*

> **Article 106a**: *Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution.*

As a result of the 2010 pharmacovigilance legislation, member states (MSs) have put in place different strategies to fulfill requirements, taking into account the Good Pharmacovigilance Practices (GVPs) modules, which provide clear advice on how to communicate and coordinate safety information in the EU regulatory network.

To optimise current risk communication methods and to improve the implementation of any necessary actions in clinical practice, it is important to have good insight into how MSs are currently performing such communications, and to explore how these activities are perceived, assessing the preferences of HCPs, patients and consumers. Comparing such information could help in the identification of good practices.

2.1 Methodology and grounds for recommendations

The sources of data taken into consideration as a basis for this document are:

- Information on risk communications practice in the EU network collected through a survey to NCAs (26 EU MS) to understand the communication channels and tools in place

- A survey to selected HCPs (mainly general practitioners, cardiologists, and pharmacists) of 9 MSs (Spain (ES), Sweden (SE), Ireland (IE), Netherlands (NL), Italy (IT), Croatia (HR), Denmark (DK), UK, Norway (NO) to investigate the knowledge, attitudes and preferences of target audiences towards different communication tools and channels.

Collating the information from the two surveys helped to identify areas of success and effective methods, which could provide useful ideas for other countries.

The data collected has been complemented with information gathered from consultations with patient and consumer organisations. The latter was obtained through the EUPATI European Project (European Patients' Academy on Therapeutic Innovation) and BEUC (the European Consumer Organisation), which became interested in the project and allowed information to be collected through national advocates.

Finally, relevant literature was reviewed and used together with selected free-text answers and examples presented from individual NCAs or from HCPs who responded to the surveys. Suggestions have been extrapolated for this guidance, highlighting success factors or potential ideas for improvement. For details on the survey results, please see the individual reports.

3. Risk communication strategies in NCAs and suggestions for improvement

Following the implementation of the new pharmacovigilance legislation, MSs have put in place different strategies to fulfill legislative requirements. Good Pharmacovigilance Practice (GVP) module XV provides guidance on how to communicate and coordinate safety information in the EU regulatory network; however, general guidelines have been adapted, over time, to different situations and local contexts. The experiences of NCAs and the assessment of the impact on their target audiences allows WP6 to highlight useful areas of operational good practice. The following chapters deal with key recommendations, from planning the communication strategies to methods for communication (DHPC, NCA communications, educational materials), dissemination and impact evaluation.

3.1 Processes and Procedures

Clear roles, processes and procedures covering any aspect of risk communication should be in place to allow efficient communication. Ideally, a multidisciplinary approach involving NCA staff with different expertise and different responsibilities, as well as, where relevant, other interested parties and experts outside the NCAs, is followed for preparation of information on risk communication.

3.1.1 Operating risk communication

Safety communications originate either at a national level or come from the recommendations or opinions of EMA scientific committees. However, the final decision to disseminate a safety communication is the responsibility of the individual NCAs and reflects the relevance of the issue for their MS (e.g. usage of the medicine, public health impact, authorisation status, knowledge about target groups and channel preferences).

According to the results from the NCAs survey, the majority of MSs have a quality system in place for handling safety communications, covering, to a varying degree, aspects such as: planning, review of the materials (e.g. structure, content, language, grammar, figures, statistics), approval of the materials (e.g. sign-off) and distribution of the safety communication to the different targets (WP6 Survey Report – Audit of National Methods of Communications, Q8 and 9, Annex 5.1).

NCA quality systems cover not only aspects related to the management and development of safety communications, but also a wider range of related topics, such as answering external queries, handling communications related to DHPCs and systems for alerting HCPs on new safety information linked to a relevant medicinal product in the electronic prescription system.

In more complex cases, assigning a contact point/assessor team responsible for ensuring coordination is recommended; their tasks may cover arranging meetings, drafting a communication plan, contacting relevant colleagues and stakeholders and ensuring that participants are notified of changes to the plan or unexpected delays.

