SCOPE Work Package 6
Survey Report

Patient and Consumer Consultation

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SCOPE

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Contents

Acknowledgments

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1. Introduction

1.1 Background

As one of the key stakeholder groups for WP6 Risk Communications, it was planned to consult with patients and consumers on risk communication areas of interest identified within WP6. The areas were outlined in an 'aide memoire' document to facilitate discussion amongst members of patient and consumer organisations. The document was then sent to the European Patients' Academy on Therapeutic Innovation (EUPATI), patient advocacy programme students, and disseminated via BEUC (The European Consumer Organisation), EURORDIS (The European Organisation for Rare Diseases) and EUPATI National Platforms (ENPs). An electronic version was also made available within SurveyMonkey.

1.2 Respondents

Eleven patient/consumer organisations responded, representing seven countries (Belgium (BE) – 3, Spain (ES) – 2, Portugal (PT) – 2, Ireland (IE) – 1, Italy (IT) – 1, Lithuania (LT) – 1, Macedonia (MK) – 1).

Patient Organisations (POs):

- HTAP Belgique – Association of Patients with Pulmonary Arterial Hypertension (60 members) – Belgium
- European Haemophilia Consortium (9000 members) – Belgian respondent
- Portuguese League Against Rheumatic Disease (total number of members unknown) – 9 on panel reviewing the topics of interest, Portugal
- Action Psoriasis (total number of members unknown) – Spain
- Vasculitis Ireland (250 members) – Ireland
- POLA – Lithuanian Cancer Patient Coalition (5000 members) – Lithuania

Consumer Organisations:

- Deco proteste, Portugal
- Altroconsumo, Italy
- Testachats, Belgium
- Organisation of Consumers and Users, Spain
- Consumer Organisation of Macedonia, Macedonia

2 Response summary

Whose information about medicines are patients & consumers most likely to rely on?

Doctors were considered by all groups to be the most reliable sources of information about medicines followed by pharmacists and other healthcare professionals (HCPs). POs and fellow patients also featured as a trustworthy source. National Competent Authorities (NCAs) were only mentioned by 3 organisations as a source of medicines information, and only after HCPs and other sources. In a 2007 Portuguese survey (n = 4832) referred to by one of the respondents, NCAs were not mentioned at all by the public as a source of information on medicines. Media/social media sources were mentioned by some. One group highlighted that the HCPs will always be the primary source and that, while information may be sought from other sources, this would only be to clarify what information the HCP had already provided. One group indicated that patients would be happy to get information from Marketing Authorisation Holders (MAHs), but may not trust it. A 2008 study conducted by a Belgian consumer organisation noted that, although patients indicated they would only use reputable websites to access information on medicines, in a follow-up exercise the patients were found to select one of the first three websites suggested by the search engine and to believe the information provided.

What are the preferred channels to access information about medicines?

The primary preference according to all groups was face-to-face discussion with their HCP. The hardcopy version of the Patient Leaflet (PL) was frequently mentioned, along with online resources such as POs/NCA websites and social media patient community discussion forums.

Patient Leaflets – do patients read them and where do they access them?

The answers to this question were varied, some of the consumer organisations had survey data suggesting up to 80% of patients read the PL, and more if the medicine was available 'over-the-counter'. Another group estimated that one third of patients read the PL. It was mentioned that those who do read it probably only do so at the time of first using the medicine. Some groups commented that they would like patients to have input on the content of PLs, as they felt these could be improved. Most mentioned accessing the PL that was provided with the medicine, although one group mentioned accessing PLs on the European Medicines Agency (EMA) website also.

What sources of information are used to weigh up the benefits and risks of a medicine and how it is decided as to whether these sources are credible?

Doctors and other HCPs were given as the most usual source of information to allow a patient to weigh up the benefits and risks of a medicine. Fellow patients were also considered useful to discuss the benefits and risks with. Websites such as the Mayo clinic, the European public assessment report (EPAR), academic literature and the PL were mentioned by some.

Are patients and consumers in general aware of their national regulatory agency and have they used the website?

The respondents all acknowledged that, while those on the discussion panel were aware of the NCA, they felt most patients are not, and that patients do not use the NCA websites unless involved with a PO or EUPATI, etc. One group mentioned a recent public awareness campaign launched by the Portuguese National Authority of Medicines and Health Products (INFARMED) that was seen to be useful. A Spanish consumer organisation highlighted that they linked to Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) information on their website to raise awareness of NCAs. Some commented that, while they were aware of the NCA website, they found it difficult to locate citizen-specific information.

Does your organisation think the relationship between patients and regulatory agencies should be strengthened and, if so, how?

All felt strongly that it would be beneficial for patients/consumers and regulators to strengthen existing relationships. The ENPs were highlighted as being useful to develop links with POs. A number of groups would like better representation of patients and consumers on NCA committees, with more opportunity to contribute formally and weight given to the patient opinion. The EMA Working Group (WG) was flagged as a positive model. Patient and consumer education events to highlight the work of the NCA, and how medicines are authorised and monitored would be very useful. One group felt that NCAs should be careful about their engagement with patient and consumer organisations and first ensure their independence from the pharmaceutical industry. The lack of financial reward for patients was flagged as problematic by another group.

