SCOPE Work Package 6 Survey Report

Audit of national methods of communication

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1 Introduction

1.1 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
CHMP	Committee for medicinal products for human use
CMDh	Coordination group for mutual recognition and decentralised procedures - human
DHPC	Direct healthcare professional communication
EMA	European Medicines Agency
LTT	Lines to take
MAH	Marketing authorisation holder
MS	Member State
NCA	National competent authority
PIL	Patient information leaflet
PRAC	Pharmacovigilance risk assessment committee
SmPC/SPC	Summary of product characteristics
SOP	Standard operating procedure

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1.3 Executive summary

The objective of this audit of national methods of communication of safety messages was to lay the foundation for the development of tools and strategies within SCOPE Work Package (WP) 6 and to contribute to the overall deliverables of the project.

The survey was executed through a web-based survey in 2014 and developed in co-operation with all active participants and covered different aspects of the safety communication processes. It was structured in a logical way and included sections on national authorities' internal procedures for safety communication – organization and process, external safety communication in practice, communication channels and target audience, Direct Health Care Professionals Communications (DHPC) and general experience with the national safety communication. Twenty-six national competent authorities completed the survey.

Most competent authorities have an internal organization for safety communications where pharmacovigilance experts and communication professionals/press officers cooperate on safety communications. There are different approaches to risk communication but systems and processes are in place. The majority of the competent authorities have general spokespersons for all safety topics and experts in contact with media get specific training and support.

In general, the competent authorities use their websites as the main channel for safety communications. Around 90% publish public health communications and 60% publish summary of the recommendations issued by the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency (EMA). Adaptation to the national situation and translations are practiced and relevant links to the EMA website are provided.

Regarding follow up of the effectiveness of communications, different follow up options are used, however mostly on a case by case basis. Media attention is followed most often as well as website/page visits. Follow up of recommended actions is, if at all, only performed on a case by case basis.

From the survey the following main conclusions can be drawn that could be elements in the further work to identify good general strategies, plans and tools for safety communication that could be used and adapted to the available communication resources and organization of the competent authorities.

1. It would be effective if systems could be developed by which safety or alert messages could be directly linked to the medicinal product information in electronic prescription systems and the SmPC-PIL databases at the

competent authorities' websites or sent to the pharmacy/prescription/patient electronic interface.

2. Using multiple tools/channels and repetition of the message is considered valuable for strengthening the uptake of the information.

3. Collaboration with opinion leaders and key specialists in the relevant field as well as with patient organizations is considered as key to a successful communication of the safety messages and for better understanding of the needs of different stakeholders. The advantages of DHPC distribution via scientific organizations could be further assessed.

4. The Standard Operating Procedures (SOP) on safety communication normally contained sections on planning, structure of content of messages including conclusions and recommendations, language, communication routes and sign-off.

5. 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.

1.4 Background

The revised legislation on pharmacovigilance for human medicinal products in the EU that came into force in July 2012 includes a number of provisions to strengthen safety communication and its coordination:

Article 102 of Directive 2010/84/EU amending Directive 2001/83/EC: The Member States 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-portal and through other means of publicly available information as necessary;

Article 106a of the same directive
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.

Experience has demonstrated the need to coordinate the safety communication process within the European Union (EU) regulatory network and that there are many different ways to reach out to the public and to the variety of stakeholders.

Reinforcing transparency, dialogue and coordination between EU regulatory agencies is crucial for a successful and timely risk communication.

The starting point of this work was to find out more in depth what tools and channels for safety communications that NCAs are using today and to exchange experience on current methods and their impact through a web-based survey among all the 27 national competent authorities (NCAs) participating in the SCOPE project (http://www.scopejointaction.eu).

Based on the results, the further aim is to assess if there are areas where it is possible to identify good general strategies, plans and tools for safety communication that could be used and adapted to the available communication resources and organization of the competent authorities.

The objective of this audit of national methods for communication of safety issues was to lay the foundation for the further work within SCOPE Work Package (WP) 6 and to contribute to the overall deliverables. The report should also identify, where possible, future developments in this area that can simplify the delivery and take-up of individual safety communications by the health care professionals and patients.

1.5 Context and scope of report

The report of the results of the audit of safety communication practices in the participating MS is aimed to provide a basis for the further work within WP 6 and for information to the entire project. It may be of interest to produce a shorter version at a later stage for publication.

1.5.1 Main goal

The further aim is to assess if there are areas where it is possible to identify good general strategies, plans and tools for safety communication that could be used and adapted to the available communication resources and organization of the competent authorities.

1.5.2 Objectives

The objective of this audit of national methods of communication was to lay the foundation for the further work within SCOPE Work Package (WP) 6 and to contribute to the overall deliverables. The report should also identify, where possible, future developments in this area that can simplify the delivery and take-up of individual safety communications by the health care professionals and patients.

1.5.3 Challenges

Among the challenges that could influence the interpretation of the survey results is the potentially different interpretation of terminology on communication. Also, the fact that it was decided to not have a questionnaire with compulsory questions may influence the possibility to fully correlate related answers. In addition the national specific contexts, for example the role of media and different stakeholders, the responsibilities of the authorities as well as resources and priorities may induce uncertainties in generalization of the results.

2 Methodology

2.1 Tool and survey method

The questions for the web-based survey were developed in co-operation with all active participants in the WP 6 mainly through e-mail and teleconferences but also in one face-to-face meeting. The structure of the survey was divided into five main sections covering different aspects of safety communication processes and an additional free text section on good examples. The five main sections were:

- National internal procedures for safety communication – organization and process;
- External safety communication – communication in practice;
- Communication channels and target audience;
- DHPC (Direct Health Care Professionals Communications) and;
- General experience with the national safety communication.

The survey comprised 53 questions. In addition, 4 questions (question 51-54) on research on impact assessments were included to provide background information to impact assessment of risk communication measures section of this WP and the findings for these additional questions will be included in the report for that topic.

