



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Benefit-risk communication to medicines users

How can regulators best meet the information needs of patients and healthcare professionals?

Workshop report

### Introduction

Effective communication between regulators and medicines users (patients and healthcare professionals) is vital if people are to make informed decisions about their treatment and the regulators' ultimate goal of improving public health is to be met. Communicating the risks of medicines in an accurate and understandable way is hard enough, but for informed decision making it is essential that risks be communicated in the context of benefits.

Benefits and risks of a medicine are not fixed formulas, since they are affected by many factors such as the context in which care is given and the values and perceptions of those making the assessment. Communication of those benefits and risks must therefore be equally flexible. It is vital that medicines authorities take account of their ultimate audience, who they are and what their needs, interests and concerns might be, and also what message they are receiving from regulators. The search for improved methodologies and tools for assessing and communicating benefit-risk has therefore never been more relevant for all the parties involved.

The European Medicines Agency continues to work to incorporate the voices of medicines users in the regulatory process. As part of this work, it has been running a series of workshops involving representatives of patients and healthcare professionals together with members of EMA staff and scientific committees and other interested stakeholders. The first of these, held in September 2013, looked at [how to involve patients' voice in the evaluation of benefit-risk throughout the product lifecycle](#). This was followed by a workshop in February 2014 exploring [methodologies and standards for the evaluation of benefit-risk](#).

On 17 September 2014, the EMA convened a third workshop to look at how we communicate benefit-risk to medicines users, attended by representatives of patients, consumers and healthcare professionals, academic researchers, representatives of national regulators from Europe and beyond, members of EMA scientific committees including the chairs of the Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC), members of EMA staff and representatives of the Agency's Management Board.



The objectives of the workshop were to review current practice in communicating benefit-risk, to examine recent initiatives into how research can help inform best practice, to discuss the role of communications in risk minimisation and to explore how they can aid patients and healthcare professionals in making decisions throughout the therapeutic journey.

## Helping people make sense of risk

A considerable body of research now exists in psychology and the social sciences examining the way that people perceive and interpret risk and communications about risk, and how the latter can be framed to help people make better decisions. Professor Wolfgang Gaissmaier of the University of Konstanz gave a keynote presentation to the workshop on how this research can inform and improve benefit-risk communications in the field of healthcare.

Clinical evidence often fails to be properly understood. Statistics can be an educational blind spot, even in well educated people (including healthcare professionals). In addition, the way that the evidence is presented can intentionally or unintentionally bias the perception of effectiveness and risk. Finally, there is a lack of an 'evidence culture' in which people understand how to critically appraise and apply evidence.

Yet it is vital that patients are able to understand the evidence, in order to make informed decisions about their treatment. This is not only because some physicians may themselves have trouble interpreting statistics but because we know that patient preferences may differ from those of healthcare professionals. Simple, transparent representations can help patients and healthcare professionals assess the benefits and harms of treatment and make decisions according to preferences and values.

The presentation explored some of the common causes of interpretation bias in risk communication, and discussed those measures that are likely to cause confusion and the alternatives that research has shown are more readily understandable:

- absolute risks are preferable to relative risks
- giving the reference class for probabilities is important (a 30% probability of an adverse event means that 3 patients in 10 may experience it, not that it occurs 30% of the time) is important
- use of natural frequencies (e.g. the number of study patients with and without a symptom, and the number of each group who have a particular disease) is better than conditional probabilities (the percentage of those with the symptom who do or don't have the disease)
- mortality rates are better understood than survival rates (particularly in the context of screening).

The presentation also discussed the format of communications, including the use of facts boxes for an overview of benefits and harms and the value of graphical representation of numbers in reducing the influence of biases and helping people to digest numbers and achieve healthy behaviours.

In a lively debate, the workshop discussed further examples from personal and professional experience, and noted that in practice benefits and risks can be multidimensional and difficult to represent. New technologies such as tablets and smartphones may offer opportunities to develop more sophisticated ways to prioritise those areas which are of most interest to a particular patient. Participants also raised the question of ways to further improve current medicines labelling, which although it now more clearly quantifies risk, offers little quantification of benefits for the patient.

