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Stakeholders and Communication Division

Communication on medicines — now and tomorrow

Report of a joint EMA workshop with patient and healthcare professional representatives about communication on medicines

Overview of the day

The work of the Patients' and Consumers' Organisations Working Party (PCWP) and the Healthcare Professionals' Organisations Working Party (HCPWP) has, over the years, added to and deepened EMA's knowledge of the perspective of the prescribers, dispensers and end users of medicines. Nowhere are these viewpoints as immediately relevant as in the communication of information on medicines.

On 8 March 2016, EMA hosted a workshop with PCWP and HCPWP on communication and information on medicines. The workshop began with an overview of the current situation presented by speakers affiliated with regulators, medicines information bulletins, pharmacists, academia and the European Commission. The keynote speaker Sara Rubinelli (chair of the research implementation committee of the European Association for Communication in Healthcare [EACH]) pinpointed tactics for effective and persuasive healthcare communication. Breakout sessions allowed participants the opportunity to discuss opportunities and challenges in the production, dissemination and use of medicines information in greater depth. Areas for future research were further discussed before bringing together the various strands of the day's discussions to define key messages and focus areas for future work.

How things stand

Juan Garcia Burgos of EMA presented the results of an EMA survey regarding perception of the Agency's communication material. The survey, conducted in February 2015, targeted EMA stakeholders and partners and had around 400 responses. The findings generally indicated wide use and a high level of trust in EMA communications. Opportunities identified for further development included improving findability of information on EMA's website, further simplifying the language used, increasing provision of targeted information to stakeholders and engaging in more active dialogue with stakeholders.

Editors from the International Society of Drug Bulletins (ISDB) took part in a survey described by **Giulio Formoso (ISDB)** regarding information on medicines provided by the regulatory authorities and public health institutions in their countries. Run from April to July 2015 and covering eight countries, the survey revealed heterogeneity in the quality of information provided in different countries.

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Issues that appeared included low transparency on the sources and quality of evidence and how the latter was linked to conclusions about safety and efficacy, as well as lack of primary data from pharmacovigilance and lack of implementation of evidence-based information at national level. The ISDB survey highlighted a common theme of high volumes of information and the difficulty in extracting relevant and high-quality information. Suggested areas for future work included enhancing content by clearly describing the application and relevance of data, use of well-known techniques for clarity such as expressing absolute risk and the Number Needed to Treat (NTT) and using web formats to layer information, offering different information to different types of stakeholders and facilitating dissemination. A central theme to the results was placing medicines in the context of current treatments and expressing added therapeutic value (ATV). EUnetHTA (European Network for Health Technology Assessment) was identified as an actor that could enhance provision of this information across Europe.

Laurent Brassart (EMA), together with **Joan Peppard of the European Association of Hospital Pharmacists (EAHP)**, outlined the findings of a HCPWP topic group survey that set out to understand whether and how currently provided medicines information is used by healthcare professionals (HCPs). Looking at responses from around 600 HCPs across Europe, they found that the Summary of Product Characteristics (SmPC) was very highly used (used by 95%) across all professional groups. The Package Leaflet (PL) was also highly used (80%), especially by nurses. This is probably as they are most likely to use it in communicating with patients and for certain medicines, such as those given by injection or intravenously, they may even be the ones to open the package. HCPs also used various other sources of information such as Direct Healthcare Professional Communications (DHPCs), educational material requested as part of risk minimisation measures, formularies and medicines compendia, guidelines and journals. The Public Assessment Report and European Public Assessment Report (EPAR) summary were less widely used (50-60%) due to lack of awareness or lack of knowledge of where to access these tools. How the documents were used was also examined. The SmPC was used for many purposes including for therapeutic decisions, dosing information, safety, storage, use, guideline preparation and informing patients. The principal use of the PL was informing patients. DHPCs and educational material were mainly used for safety management. The Public Assessment Report was principally used for therapeutic decisions, preparation of clinical practice guidelines and safety management. Results were similar across European regions.

Dolores Montero Corominas of the Spanish Agency of Medicines and Medical Devices (AEMPS) spoke about SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe), a project aiming to strengthen implementation of pharmacovigilance legislation (which came into effect June 2012). Part of this project (called Work Package 6) covers risk communication and has surveyed 26 national competent authorities (NCAs) looking at their current risk communication practices as well as 3,625 HCPs examining how these communications are perceived. Results highlighted a need to link safety messages to medicines information in electronic prescription systems and SmPC-PL databases. Repetition of safety messages through multiple channels was considered valuable for increasing uptake of information. Strong collaboration between NCAs and key opinion leaders, specialists and patients' organisations was considered vital for successful communication. Further assessment should be done to consider DHPC distribution via scientific organisations.