During the development process many constructive suggestions and comments were made by the participants. The participants were encouraged to test the preliminary questionnaire internally within their respective NCAs and the final questionnaire was considered validated through this process. It was also decided to that it should not be compulsory to answer any of the questions, as it could be problematic for various reasons to provide answers to some of them and preferable to allow flexibility in order to get as many answers as possible.

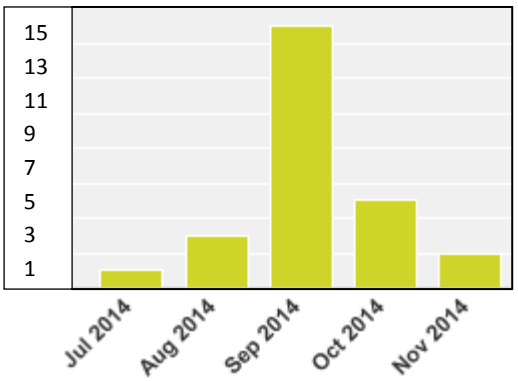
A web based questionnaire was considered a relevant and efficient method to easily gain information on tools, methods and strategies for safety communication used by NCA. The SurveyMonkey web-based tool would also provide for relatively easy analysis of responses and graphic presentation and it was chosen by WP 6 as the web-based tool to be used.

The questions for the audit of national methods of communication were then incorporated in the SurveyMonkey web-based tool and sent out on 3rd July 2014 to all Member States participating in SCOPE. The deadline for completing the questionnaire was 12th September 2014.

2.2 Setting and participants

Out of the 27 possible respondents (Germany, Austria, Liechtenstein and Luxembourg were not involved in the project), 26 NCAs completed the survey. A few questionnaires were not initially submitted by the deadline of 12th September 2014 and thus reminders were sent out in order to avoid delays of the progress of the work. WP6 participants also decided that it would be beneficial to extend the deadline from 12 September to end of November 2014, to allow more responses to be collected. The fact that the response rate was exceptionally high should make it possible to get good insight in present practices that can serve as a basis for the remaining work in WP 6 to develop tools for efficient safety communications.

Figure 1. Response rate per month during the survey



2.3 Data analysis (quantitative and qualitative)

As a first step, the responses to all individual questions where alternatives were given were analysed in terms of response rate (%). For all questions where comments could be given in free text, the answers were analysed and attempts to group the individual answers were made and the results were summarized. A preliminary summary of the first 40 questions was presented at the face-to-face meeting in Madrid in November 2014 and a compilation of the answers to the full questionnaire, including all individual comments and clarifications was sent to the WP 6 participants on the 24th of November 2014. Feedback with proposals for presentation and analysis of the data was requested. For in depth information on the results of the first 5 sections of the survey, please see below, point 3.

Regarding the free text questions on good examples and descriptions of methods/tools/channels that work particularly well, success factors and ideas for improvement an attempt to group the answers and find patterns through key words

was made. An attempt to see if there was any geographical specificity with respect to the information provided was also made, but no such tendencies were noted.

3 Findings/Results

3.1 Response rates analysis

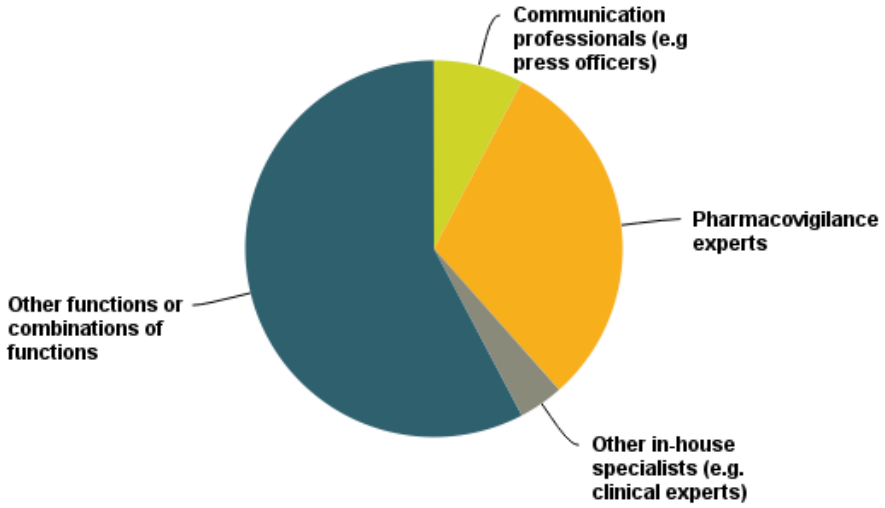
In total, 26 out of 27 MS responded to the survey. All questions were optional to respond to. For most questions, the response rate was very high. The results are indicated both with the number of responses (X/Y MS) and percentages. The concluding questions with good examples, problems and success factors and specific suggestions (no. 55-57) were completed by 19, 12 and 17 MS, respectively.

3.2 National internal procedures for safety communication – organization and process

Question 1. Which organisational function(s) is/are involved in the safety communications within your NCA? Tick all that apply.

Due to a bug in the questionnaire it was not possible to tick more than one option. Many responders, 15/26 MS (58%), commented on this and listed instead as free text the functions which were involved in the process. They included some or all the options given, communications professionals, science/medical writers, pharmacovigilance experts and other specialists within the agency (e.g. assessors, clinical and other experts). Pharmacovigilance experts were the sole function indicated in 31%, 8/26, of the MS and communication professionals and other specialists were the sole function involved in one MS each. Only two MS mentioned science/medical writers under the option other functions, while pharmacovigilance experts and communication professionals/press officers were mentioned by the 15 MS that responded with this option. In conclusion, most MS have an organisation for safety communications where pharmacovigilance experts and communication professionals/press officers cooperate on safety communications, sometimes with additional expertise involved.

Figure 2. Functions involved in the safety communication procedure



Question 2. Do you have a specific communication function that is involved/available out of office hours?