## How the EMA communicates today

Juan Garcia Burgos and Monica Benstetter of the EMA's Communications Department explained the Agency's current communication processes.

### ***Communicating benefit-risk in the EU regulatory network***

The EMA recognises that good communication describing the risks of medicines in the context of their benefits is a key element and major output of the regulatory process, allowing informed decisions on treatment and contributing to its aim of safe and appropriate medicines use.

Good benefit-risk communication can be considered as being material that is:

- of good quality – that is, evidence-based, clear and accurate. The Agency's communications are produced by expert scientific and medical writers, in line with the scientific assessment, and reviewed by the assessors who evaluate the medicine
- unbiased and independent – EMA has rigorous procedures to avoid conflict of interest, recognising this as essential to build trust
- timely and up-to-date – as well as regular and predictable release of information according to the workcycle of its committees, the EMA seeks to communicate promptly when an issue arises, accepting that this may mean addressing uncertainties since the final outcome may not be known, and recognises the need to update existing information as new data becomes available
- adapted to the target audience – the Agency has made progress in adapting its communications to different audiences such as patients and healthcare professionals, although it recognises that more needs to be done. Representatives of these groups contribute by reviewing and user-testing relevant documents. Key information is available in all official EU languages.

In order to ensure that clear consistent messages are given throughout the EU, the EMA co-operates closely with other sources of benefit-risk information in the national regulatory authorities (NCAs) and the European Commission, co-ordinating the publication of safety announcements through its 'Early Notification System'. It was acknowledged that the timelines for such coordination, particularly in the complex language environment of the EU where information often requires translation and localisation, can prove challenging for all parties.

Benefit-risk information on medicines is provided both at the time of authorisation and post-authorisation. The former consists of the *EPAR summary*, which summarises the benefits and risks of the medicine and why it was approved, the *product information* (SmPC aimed at healthcare professionals, package leaflet for patients), *public summaries of the risk management plan* (currently being trialled in a 1-year pilot), and the details of the full scientific evaluation in the form of the *assessment report*. Post-authorisation communication includes updates of these to reflect new indications or contra-indications or other variations to the marketing authorisation, as well as communication on emerging safety issues, e.g. stage-by-stage communication on safety referrals. Importantly, both types of communication involve collaboration with representatives of EU patients, healthcare professionals and consumers, who provide invaluable feedback, and who also play an important role in disseminating the information to their constituencies (although the impact of this on behaviours remains to be measured).

Moving forward, finding the right tools to communicate and evaluate the effectiveness of communications is a key part of the EMA's strategy. The development of a European medicines web

portal is keenly anticipated as offering a single point of access for information on authorised medicines to all EU citizens.

### ***Managing communication in media channels***

The EMA disseminates information via three types of media channel:

- self-owned channels – the EMA website and various newsletters
- traditional media – print, broadcast and online
- social media – particularly Twitter and YouTube

The EMA website is the main source of information about the Agency and its activities. It provides access to over 150,000 documents, with about 650 new documents published each month, and is accessed by around 220,000 unique visitors each month. Its aim is to provide high quality content that is clear, consistent, accurate and useful. However, because of the sheer volume of information it provides, it is essential to make that information findable and usable. The EMA recognises that work needs to be done to improve the ease of navigation and the functionality of searching, and this work is ongoing. Because online search engines are consistently rated as having high levels of trust as sources of information, it is also important that information on the website be indexed and readily accessible online.

In dealing with the traditional media, one of the main difficulties is trying to ensuring that messages are transmitted clearly. Media stories may be shaped by many influences, commercial, editorial, and practical, and this can result in communications that are unhelpful to the public health. Nonetheless the third-party scrutiny they provide is important in holding regulators to account and improving public trust, and their role as wide-reaching disseminators of information and opinion formers in civil society offers an opportunity for much broader public engagement and wider broadcasting of important messages. Over 51,000 media stories featuring the EMA appeared between August 2013 and July 2014. Managing media channels requires the Press Office to provide regular, reliable and clear information (including anticipating information needs), providing supporting material that helps make stories engaging, building relationships so that the Agency is seen as a trusted and helpful point of reference, and monitoring and understanding the media landscape so that likely issues of interest can be anticipated and prepared for.