An essential part of the communication process is engaging those interested and affected by the risks (3). Scientific literature notes that effective communication is a two-way process, and should enable the active participation of all interested parties at each stage, applied here to increase efficiency and trust in regulators (2, 3). A specific question in the survey to NCAs (WP6 Survey Report – Audit of National Methods of Communications, Q28 and 29, Annex 5.1) was aimed at collecting information on the involvement of stakeholder groups in safety issues of particular interest. In this respect, several NCAs highlighted consultations with internal and external experts in different fields: collaboration with stakeholders such as specialist organisations, patient and consumer organisations, pharmacist organisations, learned societies and national health services, as well as scientifically sound clinicians/academics, were all reported as key success factors. It was also suggested that collaboration with learned societies and patient organisations allows greater distribution of safety messages, giving a consistent and official position to media, the public and prescribers.

Similarly, consultation with the patient/consumer organisations (WP6 Survey Report – Patients and Consumers Consultation, Annex 5.2) reflected that such organisations are keen to become involved with NCAs on risk communication issues, and such involvement may enhance the dissemination of safety information to patients.

Key aspects

- Operating processes for risk communication should cover all goal setting, allocating responsibilities, planning, implementing, monitoring and evaluating.

- Adapt the communication process to national context: use of the medicine, public health impact, authorisation status, knowledge about target groups and channel preferences.

- Appoint a person to coordinate the communication process.

- Implement two-way risk communication with HCPs and patients/citizens.

- Build "links" with patient/consumers organisation and learned societies.

3.1.2 Personnel

3.1.2.1 Multidisciplinary team

The majority of MSs already have a multidisciplinary approach towards risk communication, where involvement of pharmacovigilance experts is indicated as a major contributor to work. Other staff normally involved are, from communications and IT units, medical writers, clinical assessors, or experts in the area of the subject to be communicated.

The engagement of external expertise, either routinely or occasionally, is an adopted practice among several NCAs. Collaboration with opinion leaders/key scientists/clinicians/patient organisations was mentioned by several MSs as a key to success (WP6 Survey Report – Audit of National Methods of Communications, Q55, Annex 5.1). This interaction can help spread messages at national level and to implement recommendations in clinical practice.

In the survey to NCAs (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1) it was highlighted that identification and collaboration with relevant experts can take time and that this, in cases of urgent safety issues, could be challenging. This is of special concern when transmitting PRAC recommendations after a referral, with just a few hours for preparing communications. In general terms, it is advisable to build a network of expertise that can be contacted in a timely manner.

Key aspects

- Involvement of NCA personnel with relevant expertise is important.

- Where time allows, engage in dialogue with external experts when needed.

- It may be helpful to have a network of experts available for consultation at short notice.

3.1.2.2 Training

Implementation of a training program aimed at ensuring a good level of expertise for new employees and for maintenance of an adequate level of knowledge is recommended.

Based on the identification of staff needs, regular training should be considered for all personnel dealing directly with the media. More details on training activities are presented in other areas within the SCOPE project (WP7 – Resource Management). It emerged from the survey to NCAs that systematic training on risk communication is not always performed (WP6 Survey Report – Audit of National Methods of Communications, Q4 and 5, Annex 5.1). In NCAs where specific training in communication is in place, it is mostly performed on a case-by-case basis, i.e. on request from staff or for new employees. Training courses can be led by external sources and/or internal staff, depending on the NCA's internal competence and resources.

Training by hiring external sources was suggested by several NCAs to add value (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1), although it requires financial resources.

Some NCAs have a general spokesperson, while others have dedicated spokesperson for each unique topic or therapeutic area (WP6 Survey Report – Audit of National Methods of Communications, Q6, Annex 5.1). This seems to be consistent with approaches adopted by regulatory bodies outside the EU, with one or a few high-profile and easily recognisable spokespersons as the face and voice communicating on a NCAs behalf (2). Having a lead spokesperson could simplify information flow and promotes a consistency in message content.

Several NCAs mentioned that the agency's spokesperson gets dedicated training from the communication unit and pharmacovigilance experts, particularly in cases where a safety issue is expected to draw media attention. In EU NCAs, the position of the spokesperson in the organisation varies, but the communication unit is almost always involved, either as a spokesperson or in support of the spokesperson.

