EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 May 2017
EMA/225307/2017
Stakeholders and Communication Division

Patients' and Consumers' Working Party (PCWP) / Healthcare Professionals' Working Party (HCPWP) topic groups

Consolidated report on the activities of topic groups established in 2015

1. Introduction

In March 2015, both PCWP and HCPWP agreed to set up a number of *ad hoc* working groups to brainstorm on specific topics of mutual interest to the European Medicines Agency (EMA) and the working parties (referred to as 'topic groups' hereafter). The aims were to provide more time for ideas to be brainstormed in smaller groups between the plenary meetings of the working parties, promote further discussion of specific topics as well as to enable better utilisation of time during the face-to-face meetings, with the ultimate goal of further stimulate participation and engagement.

The initial topics selected are listed below along with the specific working party they were assigned to:

- Measure the impact/value of patient involvement in EMA activities (PCWP)
- Acknowledge and promote visibility of patient input into the Agency's activities (PCWP)
- Training for patients involved in EMA activities (PCWP)
- Involvement of young people in EMA activities (PCWP)
- Social media (PCWP and HCPWP)
- Risk minimisation measures and assessment of their effectiveness (HCPWP)
- EMA/CHMP/PRAC projects on information on medicines (HCPWP)
- Academia, learned societies and healthcare professional organisations (HCPWP)

The topic groups started their activity between June and October 2015, with different levels of progress made according to the pre-agreed set of objectives, as outlined in the background section of this report.

The current report provides an overview of the key milestones/activities and outcomes covering the period June 2015 to May 2017 and incudes as annexes all the recommendations adopted by PCWP and HCPWP during that period.

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2. Background for each topic group

The topic groups' intention was to present concrete recommendations to the working parties based on their objectives. The key objectives of each topic group are listed below.

In order to facilitate the work of each group, a topic leader was nominated amongst members of the group supported by a co-leader nominated by EMA. Work was mainly carried out via email and conference calls with periodic updates provided at PCWP/ HCPWP meetings.

2.1. Measure the impact of patient involvement in EMA activities

The Agency has developed a robust system for involving patients, consumers and their representative organisations in its activities including the development of policies, regulatory guidance, and product related evaluation.

This annual report on interactions is presented to the EMA Management Board, to the EMA committees, and subsequently published. The Agency does provide some quantitative and qualitative feedback on the impact of patient input on particular activities and also includes an analysis of feedback from patients (survey) on their satisfaction as seen within this annual report.

The Agency is frequently asked to further quantify the impact of patient involvement in its activities. There is a need to review the adequacy of the current methodology and determine whether and how it could be improved and/or expanded.

The key objectives include:

- Explore how to measure the benefit/value of patient input on regulatory outcomes;
- Explore the impact that involvement in EMA activities has on empowerment of PCOs;
- Establish a system for regular cross-Agency collection of quantitative and qualitative data for monitoring and reporting purposes.

2.2. Acknowledge and promote visibility of patient input into the Agency's activities

There is a need to raise awareness of the involvement of patients, consumers and their organisations in the work of the EMA and also to further acknowledge the value of their input.

The key objectives include:

- Explore how to raise awareness and visibility of patients/consumers work at the EMA;
- Explore how to best acknowledge patient/consumer input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups.

2.3. Training

To maximise the contribution and experience of patients participating in EMA activities, patients must have an understanding of both the Agency's mandate as well as the expectations of the role they play in the evaluation process.

An EMA training programme, based on an adapted approach depending on the type of participation of the individuals, is available. It is complemented by personalised and one-to-one support to patients involved in specific activities.

Some organisations and collaborative projects have also developed trainings in order to empower patients to play a recognised advocacy role at European level.

A reflection involving the different actors including the EU network Training Centre could further define a core curriculum and look for synergies of action in order to use training resources (both human and financial) in a more efficient way.

The key objectives include:

- Explore synergies with existing training initiatives;
- Discuss and explore further training methods and tools for patients involved in EMA activities.

2.4. Involvement of young people/children in EMA activities

The EMA has a long history of involving adult patients in its work and has systems in place for their participation across many activities; however this has not as yet included the involvement of young people.