In contrast to the traditional media, whose strengths and weaknesses are well appreciated, the use of social media to communicate benefit-risk is an evolving field and EMA communication strategies in this area are still developing. However, the Agency makes substantial use of its Twitter feed, with a steady increase in number of followers to nearly 13,000 at present. A policy of only including in tweets material that is available on the website allows access to the necessary detail of communications, and Twitter is used to spread knowledge of topics as diverse as new medicines, news releases, agendas and minutes, guidelines, public consultations and events and employment opportunities. Another medium used selectively but with good effect is YouTube, where the EMA has posted videos on topical areas of pharmacovigilance (new legislation, black triangle, orphan medicines) as well as recordings of workshops, conferences and training.

# What can we learn from medicines users?

## ***The public impact of communication – the example of NSAIDs***

Professor Frederic Boudier of Maastricht University gave the workshop an overview of some of the key findings in decision sciences as they apply to healthcare. Benefit-risk communication in this area operates in a changing environment. A series of high-profile regulatory failures in the 1990s (such as BSE and HIV contamination of blood products) were exacerbated by extensive media dissemination of concerns about the side effects of medicines such as the COX-2 class of anti-inflammatory medicines (NSAIDs) and the diabetes medicine Avandia, some of which led to restrictions and withdrawals of medications from the market

As a result, the communications context has come to emphasise greater stakeholder participation with more consideration of environmental and social values, and to some extent a de-emphasis of the value of science, with scientists seen as just another group of stakeholders. This has been accompanied with more emphasis on transparency and accountability in the regulatory process, with an increased role for the media as 'guardians' of the public interest and a move towards a more precautionary mindset in regulation.

Evidence suggests that the general public is not convinced that regulators or governments are effective in communicating information about medicines – the most trusted health communicators remain general practitioners and pharmacists. The science also shows that drivers of risk perception include various dichotomies including concepts of the natural versus the technological, personal control or autonomy versus lack of these, familiarity versus unfamiliarity and the contrast between high frequency but low consequence risk and low frequency but high consequence risk. Patients often have established views about the risk of various types of medicine which must be taken into account, and the media may act as amplifiers or attenuators of the perception of risk. However, the key variable in how information about benefit-risk is likely to impact is the degree of trust in the source.

Many of these points can be seen in the concerns that arose in the middle of the last decade about the nonsteroidal anti-inflammatory medicines known as COX-2 inhibitors. Originally seen as reducing a serious risk (ulceration and bleeding in the gut), there were a number of high-profile withdrawals and restrictions of these medicines following the emergence of data suggesting an increased risk of effects on the heart and circulation. Intense media coverage led to public scrutiny by politicians and a serious impact on trust in both the pharmaceutical industry and the regulators. Factors that exacerbated the problems in this case included the perception that the manufacturer of the medicine had presented biased evidence and aggressively targeted consumers; whistleblowers suggesting that the regulators should have taken earlier action; and the ambiguity of some communications from the regulator on the size of the risk, which appeared to conflict with the breadth of the action that was actually taken.

The lessons learned should include the need for communications to be based unequivocally on the evidence, and that regulators should be clear about not only benefit and risk, but the balance between conflicting risks. Messages need to be proactive and well articulated, and the level of public trust should be assessed and where necessary important points conveyed in association with more trusted actors.

## ***What can we learn from medicines users? The example of diclofenac***

The practical application of many of the points raised were reviewed in an exercise led by Jane Ahlqvist Rastad of the Swedish Medicines Agency, which examined previous EMA communication about diclofenac.

This NSAID was the subject of a referral in 2013 which looked at its cardiovascular safety, and made recommendations for amending its product information. The workshop participants examined the EMA public health communication and the Dear Healthcare Professional Communication (DHPC) which were subsequently issued, and considered both the content and presentation of the information, and the way in which in practice this information had been disseminated.