Key aspects

- Assess the training needs of personnel.

- Provide a plan for training in risk communication.

- Consider training with internal and/or external sources on risk communication.

- Appoint a spokesperson, either on a general or case-by-case basis. The agency's spokespersons need to receive dedicated support from the communication unit and scientific experts.

3.2 Message preparation

Patients, consumers and HCPs are the primary target audiences for safety communications issued by regulatory authorities and Market Authorisation Holders (MAHs). Tailoring the message to their respective expectations and needs is crucial for successful communication. Surveyed HCPs are, overall, familiar with the three main safety communication methods (DHPCs, NCAs communications and educational materials) and consider them useful. Some suggestions emerged from the report, which have been included below as possible recommendations for improvement (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1).

3.2.1 Review of the materials

In preparation of the message, it should be ensured that the purpose of the communication is clear and that the message is comprehensible to the target. Key advice suggested in the literature about writing and designing strategies for the public include the use of plain language, avoidance of medical jargon, using short sentences and short words, avoid using passive forms and using positive rather than negative messages (3). These points were confirmed after consultation with patient/consumer organisations, who expressed a preference for succinct information, suggesting that educational materials should not be too lengthy (WP6 Survey Report – Patients and Consumers Consultation, Annex 5.2).

When surveyed, varying HCP preferences emerged (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q21, Annex 5.3); where some prioritised having clear and concise clinical instructions, others requested available evidence supporting the recommendations to be communicated. A suitable solution to accommodate both preferences could be to use an 'onion layer' format. This means presenting a high-level overview of the key safety information at the start of the communication and going into more detail as readers progress through the document. Summarising significant points in an introduction box could improve understanding of the key messages. Inclusion of links to supporting evidence could also provide a source of more details to the interested readers.

Pre-testing of safety communications is rarely performed by MSs (WP6 Survey Report – Audit of National Methods of Communications, Q31, Annex 5.1), likely owed to time constraints. An example of good practice could be to test safety communication, at least on a case-by-case basis, especially for information with high public interest. Some interesting suggestions are drawn from the NCAs' responses, for example, setting up an in-house group assessing readability (WP6 Survey Report – Audit of National Methods of Communications, Q31, Annex 5.1) and consisting of personnel not directly involved in drug evaluation. This allows them to represent the public, particularly important if the topic is controversial. Suggestions were also made to contact specialists in given subject areas.

Key aspects

- Identify the purpose of the communication and the specific audience.

- Tailor the language to the target audience.

- Focus on a few key messages, being concise and direct, but facilitate access to more detailed information.

- Include a clear summary of the key information at the beginning of the communication.

- Assess the understanding of the key message from a sample of the audience/test group, especially in cases of critical issues.

3.2.2 Sender of the communication

An important finding from the HCP survey was that trust in the sender is a key influencing factor in outcomes (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q15, Annex 5.3), with the majority of HCPs reporting that they were more likely to read a safety communication and act upon the recommendations therein when received from a trustworthy source. When questioned as to the most reliable sources of safety information, NCAs and learned societies emerged as the senders that HCPs would be most likely to trust. Pharmaceutical companies were viewed quite negatively in this regard. It is therefore recommended that NCAs should explore the possibility of sending communications directly to HCPs, rather than via pharmaceutical companies.

Some countries have implemented other strategies to try to highlight to HCPs that DHPCs are approved by the NCA and to distinguish them from promotional materials. These include using envelopes with a particular symbol or statement printed on the outside to indicate that important safety information is enclosed (WP6 Survey Report – Audit of National Methods of Communications, Q45, Annex 5.1). However, the survey, as well as previous research, has suggested that such measures do little to dispel the concerns of HCPs regarding the independence of the information received directly from pharmaceutical companies (5).

Educational materials are also distributed to HCPs by pharmaceutical companies once approved by the NCA. While it is not considered feasible at this time for NCAs to produce and distribute such material, publication on NCA websites may highlight to HCPs that the content has been developed in association with, and reviewed by, the NCA. This could enhance trust and encourage the relevant recommendations to be followed, providing at the same time an additional access route for patients. Inclusion of a standard statement indicating that the materials have been reviewed and approved by the NCA may also be of value.