Twenty-five MS responded to this question, 14 (56%) responded Yes and 7 No (28%). Of the 4 MS that responded "Other, please specify", one MS responded that they had persons available on an ad-hoc basis for issues of potential media attention, another that several members of the agency were available out of office hours. Another MS was not sure how to interpret the question, but responded that they did not have any person available out of office hours. One other MS referred generally to crisis telephone and electronic communication channels.

In conclusion, the majority of MS have an out of office communication function (permanent or ad hoc) or other arrangement set up (16 MS), while the rest did not.

Question 3. Are your pharmacovigilance or other experts ever in contact with the media?

Question 4. Do pharmacovigilance and other experts get training/support in communications/handling of questions from the media? And

Question 5. What kind of training/support do they receive?

In the majority of the MS that responded to questions 3 and 4, experts were in contact with media (19/26, 73%), and in 58% (15/26) of the MS the experts received training.

In response to question 4 on dedicated media training of pharmacovigilance and

other experts, 15 MS responded Yes and 11 No. Twelve MS responded that formal external courses were used and 10 that regular in-house training was provided (some MS used both options). Fifteen MS provided additional information. External training courses, either ad hoc, at request or at regular intervals (e.g. new employees) were used by 8 MS. One MS responded that relevant staff receives both internal and external support and training. One MS practiced regular in house training/practical support by internal communication experts, and one Member State was planning a safety communication course later that year. One Member State relied on the press department of their Ministry.

In conclusion, the majority of the MS responding to question 5, indicated that external training of experts (other than the press/communications office) in different forms had an added value and it was also mentioned that dedicated support from the press office before giving interviews etc. was practiced. For one Member State, assistance from the press department of the Ministry was practiced.

Question 6. Do you have a general media spokesperson for all safety topics?

The majority of MS (17/26, 65%) answered Yes on this question. Most MS indicated that they had general spokespersons, either the Director General, department director according to the topic or a dedicated spokesperson or public relations/press function. A number of authorities indicated that in cases of safety issues, pharmacovigilance experts or PRAC members could be assigned as a spokesperson and could make media statements.

Question 7. Do you have a dedicated spokesperson for every unique topic or for therapeutic areas?

The vast majority responded No to the question for every unique topic (81%, 21/26) and for therapeutic areas (88%, 23/26). One authority responded that they had unique spokespersons for every topic, including for therapeutic areas, while one other authority had spokespersons for certain predefined topics. Another authority had spokespersons for a number of divisions/therapeutic areas.

Question 8. Do you have a quality system (e.g. standard operation procedures, SOPs) in place for the development and distribution of safety communications such as: Press releases, safety communications, other?

The majority responded positively on press releases (81%, 21/26), safety communications (92%, 24/26) and other (75%, 15/20). Of the other types of safety communications, DHPC and rapid alerts/attention messages were mentioned by many respondents. A few other communication tools were mentioned as well, such as educational materials, drug safety/adverse reaction newsletters and recalls/quarantine due to quality defects or falsified/stolen/illegal medicines. Two MS had a system by which a safety or alert message could be linked to the medicinal product in the electronic prescription system/SPC-PIL database at the agency's

website or sent to the pharmacy/district electronic interface.

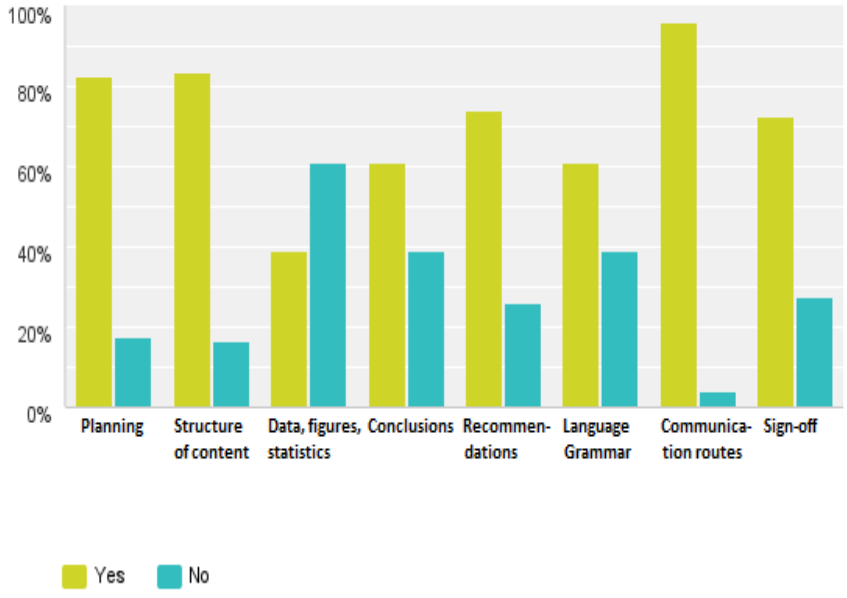
Question 9. If Yes to any of the questions above, which aspects are covered by the quality system?

The majority of the MS authorities included the following elements in the different SOPs/internal guidelines:

Planning (83%, 19/23), structure of content (83%, 20/24), conclusions (61%, 14/23), recommendations (74%, 17/23), language and grammar (61%, 14/23), communication routes (96%, 23/24) and sign-off (71%, 16/22).

Only 36% (9/23) indicated that the SOPs/internal guidelines included guidance on how to present data, including figures and statistics.

Figure 3. Items included in quality systems/SOPs/internal guidelines



Question 10. Please describe the process for a "typical" safety communication process, including who is involved and who takes the final decision on individual safety communications.

Twenty-five MS responded to this question. A typical safety communication process was interpreted differently by the respondents, e.g. also processes related to crisis situations, internal communication, quality defects, media enquiries and DHPC distribution were described. In some of the answers, description of or reference to internal SOP for various communication processes were provided.