In general the *EMA communication* (which addresses the media, patients and healthcare professionals in a single document) was felt to be rather long and participants suggested that key messages needed to be presented at the start, with less emphasis on the regulatory details. In addition, although the referral specifically considered cardiovascular risks, participants wanted the regulator to provide more contextualised information which gave a picture of the size of the risk relative to the other risks of the medicine and to its benefits, and how these compared with other treatments. This would help to manage risk perception. Despite concerns about length it was also suggested that additional information on benefit and risk for particular subgroups such as pregnant women and the elderly should be included.

The *DHPC* was criticised for an excessive focus on risk, and a lack of a clear explanation of potential mechanisms. The workshop also discussed the need for localisation of the information to take account of differences in the healthcare systems of different member states, although it was acknowledged that this was the role of national competent authorities as part of the translation process.

It was recognised that wider *dissemination of communications* was a joint effort between the EMA and its partner organisations. Not all participants recalled the original communication on diclofenac, and it was stressed that sending information to the right contacts within partner organisations (particularly in smaller patient organisations) was vital to ensure prompt distribution. It was also important that key messages be identified as such, for resource prioritisation. Participants felt that using Eudralink (the EU network's secure email connection) would help ensure that emails were not missed, and it was suggested that other channels for communication, such as Facebook, should be explored. Communications should ideally be in a form that was easy for partner organisations to upload and re-use.

## **Applying research in the field of risk communication**

### ***Research to inform risk communication: drivers of vaccine acceptance or refusal***

In another key presentation, Dr Heidi Larson of the London School of Hygiene and Tropical Medicine, a former chair of the Advocacy Task Force for the Global Alliance for Vaccines and Immunization (GAVI), and now one of the driving forces behind the Vaccine Confidence Project, discussed examples of her research and extensive experience of drivers of vaccine confidence (or vaccine hesitancy) and drew some conclusions of wider relevance for risk communication about other medicines or public health issues.

Recent years seem to have produced an exponential increase in public concerns about the safety of medicines, not least vaccines. Interestingly, however, the reasons for lack of uptake of vaccination today are not substantially different from those reported 100 years ago: a lack of understanding of the principles, a perception that vaccination is unnecessary, concerns about vaccine safety, religious and philosophical objections, or an objection to the compulsory nature of some government-mandated vaccination.

To respond to these concerns it is important that scientists and regulators are honest about what they do and do not know, and do not ignore the dimensions of risk beyond a simple probability of an

adverse effect or the factors that may increase it. Although the scientific focus may well be on the logical, quantifiable aspects of risk, in the social sphere the emotional and perceptual aspects, not to mention the political dimension, may be at least as important, and may conflict with the science.

Even where safety issues are not causally related to a medicine, ignoring negative sentiment that leads to a perception of risk can cause major public health problems. The severe fall in uptake of MMR vaccine following now discredited claims of an association with autism, the problems in Japan with HPV vaccination, and the issues in the Philippines following claims that tetanus vaccines could cause sterility are all real-world examples of this. The problem is particularly acute in today's hyperconnected world in which traditional and social media can act as amplifiers of concerns, creating a 'digital wildfire' that may have consequences not only in widely separated geographical areas but also (since little is lost on the Internet) at widely different times.

Monitoring of public perceptions of vaccine-related risk is therefore very important. This has confirmed that drivers of concern may vary widely between cultures and between individuals, and will change depending on the vaccine and over time. It is important to note that stated reasons for objections may mask other, hidden concerns that can only be teased out by engagement with the communities concerned.

Where a concern exists, it may be impossible or even counterproductive to attempt to change the opinions of those with strong views, but this does not necessarily mean that scientists and regulators should not engage with those views, since it remains eminently possible to persuade undecided individuals. It should be borne in mind that safety is only one of many issues related to medicines use, and that risk communication is only part of the ongoing process of engagement. However, if risk communication is to be effective, the principles cited in the WHO's 2002 World Health Report should be borne in mind, and in particular:

- to establish credibility, it is important to establish trust
- trust can only be generated by openness
- openness requires recognition of uncertainty, where it exists.

Participants went on to discuss ways to manage controversial issues related to medicines safety. It was suggested that healthcare professionals need better training in coping with challenging conversations: it is important that patients feel their concerns have been listened to and not dismissed. There may exist a role in healthcare for specialist communicators, whose job is to listen and explain, thus relieving the burden on other healthcare workers. It was also noted that uncertainties may be hard to explain, since patients often want evidence that there isn't a problem, rather than no evidence that there is one. The role of public hearings in controversial regulatory issues was also discussed, and it was noted that where these are held it is vital that there is clarity of purpose about what they are intended to achieve – they are not always the right tool to generate usable outcomes that can contribute to the regulatory process.