Another trusted source of safety information was HCP professional bodies (WP6 Survey Report – Patients and Consumers Consultation, Annex 5.2). Therefore NCAs should consider links with such organisations locally with a view to arrange the cascade of safety information to their members where appropriate.

Consultation with patient/consumer organisations indicated that HCPs are overwhelmingly the preferred source of safety information for patients. Material from pharmaceutical companies was reported to be viewed as potentially promotional in nature (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Annex 5.3), whereas respondents considered patient/consumer organisations to be viewed positively by patients. These groups could be explored as amplifiers of the information targeted to patients, such as some educational materials (where they exist nationally for the relevant therapeutic area), either forwarding the information to their members or making it available via their websites. Publishing such materials on the NCA websites may also enhance patient trust and help to mitigate concerns regarding pharmaceutical company-produced materials.

Key aspects

- As one of the most trusted sources of safety information, NCAs should consider direct distribution of safety communications rather than via pharmaceutical companies.

- Publication of educational materials on NCA websites could help to enhance trust in the materials amongst HCPs and patients and increase the likelihood of the risk minimisation recommendations being followed.

- NCAs should build links with HCP professional organisations and with patient/consumer organisations, as other trusted sources of safety information, with a view to arranging onward dissemination/reiteration of safety information amongst their members.

3.3 Tools and channels for safety communications

The reference to the term "tools" in this document refers to different strategies used by NCAs in order to provide up-to-date safety communications to their target groups, such as newsletters, bulletins and point-of-care-alerts. Common tools among MSs in the EU are DHPCs, educational materials and NCAs communications.

Reference to the term "channels" refers to the variety of strategies that NCAs can use in order to disseminate safety communication and reach their target groups, such as the web, social media, electronic prescribing/dispensing systems, medical journals and media.

The safety communications issued by NCAs are transmitted to the intended receivers through different channels depending on the target audience. It is important to carefully identify the receivers and choose suitable channels, which are tailored to their preferences. MSs use their websites as the main channel for safety communication, this gives the advantage of potentially reaching a large population in a short timeframe.

Respondents state that they are more likely to take action for severe ADRs, if the safety information is relevant for their daily practice and if the sender is trusted (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q21, Annex 5.3). Some proposals for NCA safety communications clearly emerged from the survey (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Annex 5.3), and could be taken into account for future improvement. A national repository for safety communications was consistently suggested by HCPs as a clear preference to access the information more easily. A dedicated section or a repository on the NCA website could allow access to all previous and current safety communications, including DHPCs, educational materials and tools such as national bulletins. The incorporation of safety communications through point-of-care-alerts in the electronic prescribing/dispensing systems is another suggested option. These alerts can act as a timely reminder of important safety communications for a specific product at the point of prescription/dispensing, i.e. at the moment when HCPs most need it (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Annex 5.3).

Key aspects

- Identify the receivers and choose the suitable channel/s tailored to their needs.

- Provide methods to store and retrieve safety communications, such as repositories on NCA websites

- Consider incorporating the safety communications into electronic prescribing/dispensing systems.

3.3.1 National competent authority communications

The majority of surveyed HCPs were familiar with the main safety communication strategies used by NCAs, and find them useful (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q6, Annex 5.3).

NCAs are committed to informing audiences of new safety issues, in compliance with the legislation; communication is immediate, in case there is the need to rapidly inform HCPs and/or the public, but communications may also be periodical (weekly/monthly) as a reinforcement of DHPCs/other communications or to communicate less urgent issues.

Regarding how NCAs deal with communications from EMA scientific committees, high-profile cases with public health implications are normally published immediately after the PRAC/CHMP meeting, in compliance with embargo dates (WP6 Survey Report – Audit of National Methods of Communications, Q14, Annex 5.1). For less urgent issues, publication is postponed to the following week, but no later than 5 days after. Examples of "high-profile issues" include situations in which there is an urgency to inform HCPs, or when there is a previous or an expected public and media interest, or a high usage pattern. Prioritisation can be established on the basis of impact on patient safety, on media attention, and on the urgency of the safety issue.