In June 2016, the results of this work package will be presented at a workshop in Madrid. These will include presenting practical tools for risk communication that can be used by all Member States, suggestions of communications methods based on current best practices, and input from HCPs and consumers on the effectiveness of different methods. Recommendations of websites that represent good examples of risk communication will be provided.

Dominic Way of King's College London and **Frederic Bouder of Maastricht University** have researched patients and doctors reactions to public health information from a wide variety of sources, including HCPs, internet, friends, patient groups, journals, companies, media, regulators and politicians. Over 1,000 patients and a similar number of doctors (specialists and general practitioners) responded to surveys. Results showed that patients desire more medicines safety information, but would react to such information differently: while over 50% would seek additional advice if they were told of safety problems with their medicine, 20-30% would stop taking the medicine. These reactions were highly dependent on the region the patient was from and to a lesser extent on their disease, highlighting the challenge of regional variations in responses to health information. Patients and doctors differ in their opinions of when potential risks should be communicated, with patients choosing that safety information should be communicated at the first sign of a possible new problem whereas doctors would prefer to wait until the issue has been investigated and regulators believe there is a problem with the medicine. Patients obtain trusted information from doctors or pharmacists, and while they also use the internet, they trust this information less. Positively, patients trust the regulators although they do not go to them as a source of information. In contrast to the high visibility of the Food and Drug Administration (FDA) in the US, in the EU situation, patients' awareness of regulators is low and both patients and doctors are not familiar with the role of regulators.

The researchers suggested that regulators should work more through HCPs, although noting that doctors are time-poor which restricts their ability to optimise patient knowledge. Their future research will involve interviews with patient and doctor representatives and patient focus groups with the aim of finding ways to improve benefit-risk communication to increase public understanding, thereby enhancing transparency in this area.

Martin Dorazil from DG SANTE at the European Commission spoke about two studies (called PIL-S and PILS-BOX), carried out by the Netherlands Institute for Health Services Research and University of Leeds, on the SmPC and the PL. These studies were carried out in response to a Commission directive that requested a study of shortcomings in the SmPC and PL and how they could better meet patients and HCPs needs (Article 59(4) of Directive 2001/83/EC).

The PIL-S study assessed the readability and comprehensibility of the SmPC and PL using literature research, stakeholder surveys and online forums, and made recommendations for improvement. The PILS-BOX study used literature research, stakeholder consultation and a SWOT (strengths, weaknesses, opportunities, threats) analysis to look at the impact, feasibility and cost of adding a 'key information' section to the PL.

Conclusions focused on the PL, suggesting an improvement to design is needed, with the possibility of providing anonymised, best-practice examples to marketing authorisation holders. More flexibility in the template was recommended as well as closer attention to the PLs after translation, with guidelines possibly needed. The marketing authorisation holder is currently obliged to perform user testing of package leaflets to ensure they are easily usable by patients, however this study suggested that it should be more iterative, with retesting after changes are implemented. The potential role of electronic media should be examined, such as the possibility of an e-PL which could be used as part of the care process by HCPs and could assist in alerting long-term users to changes in the PL. Nevertheless, 10-15% of users do not have internet access, so a printed PL should always be available. A key information section should not be mandatory, and further work was needed to define criteria for content and provide user-tested evidence of its value.

The study results had been presented to EU Member States, who considered that update of guidelines (rather than legislative change) would allow the conclusions of the studies to be implemented and tested. There was broad support for electronic as well as paper formats and increased user testing.

These study results will next be included in an assessment report to the European Parliament and Council.

Another outlook

Keynote speaker **Sara Rubinelli (EACH)** spoke about the best ways to enhance health communication at the patient and population level.

She highlighted that effective information requires not only persuasive communication, but also consideration of sociological, psychological and cognitive aspects. There are many good guidelines on how to communicate information, yet still a gap exists in uptake of that information. This can be due to variations in health literacy, from ability to read to ability to appraise and critically analyse. Low-quality information can be persuasive and high-quality information not so, and the individual's decision about which information to believe depends on their ability and desire to engage with, think about and judge the information. This is influenced by individual judgement, but also other factors such as personal situation, prior knowledge and beliefs, past experiences, newness of information, first impressions and what you want to believe. The situation is not helped by the fact that medicine is not an exact science and the results of research are often contradictory. In this era of information overload and unregulated discussions online, it is always possible to find the message you want to hear.

Where possible, it was suggested that production of new health information should be limited and instead users should be better guided in navigating existing information. This does not mean providing a list of links, but rather partnering with appropriate stakeholders to create websites dedicated to specific health topics with content managers that screen and guide users to appropriate online information. When new information is created, it should be generated through participatory design and target not only the needs but also the attitudes, beliefs, values and behaviours of the audience. The wider context of providing health information should be developed, including communication training for HCPs, empowering interventions to tackle health literacy, consideration of the emotional toll of a health condition and avoidance of marketing material as a source of health information.