Empathy, respect and understanding remain the key to managing communications about areas of public concern.

### ***Research to inform risk communication: evidence-based guidance for risk communication planning***

Priya Bahri, of the EMA's Best Evidence Development department, expanded on some of the ways that the Agency is currently incorporating evidence on communication of risk into its guidelines. Using the example of the H1N1 influenza pandemic in 2009-10, the Agency had looked at the lessons learned

from responses to its communications and crisis management plan, and had compared these with the critical issues that could be identified from the evidence base in published literature at the time. This exercise had found that the issues identified were similar, suggesting that applying current research findings can usefully support planning of communications interventions.

The EU good pharmacovigilance practice (GVP) guideline on vaccines takes account of this, and includes guidance on communication. Notably, it recommends that planning for communication should be an integral part of the process of risk assessment and management, and thus incorporated from the very beginning. The guideline also recommends:

- public accountability, addressing concerns raised by the public by communicating proactively
- careful explanation, in public-friendly language, of technical concepts
- appropriate advice to healthcare professionals, supporting their management of specific concerns in vulnerable subgroups
- planning for communication needs related to topics such as excipients, residues, and individuals with specific conditions
- monitoring the media and the effect of communication, and tailoring responses accordingly.

Similar guidance is being included in the updated guideline on pharmacovigilance for medicines used in paediatrics, which will consider the special communication needs and concerns of children and adolescents, and the possibility that different communication channels may be needed to address their preferences.

The Agency is committed to a learning cycle of improvement and continued evidence development. Communication guidance is increasingly being built in to future guidelines and GVP updates and such practical guidance needs to be informed by research, from the social and communications sciences as well as from pharmacoepidemiology. Applying guidance and then evaluating the resultant effectiveness of communications will allow opportunities to learn and develop evidence for the best communications options in the future. In this context, advocacy for research and stakeholder collaboration is vital.

## **How do regulators respond to the challenges?**

Participants in the workshop included members of the EMA's two main scientific committees, the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), including the Chairs of both committees, who were able to give their perspective on the challenges.

### ***Safety communications from PRAC: current approaches, future challenges***

The mandate of PRAC is to deal with issues of the safety of medicines, and this naturally includes benefit-risk communication.

Dr June Raine, Chair of the PRAC, explained that the committee is acutely conscious of the value and potential impact of communication as one of its tools for risk minimisation. The PRAC includes members with expertise in communication, and collaborates closely with EMA communications experts responsible for drafting these documents in order to achieve the best possible outcomes. One difficulty is that because PRAC recommendations are part of an ongoing European regulatory process, communication must be designed to evolve as further steps take place. PRAC also advises on communication at a national level and often works closely with the clinicians and experts who are responsible for identifying and triggering safety concerns.



The general principles that PRAC tries to incorporate in safety communication, very much in-line with key points made throughout the workshop, are:

- clarity about the evidence
- clarity about the uncertainties, and how they are being addressed
- explanation of the therapeutic context
- understanding of the views of medicines users (PRAC includes in its membership representatives of both patients and healthcare professionals, whose input is important in this regard).

As the committee has gained experience, it has also looked at ways of strengthening and improving its communications. This has involved learning from experience, and feeding back the lessons learned into practice; participating in research and fostering links with research communities, in order to ensure that it takes best account of the scientific evidence; fostering public understanding of decision making, for example in the work to encourage side-effect reporting; and monitoring the effects of communications as an integral part of the package of risk minimisation measures.

Challenges for the future will be to maintain the process of continuous learning and improvement, and to try to achieve the right balance between information about the risks (which is naturally the PRAC's focus) and information about the benefits of a medicine. This is made more difficult for regulators by concerns that they should not be seen to promote one medicine over another, but there is a clear appetite from medicines users for such contextualisation of safety information, to which we must respond. Another challenge is trying to reach the right audience for safety information, or at least understanding the extent to which that is possible. Finally, research is needed to evaluate the impact of the PRAC's communications.