In general, a regular update (e.g. monthly update) was suggested by the surveyed HCPs as an attractive strategy (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Annex 5.3). For example, the immediate dissemination of a safety message, followed by a monthly update on the summary of the latest information, may be a reasonable approach as a reinforcement measure. Several NCAs regularly publish national bulletins that include, or are directly devoted to, safety communication. Bulletins and newsletters, beyond providing regular updates of the latest information about medicines, can reach a large audience. These bulletins can be disseminated through different channels, for example, via electronic systems (email or publication on the website), or as hardcopies (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1). They may also have sections updating readers on aspects such as PRAC outcomes, current referral procedures, or current safety topics. To increase trust in such cases, the source, i.e. the NCA, should be easily identifiable, for example, by using the NCA's official colours and logo.

Key aspects

- Reinforcement of messages over time is considered important, and providing periodic summary updates on safety news is a proposed strategy.

- Periodic bulletins can help to remind audiences of key safety issues and to enrich the information with national data or further details on the subject.

3.3.1.1 NCA websites

From the survey to NCAs (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1) it emerged that websites are the main channels used by NCAs for safety communications. As stated in the survey report on web-based safety information, the perception of most NCAs is that their website is more relevant to industry stakeholders, less to HCPs and least to patients (WP6 – Web-portals report). More effort to optimise the communication of safety issues through websites should be made by NCAs, making it more easily accessible for users. A first step could be to perform user testing in order to determine whether the needs of the website target groups are addressed; user testing can be performed through surveys and interviews of the intended audience.

Publishing medicines information (e.g. SmPCs, PILs, PARs) in a NCAs medicines database may be the most accessible method of communicating pharmacovigilance information. According to web-portals survey data, most of the content required by the EU Directive is already presented by MSs on their websites, either in one location or using external links (WP6 – Web-portals report).

Using plain language that can be easily understood by anyone and defining technical terms is an important part of website communication. The grouping of information can also allow users to be directed to areas of interest in the most efficient way, e.g., by audience, therapeutic area and topic. For user convenience, developing apps could greatly increase the accessibility to safety information.

3.3.1.2 Social media

Other channels can be used to raise awareness on safety communications issued by NCAs, such as: social media (Facebook, Twitter, YouTube etc.), Rich Site Summary (RSS) Feeds and email alerts. Such platforms are able to reach a large population in a small timeframe and may therefore be considered as a future channel to be explored. NCAs could use social media to publish safety communications, since they are able to disseminate information to a wide audience quickly; if such a strategy is followed, however, the NCA should be clearly identified as the sender, to increase trust in the communication.

Social media could also be considered for collecting user feedback on whether the information provided by regulators is appropriate, with feedback being used for continuing development. Other channels, such as television/radio and blogs were considered negatively in all participating countries (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q18, Annex 5.1).

Other alternative methods mentioned by NCAs, which could be of help for further spreading an urgent message, are subscriptions to a NCA's news RSS feeds and urgent alerting systems, with newsletters to targeted recipients being used on a periodic basis.

Key aspects

- Ensure that content of the website addresses the needs of users (e.g. perform user testing).

- Use plain language that can be easily understood by all audiences and define technical terms.

- Consider an official social media account (e.g. Twitter/Facebook) as a way to disseminate safety information and interact with your audience.

- Collect user feedback from social media to assess the appropriateness of communications.

- Subscriptions to NCA's news RSS feeds and urgent alerting systems can rapidly spread urgent information.

3.3.2 Safety communications agreed with MAHs

In the preparation and distribution of DHPCs and Educational materials, NCAs cooperate with the MAHs and, before issuing any communication, MAHs and NCAs must reach an agreement on the content, format and communication plan.

3.3.2.1 DHPCs

The surveyed European HCPs are generally familiar with DHPCs as a safety communication tool, although awareness is not homogeneous among countries (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q1, Annex 5.3). The received DHPCs are read by the majority of the respondents, however two-thirds indicated reading only those DHPCs that contain important information for their own practice or where it is clearly indicated that they contain non-commercial safety information (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q2, Annex 5.3).