Do patients and consumers know that they can report side effects of medicines directly to their national regulatory agency and how to do it?

If not, what is the best way to communicate this?

All groups considered that this is not well known and, where patients are aware they can report, they do not know how to do it. A few groups considered the low number of patient reports received by NCAs to be evidence of this and highlighted that 7 – 9% of reports received in PT in 2015 were from patients.

Many of the groups felt that HCPs should inform patients about how to report, and remind patients to do so each time a medicine is prescribed and dispensed. Other suggestions included:

- Including adverse drug reaction (ADR) reporting instructions in the PL; it was not clear if patients and consumers were unaware that reporting information is already included or if they meant more detailed information should be provided.
- NCAs/POs presenting on this topic at patient conferences.
- Adding ADR reporting details to the outer carton of a medicine.
- Using media campaigns to highlight not only how patients can report, but also why it is important that they do so, i.e. to flag that there is a different type of information provided by patients compared to HCPs, but that it is all useful.
- Providing leaflets and posters to be displayed in locations such as doctors' offices and pharmacies.
- Uploading videos showing how to fill out the ADR report forms on the NCA and PO websites.
- Increasing the prominence of the ADR reporting section on the NCA website.
- Utilising POs in raising awareness amongst patients.
- Simplifying the ADR reporting process, a number of respondents commented that too much information is required and it is off-putting for patients.

Do patients and consumers recognise the black triangle symbol and know what it means?

In general, the groups felt that only the more informed patients were aware of the additional monitoring scheme and considered that more work was needed to enhance recognition and understanding of the symbol amongst patients. Some appeared to think the symbol appeared on the outer carton of the medicine.

What are patients' and consumers' views on the timing and availability of communications of information on safety reviews and the types of reviews most important to them?

How do they want new safety information from such a review to be communicated?

Most commented that they wished to be informed from the start of the review for transparency reasons and in case they may be able to contribute something to the review. One group commented that enhanced transparency increases trust. One outlier response commented that information about safety reviews should only be provided at the end when there is certainty as to whether the safety issue is valid. Another group highlighted that, if possible, only patients to whom the safety review was relevant should be informed with particular targeting by regulatory authorities of POs in the medical area concerned to facilitate syndication of information. All types of safety reviews were considered important; some highlighted that telling patients about shortages of medicines was particularly important.

The preferred source of new safety information was their HCP or an alert from the NCA or PO. NCA press releases, social media updates and general media updates were provided as possible means by which to communicate new safety information, but most agreed it depended on the nature and seriousness of the information.

What are their views on how best to present quantification of risks for a medicine? (Sample graphs were provided within the document.)

The answers to this question varied, and some commented that their discussion panel filling out the document also couldn't agree. Some preferred the frequency text currently used, whereas others considered graphical presentation more helpful. Some commented that both should be provided in patient materials. There was no strong preference for any of the graph type examples provided, with almost all being chosen as the easiest to interpret by at least one respondent. Pie charts, risk ladders and statistical maps were other options mentioned as worth exploring. One group wondered whether a traffic light system could be used, whilst another suggested the frequencies be compared to real life risks, such as of a car accident.

Are patients and consumers familiar with the concept of educational materials as a way to help manage risks with a medicine? Do they know that these are reviewed by the national regulatory agency?

For the most part, the groups who responded were not aware of educational materials or that NCAs have a role in their development/approval. Some commented that they did not want industry materials, but would prefer to receive these from POs or NCAs, or ideally to have the information explained to them by a HCP.

What types of tools are useful for patients and consumers as part of educational materials about a particular risk, in what format would patients like to receive these materials, and who would they like to receive the materials from? (Examples of educational materials were provided, these included a patient card, checklist and patient brochure.)

Most groups commented that they were unaware of these materials, but felt those provided with the aide memoire seemed useful. The checklist format, in particular, received positive feedback as it was felt it would encourage more discussion with HCPs. One group commented that they would prefer if there was one resource addressing both the disease and all of the issues associated with the available medicines, rather than separate materials for each medicine. One group who were aware of educational materials commented that they can sometimes be even longer than the PL, which is not useful. A number of groups felt the materials should form part of the packaging, for ease of access, while others wanted to receive a hardcopy from the HCP so that it could be discussed there and then, with an electronic version also available. A Quick Response (QR) code on the packaging was considered useful by one group, who commented that the materials needed to be made available in a number of formats and presentations, as there was no one option which would suit all patients.

All groups would prefer to receive educational materials from their HCP, with responses varying in terms of the patient accessing these themselves or receiving them from a PO. When respondents ordered in terms of preference whom they would like to receive the educational materials from, they either listed pharmaceutical companies last or deleted them from the list. One group commented that when information was being developed by MAHs, the PO should have the opportunity to review and adapt.

Any other comments?