The output of the workshop will have the potential for significant leadership and influence over future progress in improving benefit risk communication.

### ***Strengthening national collaboration in risk communication- the SCOPE project***

The SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe) Joint Action is a project jointly funded by the EU and Member States which aims to gather information and expertise on how regulators in member states run their national pharmacovigilance (medicines safety) systems. Using this information, SCOPE will develop and deliver guidance, training in key aspects of pharmacovigilance, and tools and templates to support best practice. SCOPE comprises several work packages, of which one, WP6, focuses on risk communication.

Dr Dolores Montero, a member of the PRAC and the head of the Pharmacovigilance and Pharmacoepidemiology Division of the Spanish Agency on Medicines and Medical Devices (AEMPS) discussed the aims, progress and expected outputs of this work package.

The main aims are to audit the way that national medicines regulators are currently communicating, and to carry out research to assess the impact of their risk communications and the effectiveness of different methods. Analysis of the results of these two topics will allow conclusions to be drawn about what worked best in particular circumstances, and the creation of a toolkit of communication options that can be employed by regulators. It will also provide the basis of a forum for improving ongoing collaboration between regulators in Europe.

Once a toolkit has been developed it is envisaged that appropriately tailored training workshops will take place to help communicate the options available and share examples of best practice, followed by

a workshop to involve interested parties including not only communications staff from the national agencies but also representatives of healthcare professionals, patients, consumers and the media and wider civil society.

The work package will also contribute towards ongoing work on the development of medicines web portals. These are increasingly important as a means of providing and disseminating reliable, evaluated information on medicines to healthcare professionals and the general public. The intention is to scope the design requirements and needs that such a portal needs to fulfil, and develop guidance for the internal preparation of safety information for publication on a web portal, and for co-ordination of the way information is presented on such portals throughout the EU network, to ensure a consistent experience for users.

### ***Looking forward: better communications for better healthcare decisions***

The final presentation of the workshop, by Monika Benstetter and Juan Garcia Burgos of the EMA, outlined the Agency's current thinking on the ways in which it hopes to develop its communications going forward.

The environment in which such communications take place is a challenging one, in which public institutions are held up to ever closer scrutiny, reflecting the erosion of public trust, the drive for transparency, and sometimes unrealistic expectations driven by a lack of engagement and a relatively low level of scientific literacy. In addition, they must compete for attention with a flood of information (of varying degrees of reliability) transmitted via a plethora of channels

The ultimate aim of the EMA's benefit-risk communication is to support patients and healthcare professionals in coming to informed decisions together about patient treatment. To help achieve this, the Agency seeks to:

- improve the tailoring of communications on benefit-risk to patients and healthcare professionals
- look for new communication opportunities in a fast-changing environment
- ensure that messages are used and contribute to improved healthcare

In order to do this, the EMA is actively seeking ways to measure the effectiveness of its benefit risk communication. This is a challenging area: some research is available in relation to DHPCs, and the results of the research from the SCOPE WP6 are eagerly awaited, but much more is needed. To this end, the Agency proposes to identify a list of indicators for impact of public health communications, including how well messages are understood and reflected in media coverage, systematic measurement of their dissemination by concerned organisations, the degree to which they are incorporated in subsequent communications by national regulators, and the amount of social media activity they generate. By collecting and reporting on these indicators in a structured way it is hoped to complement research using other tools such as questionnaires to users, allowing proper analysis of impact and subsequent adaptation of communication practices and tools.

The Agency also recognises the importance of better understanding its audiences, and the potential difference between those it wishes to reach, and those people it is actually able to reach. In order to improve dissemination of communications the Agency relies on the same collaborative approach which informs its other activities, working closely with the EU regulatory network, patients' and healthcare professionals' organisations, and the media so they can not only act as amplifiers of relevant healthcare messages, but also contribute to making them more relevant to their audience.

One aspect that limits the reach of the EMA's communications is the EU's complex language environment. This is one area in which collaboration with the national regulatory agencies is vital, since

they are best placed to ensure localisation of key messages and help them penetrate beyond the immediate range of the EMA's core stakeholder groups.