As good practice for handling communication, the majority of MSs encourage relevant MAHs to collaborate on the development and circulation of a single DHPC, if more than one MAH is involved. This kind of approach seems to be advisable in order to both deliver a single and consistent message and to avoid confusion.

DHPCs are regularly published on the NCAs' websites, as a complementary method for improving knowledge on safety issues, since the surveyed HCPs consult NCAs' websites to keep themselves up to date with medicines knowledge (WP6 – Web-portals report).

Regarding the delivery of DHPCs, cross-national differences were observed among surveyed HCP; it emerged that electronic delivery is not always the preferred option, with hardcopy versions being favoured in some cases (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q5, Annex 5.3). It was not possible to identify the best format for the delivery of DHPCs from the survey, and local preferences should be considered when planning distribution, along with making a range of formats available.

Key aspects

- Joint DHPCs, where more than one MAH is involved, are recommended.

- The formats (paper or electronic or both) of DHPCs should be adapted nationally to HCPs' preferences.

3.3.2.2 Educational Materials

Educational tools can be presented in different forms, including paper, audio, video, web, or personal training, and can be addressed to HCPs and/or patients.

Within the HCP survey (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q10-14, Annex 5.3), respondents were shown examples of educational materials that GPs, pharmacists and cardiologists were likely to have recently seen in their clinical practice. Familiarity with such materials was lower than expected for both DHPCs and NCA communications.

Responses provided in relation to other questions within the survey also suggested that the intended purpose of these materials is not clear to HCPs. NCAs should explore possible ways to enhance awareness of educational materials amongst HCPs, including their objectives, so that the relevance of following the recommendations and providing versions to their patients, where available, is fully understood. Inclusion of a reminder of the availability of educational materials for a product within electronic prescribing and dispensing systems could be valuable.

HCPs expressed a strong preference for safety communications to be succinct, clearly outlining the required actions and summarising the key information. These points should be taken into consideration when NCAs are reviewing and approving educational materials.

Consultation with patient/consumer organisations highlighted that the most trusted source of safety information for patients was their HCP (WP6 Survey Report – Patients and Consumers Consultation, Annex 5.2). With this in mind, NCAs should ensure that educational materials are developed in a way that can encourage discussion between HCPs and their patients, rather than just additional information for a patient to read. A checklist format, in particular, was viewed positively by the respondents.

Both HCPs and patients expressed concern about the independence of material provided to them by pharmaceutical companies and it was therefore suggested to publish educational materials on NCA websites, highlighting the collaboration that has taken place with the NCAs. This measure would have the added benefit of providing additional access which may be helpful where the HCP or patient requires further copies of the material or prefers online access. Considering that in some countries a substantial proportion of HCPs favour paper versions of safety communications over electronic, it would appear prudent at this time to provide users with a range of channels through which to access to this information.

Key aspects

- NCAs should consider strategies to enhance HCP awareness of educational materials and their objectives.

- Reminders embedded within electronic prescribing/dispensing systems may help to ensure these are used by HCPs and patients.

- Information within educational materials should be succinct and clearly structured, summarising the key new safety information and the actions required by the HCP to minimise risks. Materials intended for patients should be tailored accordingly.

- NCAs are encouraged to ensure that the educational materials are suitable for facilitating discussion between HCPs and patients.

- Educational materials should be made available via a variety of channels, including through NCA websites.

3.3.3 Other safety communications

3.3.3.1 Journals and professional bodies

Websites are not the most commonly used option for the HCPs to keep themselves up to date with (new) medicines knowledge; the most frequently used channels are medicines reference books (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q31, Annex 5.3). The official regulatory safety communication channels seem the most important source of information for specialised drugs while, for safety issues related to commonly used drugs, other avenues (medical journals and professional bodies) are common sources of information (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q23, Annex 5.3). Hence, writing editorials or comments for journals and professional bodies may be valuable.

Key aspects

- Consider publishing editorials or comments in medical, pharmaceutical and patient/consumer organisations' journals to amplify messages.