Involvement

In the majority of the responses provided, regarding the work around the safety communications, pharmacovigilance experts and/or departments were indicated as the major contributor of the work. Only a few mentioned PRAC/CHMP members specifically. In some authorities dedicated staff/pharmacists were responsible for identification and drafting of the communication messages. Other relevant expertise and senior management/heads of departments were involved in some of the authorities.

Decision

Final decision to publish a safety communication was taken at different levels in the organisations. How the different authorities are organized may influence at which level the final decisions are taken on safety communication. Depending on the type of safety concern, national or at EU level, the levels for final decision may also differ. Management board and/or Director General were listed in 7 of the answers, post licensing or other director/head in 5 cases and pharmacovigilance department/head in another 4 cases. Joint decisions of those involved, including PRAC/CHMP members were mentioned by three respondents.

3.3 External safety communication – communication in practice

Question 11. Do you reproduce safety communications from EMA on your website?

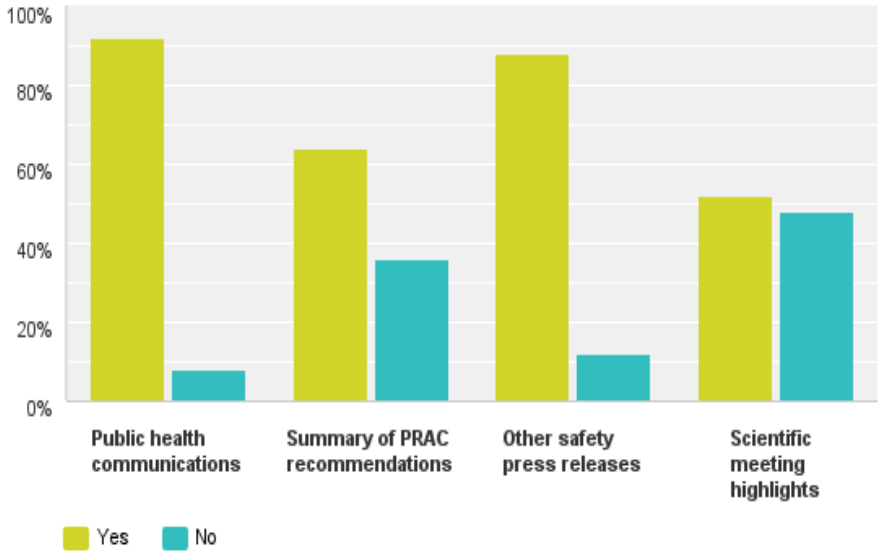
Of the respondents, 50% (13/26) reproduce all EMA safety communications and 42% (11/26) reproduce depending on the topic.

Question 12. Which EMA safety communications do you publish?

Ninety-two percent of the MS (23/25) publish public health communications and 88% (22/25) other safety press releases. Sixty-four percent (16/25) publish summary of PRAC recommendations and 52% (12/23) publish scientific meeting highlights. Some MS mentioned that only those EMA communications with national relevance are published. From the additional comments provided it seems that adaptation to the national situation is practiced as well as providing links to the EMA web site. One MS only publishes recommendations from the PRAC after CMD(h)/CHMP

decisions/opinions.

Figure 4. Publication of EMA safety communications



Question 13. Do you translate the EMA safety communications into national languages?

Seventy-two percent (18/25) of the respondents translate the EMA safety communications, but adapt them to the national situation. Sixteen percent (4/25) translate the EMA safety communications word by word.

Question 14. Do you communicate the EMA safety messages at the same time as EMA, e.g. Friday afternoon after committee meetings?

Nineteen percent (5/26) of the respondents said that they always publish at the same time as EMA and 69% (18/26) answered Yes, sometimes. A common pattern was revealed, in that if the communication is high profile with public health implications it is prioritized for publication on Friday afternoon. Otherwise MS postpone publication to the coming week. Work load, e.g. translation, and importance of the issue are other factors taken into account when deciding on a publishing date. If several messages are published by EMA by the same time some MS prefer to communicate them sequentially.

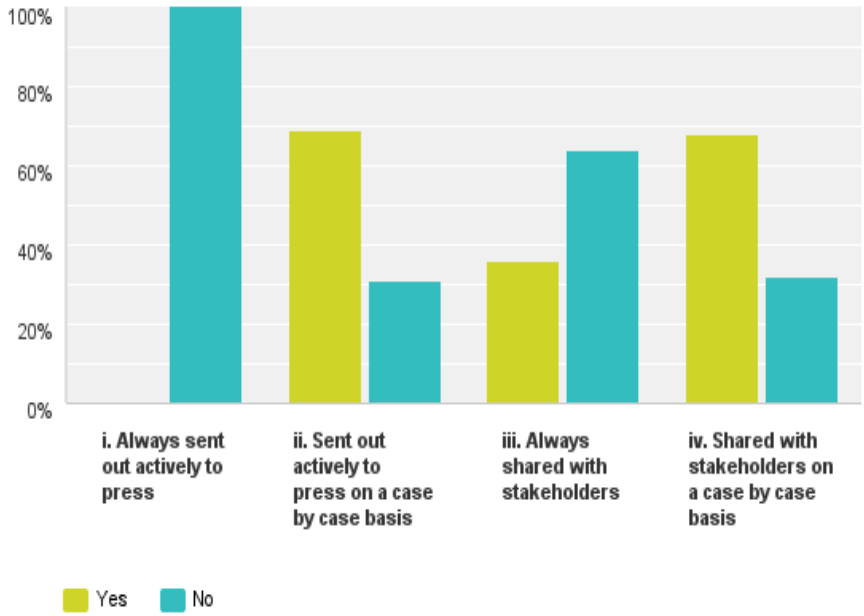
Question 15. Do you include a hyperlink to safety communications from EMA when you communicate on the same safety issue on your website?

Fifty-eight percent (15/26) of the respondents answered that they always provide a link to EMA communication and 27% (7/26) answered Yes, sometimes.