It is also acknowledged that messages must be tailored to particular audiences, allowing people to access different levels of information depending on their backgrounds and degree of engagement. Using appropriate channels and tools for dissemination of the information is vital in this regard, and the Agency is committed to continuing to explore new technologies and modes such as smartphone apps and a greater engagement with social media. Furthermore, the ongoing work to develop a European medicines portal opens the vista of a 'one-stop shop' for medicines information.

Beyond their immediate message, the EMA's communications and its close collaboration with partner organisations also serve an educational function in building public knowledge of medicines development and regulation. This includes being prepared to communicate about uncertainty. The Agency is moving towards earlier communication when safety issues arise (for example, at the start of a referral), but it is recognised that this means being prepared to communicate in situations where there is uncertainty about the outcomes, and where conclusions and available evidence may change. Explaining this, and being prepared to allow the public to see the limitations of regulation, is, as recognised by other participants in the workshop, an important step in building trust.

## Conclusions

Dr Tomas Salmonson, Chair of the CHMP, summed up his own responses to the topics covered in the workshop, which had been an illustration of the depth of expertise available, both within the EMA and the organisations with which it works, and in academia and the wider world on whose knowledge the scientific committees so often call. Amongst the points to which he drew attention were:

- the clear differences between communication needs at the time of approval of a new medicine, and those post-approval, through the later stages of the medicine's lifecycle. Giving a balanced, in-depth assessment of benefit and risk would always be easier at approval, precisely because the process involved a detailed and structured assessment of both;
- transparency and communication were not the same thing, although they go hand in hand;
- information on the benefits of medicines may not be as well or as often revised as that relating to risks. There was a clear desire for better communication on benefits, an area which regulators had tended to handle poorly and where there was a need for improvement. However, it was legitimate to ask if perspectives on benefit varied between groups and individuals, as had been shown with perspectives about risk. Overestimating benefits could lead to the acceptance of unreasonable levels of risk;
- work being carried out by the CHMP to represent benefit-risk information as effects tables in their assessments offered a possible way forward. It might be possible to develop and individualise these so that the benefits and risks of particular importance to the patient could be represented;
- the issues which needed to be communicated in real-life situations were often complex and multifactorial, and in the case of safety communications might be driven by a need to communicate within a short time-frame and against the viral spread of competing messages (memorably described by Dr Larson as 'digital wildfires'). This made communication difficult, especially when there were uncertainties that had to be conveyed;

- trust was therefore paramount – regulators had to strive to build it, by communicating accurately and transparently, and by working with others in whom patients and the wider public placed greater trust;
- a networked approach, pooling the strengths and knowledge of European and national regulators, patient representatives, and public health workers of all kinds was essential if key messages were to reach their targets.

## **Next steps**

Isabelle Moulon of the EMA's Patients and Healthcare Professionals Department concluded on the next steps.

- Regulators had heard, loudly and clearly, the need to incorporate the views of those most affected when assessing and communicating the benefits and risks of medicines.
- The next challenge was to understand how best to incorporate research outcomes into those communications, as part of a process of continuous improvement.
- There was much work to do in understanding how to carry this out, and the best formats remained to be established, but the EMA would continue to work closely with the Healthcare Professionals Working Party (HCPWP) and the Patient and Consumer Organisations Working Party (PCWP) in future development, as well as inviting the national medicines regulators to participate via the EU regulatory network.
- A report detailing the topics and outcomes of the workshop would be published by the EMA, along with the presentations seen by the participants. In addition, an audiovisual recording of the workshop would be made available.
- Thanks were due to the participants and to the day's outstanding speakers for contributing to the ongoing work of better communication about the benefits and risks of medicines, so that medicines users could make the best choices about their treatment

The participants also expressed their view that the workshop had been extremely valuable. Dr Almath Spooner of the Irish Health Products Regulatory Authority, vice-chair of the PRAC, expressed a widely shared view that the output of the workshop and the established partnership approach will be important enablers for the EMA (and its Committees) in their vision of becoming a trusted and relevant source of authoritative information on the benefit and risks of medicines.

## **Further information**

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