3.4 Dissemination

An efficient dissemination system should be able to amplify the message and reach the relevant audience in the shortest possible time. Figure 1 shows examples of potential amplifiers of risk communications, as reported from NCAs.

Figure 1. Possible amplifiers of safety communications

Involving HCP organisations is reported to be an example of good practice in disseminating safety information and enhancing its reliability, since they are reported by HCPs to be trusted sources (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Annex 5.3). Some NCAs already send their own communications to patient/HCPs organisations (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Annex 5.3) and ask that they disseminate directly to their members on a case-by-case basis.

HCPs could be reached directly by email correspondence, as highlighted by some MSs (WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness, Q5, Annex 5.3, and WP6 Survey Report – Audit of National Methods of Communications, Q43, Annex 5.1); however, the maintenance of a validated list of addresses may be an obstacle.

As reported above, HCPs remain, for patients, the most trusted source of information about medicines. Patient organisations are also considered a valuable and trusted source, although this depends on the therapeutic area and country. Interestingly, and in contrast to HCPs, NCAs were not strongly reported by patient and consumer organisations as a trusted source of information about medicines, and NCA websites are not reported to be regularly consulted (WP6 Survey Report – Patients and Consumers Consultation, Annex 5.2). It would be beneficial for patients/consumers and regulators to collaboratively address the reasons for this finding and to strengthen existing relationships.

For safety issues with considerable impact on the population and with high media attention, arranging a conference with the media has been reported as good practice, both to release a common and official message and to avoid multiple contacts to the NCA (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1).

The capacity of the media to reach patients and the general public makes it a critical element for amplifying information and influencing public perception; therefore, it is important that the media receives safety information directly from the competent authorities.

Key aspects

- Consider including Patient Organisations, Regional Health Authorities, Learned societies, National Health Insurance Funds, Teaching/University Hospitals, and Hospital Pharmacies as amplifiers of communication.

- Strengthen existing relationships with patient/consumer organisations.

- Consider media conferences for high public impact safety issues.
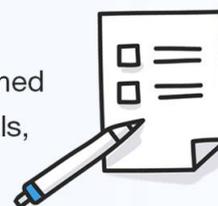
3.5 Evaluation

It is important to measure the impact of risk communication to determine which activities have been successful, and to improve practice over time. GVP XVI considers two categories of indicators to evaluate the effectiveness of risk minimisation measures (RMMs): process indicators, to assess if the communication plan has been executed as planned, and outcome indicators, to assess if the communication has achieved a certain level of risk control. It emerged from the surveyed NCAs that a systematic approach to the evaluation of the effectiveness of RMMs has not been developed yet, although some evaluation has been implemented on an ad hoc basis (WP6 Survey Report – Audit of National Methods of Communications, Annex 5.1).

To assess outcome indicators, pharmacoepidemiological studies may be performed. Such studies are recommended to be conducted for issues of high impact on a case-by-case basis. Possible examples of process and outcome indicators to monitor and evaluate the effectiveness and the impact of activities and methods of communication have been suggested in the survey to NCAs and in the literature, and are summarised in the table below.

Table 1. Examples of process and outcome indicators

Source	Output/Implementation	Result indicators
Databases		Analysis of ADR reports Analysis of drug utilisation data Analysis of prescription data Analysis of registries data
NCA Websites	One safety issue/publication	Number of website page visitors
Call Centre	Safety issue/publication	Monitoring changes in number of patient/HCPs enquiries
Internet	Safety issue/publication	Monitoring discussions, posts, comments on social media profiles/pages
Mass media	Safety issue/publication	Citations
Newsletter	Number of newsletters published	Number of subscribers HCP enquiries as the basis for the evaluation of the distribution of the safety message, as well as understanding of the content.
Publications	Number of copies printed/sent	Number of copies downloaded from the website HCP enquiries as the basis for the evaluation of the distribution of the safety message, as well as understanding of the content.
Individual interviews or focus groups	Specific safety communication	Collect perceptions on the relevance of a message and insight on why a message has or hasn't been acted upon.