Question 16. What else (if anything) is done at national level with the safety communications related to EMA (CHMP/PRAC/CMD(h)) activities?

No MS indicated that they always send messages actively to the press but 69% (18/26) send out messages to the press on a case by case basis. As regards stakeholders, such as regional pharmacovigilance centres, major teaching hospitals or university hospitals, health care professional (HCP) associations, national health services, pharmacies etc., 36% (9/25) of the MS responding always share EMA information with stakeholders while 68% (17/25) do it on a case by case basis. There was a slight overlap in these figures.

Figure 5. Distribution of EMA communications at national level



E-mail is the dominating tool for spreading information to stakeholders. Possibility for subscription to published news is also used as well as dedicated information to governing bodies and other public institutions.

Question 17. Do you use EMA 'Lines to Take' (LTT) on safety topics to manage specific (safety) issues at national level (e.g. to be prepared to answer queries)?

Of the 26 responding MS, 19 (73%) reported to always use the EMA 'Lines to take' (LTT) and the remaining use them sometimes.

Question 18. Do you find these LTT useful?

Eighty-five percent (22/26) of the respondents find the LTT useful while 15% (4/26) said they are sometimes useful.

3.4 Communication channels and target audience

Question 19. Do you use your website for safety communications?

Ninety-two percent (24/26) of the respondents always use the website for safety communications and 8% (2/26) use it occasionally. Additional communication tools are also used, e.g. news on medicines in medical journals, direct e-mail lists.

Question 20. Do you dedicate your safety web page/section to particular target groups?

Of the respondents 46% (12/26) indicated that they have sections on their websites dedicated to target groups and 54% (14/26) do not.

Question 21. Please specify the target group(s)?

HCP and patients dominate as target groups (73%, 16/22, and 77%, 17/22, respectively). Media and pharmacies were targeted by 47% (9/19) and 50% (10/20), respectively. However, some of the MS that responded that they did not have dedicated sections on their websites responded positively regarding some of the target groups in question 21. When correcting for this, the figures were for HCP 64% (11/17), patients 71% (12/17), media 33% (5/15) and pharmacies 38% (6/16), respectively. Other target groups listed were the industry, distributors, the general public, physicians of different medical specialties and regulatory stakeholders. Some responders pointed out that all the content published on the website was publicly available, i.e. no specific logins were required for certain sections.

Question 22. Do you use bulletin(s) (on paper or in electronic format) for safety communications?

Thirty-five percent (9/26) always use bulletins for safety communication, while 39%

(10/26) occasionally use this channel.

Question 23. What channels are normally used for bulletin (paper or electronic) distribution?

Twenty-five MS responded to this question. Ordinary mail is used by 16% (4 MS), e-mail from the NCA by 56% (14 MS) and e-mail via HCP organisations by 12% (3). Seventy-two percent (18/25) provided comments and in some answers described use of other channels such as the official website, articles or alerts in scientific journals and in one case direct delivery.

Question 24. How is the target audience for bulletins (paper or electronic format) identified?

HCP are invited to subscribe in 8 of 13 MS (62%) that responded. The other MS (5/13, 38%) used address register.

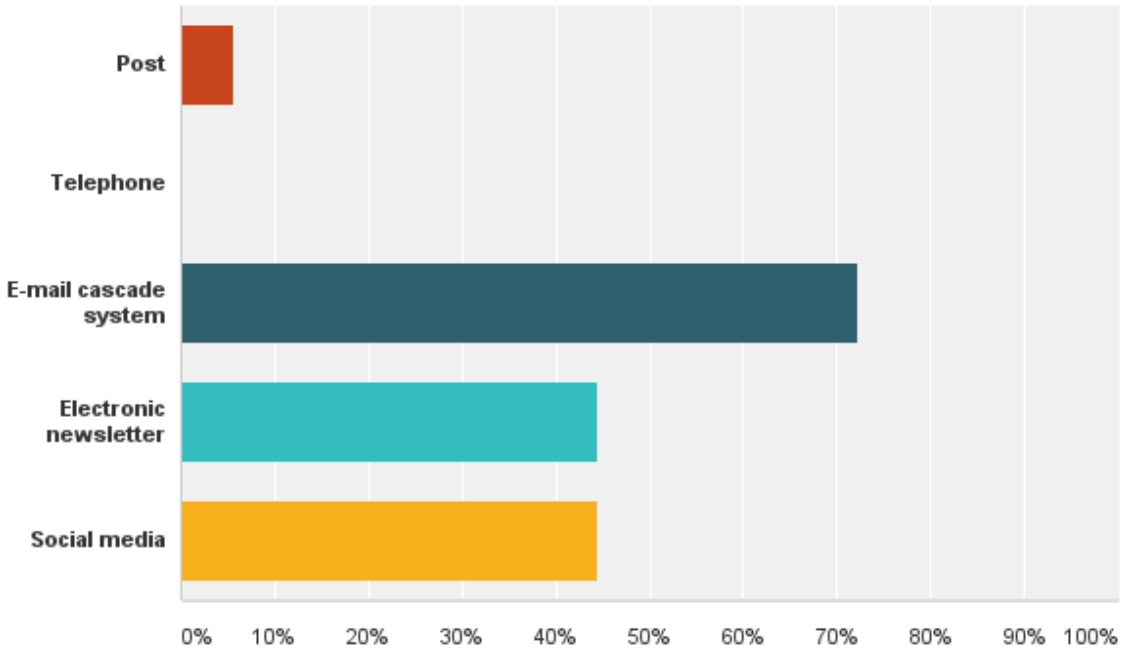
Question 25. Do you use press releases for safety communication?

Eighty-four percent (21/25) of the respondents use press releases.

Question 26. How are press releases distributed?

Only 6% (1/18) responded that they distribute press releases by post while 72% (13/18) use e-mail cascade systems. No MS distributed press releases by telephone. In addition, electronic newsletter was used by 44% (8/18) and press release distribution via social media was likewise used by 44% (8/18). Communication on the web site is often considered equal to a press release. One MS use electronic distribution to the media via the regional pharmacovigilance centres. Dedicated electronic press rooms/other commercial services are used by two MS.