Surfacing issues

Participants took part in breakout sessions to discuss the production, dissemination and use of medicines information. The aim of the sessions was to pinpoint the challenges and opportunities and the roles of different actors in achieving the goals identified. The issues raised are summarised below.

Producing information — as a producer of authoritative medicines information, what are the challenges and opportunities EMA should be looking at?

Challenges for production

- **Need for rapid reactions**
  Information needs to be based on robust evidence, yet rapid reactions are necessary in response to changing circumstances.
- **Varying levels of literacy**
  Information should be easily understandable for users with varying literacy levels.

- **Different language and cultural variations must be taken into account**
  EMA uses mainly English; however patients and HCPs prefer to receive information in their own language. Differences in culture affect how information is expressed and taken up.

Opportunities and actions for production

- **Quality over quantity**
  A focus should be placed on producing smaller amounts of high-quality information rather than large quantities of information that are more difficult to navigate.
- **Transparency on source and unknowns**
  Information should state the source and quality of starting material, and should include details of what is not known and uncertainties.
- **Balanced summaries regularly updated**
  Information should be clear, concise and easy to understand. The main points should be summarised carefully, getting the right balance so that enough but not too much information is given and the message is not lost in summarising. The information given must be regularly updated.
- **Appealing information**
  Information should be written and presented in an appealing, attractive way.
- **Individualised information**
  Defined audiences should be targeted using individualised information and appropriate media.
- **Readability testing**
  Readability tests can be repeatedly performed to assess how easy text is to read and understand.
- **Culturally sensitive translations**
  A lot of emphasis is placed on validating the English version of medicines information, however it is also important that translations are of high quality and take cultural differences in the optimal communication of information into account.
- **Changes to PL to increase its use**
  HCPs read health information such as the SmPC, but then have difficulty distilling and translating the messages into friendly language for discussion with the patient. The PL could include talking points: key points for the HCP to raise with the patient, expressed in plain language. The PL should include more patient-friendly information about the medicine's benefits to give a clearer picture of the benefit-risk balance of the medicine. Information in the PL that sounds too much like it is following a template means that it will often be ignored. When there is justification, templates should be less rigid and more flexible.
- **Side effects and how to manage them**
  When side effects are listed, information on their manageability should also be provided as a balance and so that the information is not unnecessarily off-putting. It may be difficult to provide specific information on treatment of side effects, as this varies across countries. However, it would be desirable to have a balance to side-effect information so that the user is aware that side effects may not be a problem for them and may be easily manageable.

Disseminating information — in the channelling of information from EMA to patients and HCPs, are target groups reached?

Challenges for dissemination

- **Fragmentation in access to information**
  Fragmentation in access to information across Europe makes it challenging to get the right information to the right target audience at the right time, given that information is disseminated through multiple channels and formats and users may get their information from different sources depending on their access to various resources and their preferences.
- **Maintenance of trust in regulators**
  EMA appears to be relatively well trusted as a regulator (as shown by research of Dominic Way and Frederic Bouder), but this can be challenged by events. Communication must ensure ongoing trust.
- **Lack of resources at key organisations**
  Key actors including patients' and HCP organisations recognise their role and responsibility in disseminating information but feel challenged by lack of time, personnel or financial resources to focus on communication as much as they would like.

Opportunities and actions for dissemination

- **Structured strategy**
  It is helpful to follow a clear structure when considering medicines communication by asking: what are the sources of the information? What tools will be used to communicate and disseminate? What are the goals of the communication? Who are the audiences?
- **Dissemination is everyone's task**
  No single organisation can completely cover dissemination. It is necessary to work in partnerships, where everyone has a role to play. Use of EU regulatory and partner networks for dissemination should be optimised. Patients' and HCPs' organisations have a mediator role to play in filtering and directing EMA information to the correct audiences, while returning feedback to EMA. Care should be taken that information is filtered by organisations in the manner intended by the regulators.
- **A single portal**
  A single web portal, with areas for patients, generalist HCPs and specialist HCPs would be an extremely valuable resource. It could be automatically populated with content from trusted sources. Medicines information should be available via both INN (international nonproprietary name, active substance name) and proprietary name (brand name).
- **Multiplatform use of EMA website**
  Ability to use EMA's website on multiple platforms such as phones and tablets would increase dissemination and accessibility.
- **EMA website optimisation**
  Dissemination can be hindered by difficulty in finding relevant information on the EMA website. Findability should be improved. Dissemination would be helped by provision of executive summaries on the website wherever possible.
- **Search engine and new media optimisation**
  Patients and the public need to be informed about where to get the information they need. Google

search engine optimisation so that EMA appears on the first page, identification and promotion of reliable resources and use of new technology and social media can help in informing.