The following comments were amongst those included in this section:

- NCA communications addressed to patients need to allow for differing age and education levels. They should be short, clear and focused, and include videos.
- POs should play a greater role in raising awareness of a safety issue with a medicine.
- Patients should not receive information from pharmaceutical companies.
- It should be flagged to patients that they need only report the ADR information that is applicable to them, i.e. make it clear that only a few sections on the ADR form are mandatory to complete.
- It needs to be communicated that there are uncertainties with medicines, i.e. not just known benefits and risks.

3. Discussion

Some of the organisations who provided a response represent large patient/consumer groups, whilst others are much smaller and relate to rare diseases. Two of the consumer organisations mentioned data from surveys (which they had previously carried out) to support their views on some of the questions (4832 people replied to one of these surveys). While the answers provided by the different organisations are broadly similar, the number of those contributing to these response documents is unknown, and the number of organisations that responded is too low to allow recommendations to be made. In addition, the patients who engage with these organisations are likely to be more familiar with risk communication tools by virtue of their membership/participation in these patient/consumer groups and, thus, may not be representative of the general patient population. The responses do provide useful information that allows some conclusions to be made; however, other areas could be further explored in the WP6 workshop, when there will be patients, HCPs and NCA representatives present. The responses may also provide some suggestions for further study in the area of risk communication with patients and consumers.

From the responses it is clear that HCPs remain the most trusted source of information about medicines. POs are also a valued source, although this will depend on the disease area and country. As reflected in the HCP study, patients may be unsure about the independence of information provided by MAHs. NCAs did not feature strongly as a trusted source of information about medicines, with awareness of NCAs and their websites considered to be low. Considering the level of trust in their HCP, it is not all that surprising that face-to-face discussion between patients and their HCP is the preferred channel for accessing information about medicines. However, most of the groups highlighted the need to consider a range of options when making safety information available.

While most organisations who responded did not have direct experience with educational materials, most provided positive comments, particularly regarding the checklist format. Again, it was widely considered that it would be helpful to make these types of materials available in a range of formats, including hardcopy and electronic versions, along with consideration of social media, apps, QR codes and use of videos. It was also highlighted that it may be helpful if patients could provide input into the development of such materials. Concern regarding the independence of information provided by MAHs was evident from the responses, which may be relevant for how patients view educational materials.

The majority of the groups considered knowledge of direct patient ADR reporting to be low amongst patients; it was commented that making patients aware of the importance of their reports may improve this, in addition to letting them know how to report. Awareness of the additional monitoring scheme was also poor, with most respondents themselves not being aware of the meaning of the symbol or where it appears (i.e. on the leaflet rather than the outer carton). An awareness campaign was mentioned in this regard, in order to inform the patients/consumers and to promote the NCAs' websites. These observations are noted and will be passed to the Work Package 4 Lead involved in the direct patient reporting topic. No consensus view emerged on the best presentational method for the quantification of the risks of a medicine, and it would appear that further research into this area is needed.

The importance of transparency to patients was highlighted by the groups, with the majority agreeing that communication about a safety review should take place at the beginning; this was also considered to enhance trust. A number of the groups also suggested that safety information should be directed to those for whom it is most relevant, where possible.

The interest of the consumer organisations that responded and aided in dissemination of the aide memoire is noted, along with initiatives mentioned by some, such as providing links on their website to the NCA website (ES) and inclusion of reporting information in their newsletters (PT). It may be useful for NCAs to develop links with these types of organisations where they exist in their country.

4. Conclusions

4.1 Educational materials

In addition to providing HCPs and patients with information about risks with a medicine, educational materials should function as tools to encourage discussion of safety information between the patient and the HCP, since it is HCPs that are the most trusted source of medicines information and face-to-face discussion is the most preferred channel for accessing information. The content should be clear and concise.

4.2 Safety review communications/transparency

Transparency is important to patients and consumers, communication about a safety review at the very beginning was considered essential for transparency reasons and to enhance trust. Wanting real time safety information reflects the need for risk communication to be sustainable and, thus, the need to exploit digital media for safety messages that are likely to evolve over time. Given that the groups suggested that safety information should be directed to those for whom it is most relevant, where possible, it may be helpful for NCAs to develop links with EUPATI national platforms and POs where available, so that they can optimise the dissemination of safety information to the relevant audience. Publication of educational materials on NCA websites would enhance transparency, allow immediate access to the most up-to-date version of the materials and may help to raise awareness of the NCA amongst patients. In addition, it would demonstrate that these materials are reviewed by NCAs (in many European Union countries), which may help allay concern regarding the independence of information provided by pharmaceutical companies. It is noted that some countries have already adopted this practice.

4.3 Awareness of the regulatory system

Measures are needed to enhance awareness of the regulatory system and how it works amongst patients and consumers. Links with patient and consumer organisations could be developed to help to raise awareness of the role of the NCA and ADR reporting information via these strong existing networks. More patient-accessible information could be produced with the input of these organisations, e.g. infographics to explain what happens when an ADR report is received, etc.