Figure 6. Distribution of press releases



Question 27. Do you use any other communication channels (e.g. fax, mobile text messages)?

Of the 21 respondents, 11 used no other communication channels. Other channels used were fax (2), text messages (3), RSS feeds (1), Twitter (2), an electronic cascade system (1) and an electronic prescription support system (1). Ordinary mail was used by one authority.

Question 28. Do you contact principal stakeholder groups directly on safety issues of particular interest for the group, beside the mass communication channels (such as press release/web communication)?

Twelve percent (3/26) of the respondents always contact principal stakeholder groups directly while 73% (19/26) contact them on a case by case basis.

Follow-up question: If Yes – which type of stakeholder groups do you frequently contact (e.g. patient organisations, specialists organisations, national health services)? In addition to specialists, patient organisations, the national health services, other public bodies such as health insurance bodies and ministries of health as well as learned societies, industry, leading clinics and drug advisory committees were mentioned.

Question 29. Do you have lists of stakeholder groups that are kept up to date? If yes, who or which function in your organization is in charge of this work. And
Question 30. How is the list of stakeholders kept up to date?

Seventy-three percent (19/26) keep updated lists of stakeholders and 28% (7/26) do not. The responsibility for keeping the lists updated is mostly either shared by pharmacovigilance and communication/press departments or handled by one of them. In two authorities a dedicated assistant/secretary was in charge of keeping the lists updated and in one authority the lists were updated manually based on contact lists from the national physician association. In one authority a service department was responsible for keeping the lists updated. No MS indicated that they use a commercial product to keep the list up-dated, but one mentioned in the comments that to target the larger public, databases were rented.

Question 31. Do you pre-test (interpretation and understanding of message) your national communications?

The majority (77%, 20/26) of the MS do not pre-test their safety communications. However, 6 authorities tested at least on a case by case basis and one used a peer reviewer to check the understanding of the message. One MS has an in house group for readability testing.

Question 32. Does your NCA use the same methods for communicating other potential safety issues e.g. quality defects, shortages, medication errors?

The majority of the MS used the same methods (88%, 23/26). Three MS answered No and four provided comments on how information on these issues are handled (lists, special communication structures and channels).

Question 33. Does your NCA communicate SmPC/PL changes?

Eleven of the 26 respondents (44%) answered Yes on this question.

Question 34. If Yes to question 33, is this for transparency reasons (e.g. list of all SmPC/PIL changes) or for importance of the change from a clinical perspective?

Fourteen MS answered this question, among them obviously a few that had answered negatively on question 33 as well. Some considered that the transparency reason was important (36%, 5/14) while the majority (86%, 12/14) considered that the importance of the change was the main reason for communication of SmPC/PIL changes. Of the comments, it was possible to discern that the question may have been misunderstood by some respondents, in that it was not about making updated product information available and then providing separate information at the time the updates take place.

3.5 Direct healthcare professional communications (DHPC as defined in GVP Module XV)

Question 35. Do you publish DHPCs agreed by EMA/NCA and the marketing authorisation holders (MAHs) on your website?

Eighty-eight percent (23/26) of the respondents answered Yes on this question.

Question 36. Do you publish DHPCs produced by MAH whose content is not agreed with EMA/NCA?

Ninety-six percent (25/26) of the respondents do not publish such DHPCs.

Question 37. Does your NCA request the MAHs to develop and distribute DHPCs not derived from the EU procedures?

The answers from the 26 respondents were equally divided between Yes and No.

Question 38. Does your NCA develop and disseminate DHPCs which are not derived from the EU procedures?

Thirty-nine percent (10/26) answered Yes on this question.

Question 39. When there is more than one MAH concerned by a same safety issue, e.g. affecting the same active substance or a class review:

Does your NCA normally ask all concerned MAHs to distribute a DHPC for their own medicinal product? OR

Does your NCA normally ask all concerned MAHs to coordinate the development of a single DHPC related to the safety concern so that only one DHPC is received by healthcare professionals?

All authorities normally ask all concerned MAHs to coordinate the development of a single DHPC (96%, 25/26) and in 80% (20/25) of the cases the originator is asked to take the lead.

In the comments for situations when there is no agreement or no originator authorised a trend can be seen towards letting the MAHs decide among themselves. In one MS the authority is responsible for coordinating and disseminating the DHPCs on behalf of the MAHs. In another MS the authority assigns one generic product MAH to take the lead and in another MS the MAH for the generic product with the highest sales figures is asked to take the lead. If no agreement is reached there is an option for individual letters to be sent from the MAH.

Question 40. If you have a standard routine for requesting a DHPC – please describe the process.

It was obvious from the answers that this question was not clear as it did not differentiate between DHPCs decided on a European or national level and therefore not well understood. However, some respondents referred to the GVP module XV

and internal SOPs, in particular for national requests. Sixteen MS provided comments. One MS has a legally binding procedure to request a DHPC. One MS has a more developed routine for requesting DHPCs in accordance with the agreed national communication plan.

Question 41. Does your NCA disseminate DHPCs agreed on the EU-level via electronic means (in addition to MAHs distribution of DHPCs)?

The vast majority of the respondents do not disseminate DHPCs (77%, 20/26). Free text comments were received from 6 MS. They showed that in 3 MS, stakeholder could subscribe to a news feed system to receive these messages and one also published them on their website with subscriber alerts. Two MS send out DHPCs to the HCP organisations and one MS was in the process of setting up such a system.

Question 42. Does your NCA allow the MAHs to distribute DHPCs by e-mail without posting a hard copy as well?

Forty-two percent (11/26) of the respondents answered Yes to this question.

Question 43. Do you require validated E-mail addresses (which ensures the sender of the actual delivery and receipt)?

Of the 24 respondents 50% answered Yes to this question.