- **Alert system for new and important changes**
  Patients may not be adequately informed when medicines information changes. An alert system should be in place for new and important changes to guidance. These should incorporate methods to get new health information across to patients with repeat prescriptions.
- **Clear differentiation of regulator information**
  It is important that safety information and other critical information about medicines can be clearly differentiated from other mail received by HCPs, such as promotional material from companies.
- **Links from stakeholder webpages**
  Stakeholder webpages should be encouraged to include a section about EMA and the available types of medicines information to increase EMA's visibility and traffic to the site.
- **Link to EMA on medicine box**
  Providing a link to relevant information from the EMA website on medicines' boxes could be a tactic to increase its dissemination.

Using information — what obstacles remain to using information on medicines to support communication at the point of care?

Challenges for use

- **Preparing patients and HCPs for shared decisions**
  Shared decision making requires that both patients and HCPs are prepared with the right resources at the point of need.
- **Information overload**
  We have moved from a world where information is scarce to a situation where the amount of information available is overwhelming. Information overload makes it challenging to ensure access and uptake of reliable, relevant information by the right target group at the right time in the right format.
- **Time scarcity**
  Doctors with short 5-10 minute consultation times and busy pharmacists are just two examples of time-challenged HCPs who do not have the time to review and collect information that is relevant and convey it in a short consultation.
- **Health literacy**
  Optimal use of information depends on the users ability to access, read, appraise and critically analyse. These abilities are variable across the population.

Opportunities and actions for use

- **Education on hot topics**
  Education, especially about high-risk areas such as guidelines for use of particular medicines (e.g., antibiotics), and statistics skills needed to understand risk, should be increased.
- **Explanation of role of regulators**
  Providing explanations of the role of regulators and the marketing authorisation process would increase awareness and seeking out of information from the regulator.

- **A large role for organisations**
  As for dissemination, patient and HCP organisations are key players in the use of medicines information, since they share and encourage use of information from EMA and other sources. Again, resources may limit how much these organisations can do and there is a need to ensure that they select and filter information appropriately.
- **Use of patient networks and blogs**
  Spread of information through patient networks and its presentation in more informal settings such as patient blogs could facilitate use.
- **Increased transparency of decisions**
  As decision making becomes more transparent, interest in medicines will be stimulated and the use of medicines information increased.

Where would we benefit from further research?

In an open discussion, the group reflected on ten years of collaboration on all aspects of medicines information communication. There have been significant advances in creating greater transparency and promoting shared, informed decision making. However, many topics such as improving quality of information and providing summaries of key points are still on the agenda because of changing technologies and an environment of information overload, which makes finding the right facts more difficult than ever before.

Search engine optimisation to improve EMA visibility on Google and other search engines was discussed again in this session. Currently pharmaceutical companies and Wikipedia feature higher in search results for a medicine than EMA.

An indicator to evaluate the impact of information communicated and how it affects the use of medicines would be valuable. New technologies such as smartphone apps have the potential to gather information as well as disseminate it.

Initiatives in place at FDA (such as a User's Guide on communicating risks and benefits as well as a Committee advising on risk communication issues) were highlighted, which could be considered useful for the European context.

Improvements to the PL were again discussed. There is already a link to the EMA website in the PL. 2D bar codes (QR codes) are already included in the PL, and these can be scanned with a smartphone and provide links to the latest version of the PL on the website or to instructional videos. Use of graphics, effects tables and more information about benefits to balance that provided about risks could increase the communication value of the PL and increase awareness of the PL as an educational tool.

Communication advisory boards were also identified as an area for further investigation. Learnings from public institutions where such advisory boards have been established could be collected to generate evidence-based practices.

Closing remarks

Isabelle Moulon, Head of the Patients and Healthcare Professionals Department at EMA and Chair of the workshop, wrapped up the meeting by highlighting some of the topics covered. She referenced the usefulness of a method to evaluate impact of communications on the use of medicines, for example following release of new information about risk, as an area that would certainly benefit from further field research. It is clear that multipliers, such as social media and search engines, could be better

used to enhance information dissemination and use. This point will be expanded on in an upcoming workshop on social media to be held in September 2016.

Methods to increase use of tools, including the PL, such as graphics and effects tables will be explored in a context of participatory design. There is a clear need to provide better targeted information directed towards segments of the public and patient communities. Isabelle emphasised the essential role of both patients and HCPs and their representative organisations in the medicines communication process and thanked participants for their ongoing contribution.