The evaluation of individual processes could be the basis for continuous improvement in risk communication for NCAs, using a cycle of learning and improving. The acronym DIMEA (**D**esigning communication, **I**mplementing activities, **M**onitoring, **E**valuation and **A**djusting if needed) could help improve the effectiveness of safety communication by testing real cases (Figure 2).
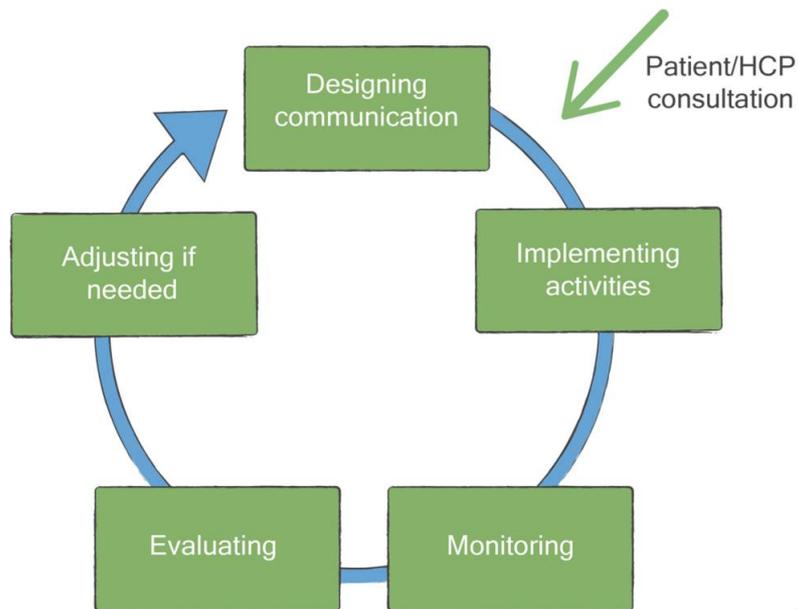
Figure 2: DIMEA cycle for continuous improvement in risk communication

Key aspects

- Evaluate communications (quantitatively and/or qualitatively).

- Define criteria for prioritisation.

- Analyse available data sources for evaluating effectiveness.

- Based on the objectives, choose indicators as needed.

4. References

1. Morgan GM, Fischhoff B, Bostrom A, Atman CJ. (2002) Risk Communication: A Mental Models Approach. Cambridge University Press

2. Fischhoff B, Brewer NT, Downs JS. (2011) Communicating risks and benefits: an evidence-based user's guide. Silver Spring: US Food and Drug Administration

3. ILGRA – (Interdepartmental Liaison Group on Risk Assessment) – Risk Communication. (1998) A Guide to Regulatory Practice. London: Health and Safety Executive

4. Hyer RN and Covello VT. (2005) Effective Media Communication during Public Health Emergencies. World Health Organization

5. Mazor KM, Andrade SE, Auger J, Fish L, Gurwitz JH (2005) Communicating safety information to physicians: an examination of dear doctor letters. Pharmacoepidemiol Drug Saf. 14(12):869-875

6. Arvai J and Rivers L (2014) Effective risk communication. Routledge

7. SCOPE Work Package 6 Survey Report: Audit of National methods of communication Report (available on the SCOPE website, www.scopejointaction.eu)

8. SCOPE Work Package 6 Survey Report: Web-portals (available on the SCOPE website, www.scopejointaction.eu)

Converted from footnote (page 4 in source text)

1. Directive 2010/84/EU and Directive 2012/26/EU amending Directive 2001/83/EC, Regulation (EU) No 1235/2010 and Regulation (EU) No 1027/2012 amending Regulation (EC) No 726/2004 and in the Commission Implementing Regulation (EU) No 520/2012. Consolidated versions of the Directive 2001/83/EC and Regulation (EC) No 726/2004 are available in EUR-Lex.

5. Annexes

Annex	Description	Item
5.1	WP6 Survey Report – Audit of National Methods of Communications	WP6 Survey Report – Audit of National I
5.2	WP6 Survey Report – Patients and Consumers Consultation	WP6 Survey Report – Patients and Cons
5.3	WP6 Healthcare Professional Survey – Medicines Safety Communications and their Effectiveness	WP6 Healthcare Professional Survey