Question 44. Does your NCA use patient/specialist organisations for further distribution of the DHPC?

Of the 26 respondents 42% (11 MS) of the respondents answered Yes to this question. Some of the NCAs specifically ask the patient/specialist organization to disseminate the DHPCs, sometimes on a case by case basis. In one MS regular contracts exist between the pharmaceutical industry and the scientific societies for this work. A few NCAs send DHPCs to the organizations directly.

Question 45. Please describe other requirements or comments on the development and dissemination of DHPCs.

Some MS elaborated further on their existing and future dissemination requirements, such as changing from fax/post to secure e-mail dissemination, from company to government logotype and ways to make HCP notice the DHPCs easier, such as specific envelopes.

In two MS, the authority had to be on the e-mail list as an extra control measure. One authority mentioned that they required proof that the DHPC had been distributed.

3.6 General experience with the national safety communication

Question 46. Do you follow up communications at different levels to evaluate the success of distribution or influence on practice?

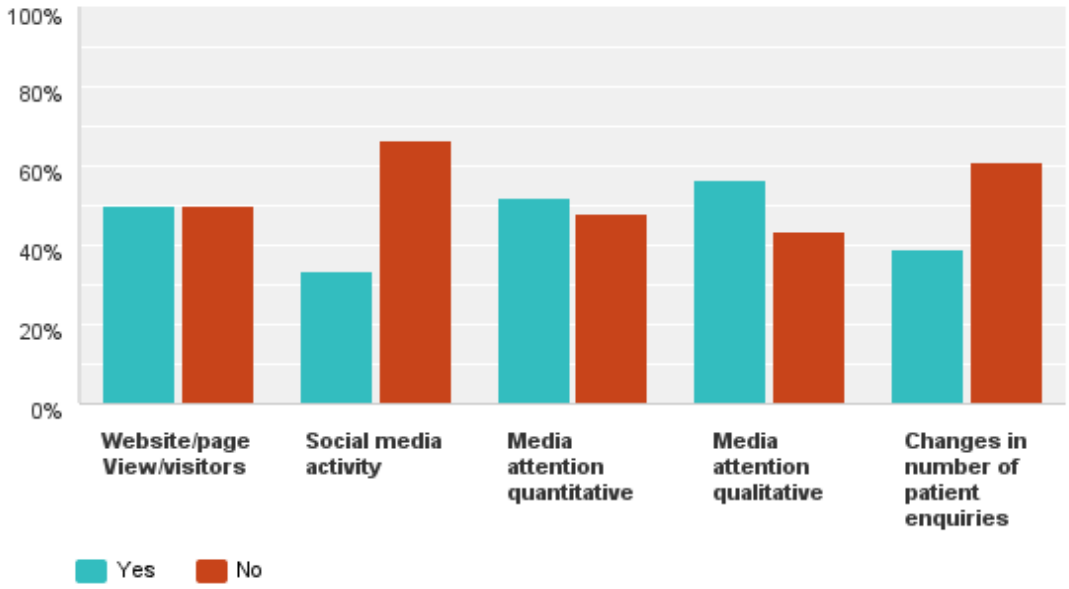
Of the 26 MS responding to this question, 8% (2/26) regularly follow up communications and 65% (17/26) do it on a case by case basis. Twenty-seven percent (7/26) do not follow up.

Question 47. How do you follow up communications?

Fifty-seven percent (13/23) of the respondents qualitatively follow media attention and 52% (13/25) quantitatively. Website/page visitors are followed up by 50% (12/24). Changes in the number of patient enquiries and changes in social media activity were followed by 39% (9/23) and 33% (8/24) of the respondents, respectively.

Under "Other" MSs mentioned case-by-case feedback from MAHs, national pharmacovigilance committee members, HCP enquiries and PhD research.

Figure 7. Follow up of safety communications at national levels



Question 48. Do you know if your information is further spread to secondary recipients and wider in the community?

Thirty-eight percent (10/26) of the respondents answered Yes and 62% (16/26) No to this question.

Of the 10 MS who answered Yes, several mention different kinds of cascade systems through HCP/ Pharmacists organisations and regional centres. From the information

provided, it seemed as if four of the MS who use cascade systems have a more formal agreement with the further distributing organisation. The other main channel mentioned is republication in specialist journals/newsletters and on websites.

Question 49. Do you investigate if the recommended actions are taken by the target audience?

Sixty-five percent (17/26) of the MS answered No on this question.Recommended actions are followed up mainly on a case by case basis and mainly through sales/prescription data. Drug utilization studies are mentioned as well as ADR reporting rates. One MS refers to a PhD thesis from Groningen University (2013) covering the national activities in this area.

Question 50. Do you measure impact of communications (taking into account that communication is often only one part of a risk minimization kit)?

Sixty-nine percent (18/26) of the respondents answered No to this question. Of the 8 MS who answered Yes, their comments overlap with the answers to question 49. No additional information could be extracted from the comments.

3.7 Good examples, success factors and areas for improvement

Question 55. Please describe methods/tools/channels that work particularly well.

Nineteen authorities provided specific suggestions. From the answers it seems that multiple channels/tools on the topic strengthens the message in particular if the topic is well prepared, such as for the recent safety referral on combined oral contraceptives, which was mentioned by 3 MS. Some MS considered that additional communication via different tools on the safe topic after some time improved the uptake (newsletters, report, expert meetings, collaboration with scientific societies).

Integration of safety communications in the prescribing and dispensing electronic tools were seen by some MS to be of particular importance for informing physicians and pharmacists in real time.

Question 56. If possible, please identify specific success factors.

Twelve MS provided specific suggestions. Some of the answers repeat comments made under questions 55. However, collaboration with opinion leaders/key scientists/clinicians/patient organisations is mentioned by several MS as key to success. Cascade of distribution of messages, not only website publications is also mentioned as a key success factor.

Question 57. Problems encountered and ideas for improvement.

Seventeen MS provided specific suggestions.

Problems identified

- Difficult to reach all relevant prescribers.
- Difficulties to measure effectiveness of communication, which is also resource demanding.

Suggestions for improvement

- Link to electronic prescribing/dispensing systems to improve information on safety issues in real time.
- Even if website communication is the main tool for distribution of safety information efforts to strengthen the message through other channels was considered important.
- Involvement with stakeholders to ensure the appropriate message is carried through.
- To have identified stakeholder contact channels in advance so they are in place when needed.
- Better follow up of communication to increase understanding of how the messages are perceived and which tools/channels are best suitable for distribution.
- One MS propose that communication from EMA should take place on Monday after PRAC meetings to allow for better preparation by the NCA instead of Friday afternoon.
- Knowledge about the EU-processes as well as understanding of the need for time and resources for communication within the NCAs is also important which was pointed out by a few respondents.

4 Discussion of the results

National internal procedures for safety communication – organization and process

In conclusion, most MS have an organisation for safety communications where pharmacovigilance experts and communication professionals/press officers cooperate on safety communications, sometimes with additional expertise involved.

The majority of MS have an out of office communication function, permanent or ad hoc, or other arrangement set up.

In the majority of MS, experts were in contact with media and the experts received training.

MS indicated that external training of experts (other than the press/communications office) in different forms had an added value and it was also mentioned that dedicated support from the press office before giving interviews etc. was practiced. For one small authority, assistance from the press department of the Ministry was practiced.

The majority of the MS had general spokespersons for all safety topics.

The majority of MS also has a quality system and SOPs for various types of communications. In the comments from the MSs on the content of the quality system the following elements were included: planning, structure of content, conclusions, recommendations, language and grammar, communication routes and sign off. Data, figures and statistics was less commonly covered in the SOPs.

Two MS had a system by which a safety or alert message could be linked to the medicinal product in the electronic prescription system/SPC-PIL database at the authorities' website or sent to the pharmacy/district electronic interface.

External safety communication – communication in practice

Around 90% of MS publish public health communications and 60% publish summary of PRAC recommendations. Adaptation to the national situation and translations are practiced as well as links to the EMA website. Most MS use the EMA 'Lines to take' (LTT) and appreciate their usefulness.

High profile safety issues were more likely to be published at the same time as the EMA communication. Work load and importance of the issue are taken into account when deciding on a publishing date. In addition, some MS prefer to communicate sequentially.

Some MS strengthen the message by sharing EMA information directly with stakeholders and press.

Communication channels and target audience

In general the MS use their websites as the main channel for safety communications. Communication on the website is often considered equal to a press release.

For distribution of safety communication one MS mentions electronic distribution to the media via the regional pharmacovigilance centres. In addition electronic press rooms/other commercial services are used by a few MS.

Nearly half of the MS have dedicated sections of their website directed to specific target groups, mainly HCP and patients.

Regular press releases are used more infrequently while e-mail cascade systems are preferred. In addition, electronic newsletters and distribution via social media are used more frequently. Also other communication channels such as text messages and social media are mentioned.

Direct contact with stakeholder groups to alert on important safety issues is practised on a case by case basis.

Pretesting of messages was only performed by a few MS, and mostly on a case by case basis.

Direct healthcare professional communications (DHPC as defined in GVP Module XV)

DHPCs agreed by EMA/NCA are published on the NCA websites in nearly 90% of the MS. Only one MS publishes non- agreed DHPCs.

The majority of the MS ask concerned MAHs to coordinate between themselves the development of a single DHPC and the originator is normally asked to take the lead.

Some MS ask the patient/specialist organization to disseminate the DHPCs, sometimes on a case by case basis. In one MS, regular contracts exist between the pharmaceutical industry and the scientific societies and in some MS the authorities themselves send the DHPC to the patient/specialist organizations.

General experience with the national safety communication

Different follow up options are used, however mostly on a case by case basis. Media attention is followed most often as well as website/page visits. Only a few MS followed up on recommended actions and, if being done, it is on a case by case basis and mainly through sales prescription data.

Good examples

It was considered important that the messages are well prepared. Using multiple tools/channels and repetition of the message is considered valuable for strengthening the uptake of the information. The information package in relation to the recent safety referral on the combined oral contraceptives was mentioned as a good example.

Integration of safety communications in the prescribing and dispensing electronic tools were seen by some MS to be of particular importance for informing physicians/ pharmacists/patients in real time.

Collaboration with opinion leaders and key scientist in the relevant field as well as with patient organisations is considered by several MS as key to a successful communication of the safety messages. This also gives a possibility for better understanding of the needs of different stakeholders.

Whether sent by post or e-mail an identification marker is considered valuable to distinguish important safety messages from commercial material as pointed out by a few MS.

5 Conclusions

The high percentage of responses by MS and the high number of individual free text comments indicate a real interest in the area and a high ambition for improvement among MS. 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. Good ideas have been presented and some of these ideas are included in the recommendations below. The information and examples provided could be used for developing the WP 6 toolkit.

6 Recommendations/best practices

The advantages of DHPC distribution via scientific organizations should be further explored. It should be considered how stakeholders could be further alerted to important safety messages in DHPCs through secure e-mail, with government logotypes, marked envelopes, etc. Integration of safety communications in the prescribing and dispensing electronic tools, use of multiple channels/tools and repeating information to strengthen messages are good practices that should be considered for the future. Development of ways to collaborate with opinion leaders and key scientist in the relevant field as well as with patient organisations with the aim to strengthen communication on safety messages and receive feedback should be explored. The lack of routines for monitoring the desired effects of safety communication suggest that methodology for follow-up and impact measures should be developed.

7 References

1. Guideline on good pharmacovigilance practices (GVP) - Module XV – Safety communication.
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/01/WC500137666.pdf

2. Communicating Risk Effectively. S. Piening, University of Groningen, 2013. ISBN 978-90-367-6441-4).

8 Acknowledgments

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