There are ongoing discussions within the PDCO on the value and feasibility of involving these stakeholders and it has been proposed to establish a young person's network with the PCWP.

The key objectives include:

- Identify existing youth groups within eligible organisations; look to create, within the umbrella of the PCWP, a "young person's advisory network" with young participants;
- Identify areas and methodologies for the involvement of young people in EMA/ PDCO activities;
- Explore how to raise awareness on the need for more participation in paediatric clinical trials;
- Plan 20th anniversary activity at the EMA with young people on 07 October 2015.

2.5. Social media

The growing trend for patients and healthcare professionals to use social media when searching for and communicating on health-related information raises the importance of the Agency engaging more with these communication channels to ensure easy, consistent and timely access to reliable and understandable information on medicines. The ever-increasing role of information technology in health-related matters, including use of e-health records and databases, and social media by consumers and healthcare professionals, also demands that surveillance methods evolve to consider these developments. In addition, the use of social media by patients to connect and exchange information about their condition, treatment and symptoms represents a wealth of information that needs to be both protected and utilised to serve the community.

As social media is changing the nature and speed of healthcare interaction we would like to stimulate discussion around what are the opportunities and the challenges for medicines development, evaluation, surveillance and information.

The key objectives include:

- Map current practices in the digital world that are shaping clinical research and clinical care
- Prepare recommendations to EMA and to patients', consumers' and healthcare professional organisations intended to raise awareness of how data and information related with real use of medicines is being collected and used for research and/or other purposes and call for actions as appropriate
- Prepare recommendations to EMA and to patients', consumers' and healthcare professional organisations on how to use their communication channels (internet and social media) more widely, to ensure easy, consistent and timely access to authoritative, reliable and understandable information on medicines
- Identify topics and speakers for a PCWP/HCPWP workshop on social media to be organised in 2016

2.6. Risk minimisation measures and assessment of their effectiveness

Planning and implementing risk minimisation measures and assessing their effectiveness are key elements of risk management. A variety of tools are currently available for additional risk minimisation and this field is continuously developing, with new tools likely to be developed in the future building upon advances in technology. In addition, the evaluation of effectiveness of risk minimisation measures is an evolving area of medical sciences with a need for universally agreed standards and approaches.

Whilst taking advantage of relevant elements of methodology from pharmacoepidemiology and other disciplines such as social/behavioural sciences and qualitative research methods, it is important to bring on board healthcare professionals (HCPs) and patients in the shaping of adequate and proportional risk minimisation measures, which are balanced with the benefit for patients and produce the desired public health outcome in the context of the healthcare delivery system. The group focusing on this topic is composed by HCPWP members and relevant EMA staff. The group aims to also have members from PRAC to support linkage to this committee. The key objectives include:

- Discuss current practices/experience (regulator and HCP perspectives) in the development and implementation of additional risk minimisation measures, using concrete examples of risk minimisation tools;
- In the context of the PRAC activities, brainstorm on how to facilitate input from HCPs into the feasibility, information and evaluation of risk minimisation measures; explore aspects around product-specific issues, therapeutic class and overall therapeutic environment and prepare recommendations as appropriate;
- Discuss how to better inform HCPs about ongoing activities and initiatives within the EU regulatory network related with post-authorisations Efficacy and Safety studies, registries, medication errors, RMP summaries and safety communications and prepare recommendations as appropriate.

2.7. EMA / CHMP / PRAC projects on information on medicines

Challenges posed by increasing data and scientific knowledge, unavoidable uncertainties, demand for more information including for individualised therapy, request for easily accessible information, and

different needs and practices raise the importance of maintaining high quality information throughout the lifecycle of the medicine, ensuring it is consistently up-to-date and meets the needs of the users.

They also raise the need to ensure that product information (Summary of Product Characteristics (SmPC), package leaflet and labelling) is integrated with other information on medicines produced by regulatory bodies and is considered in the wider context of information sources, information targets and information seekers. For example, some of the areas that would benefit from additional discussion include: a) how benefit-risk information in assessment reports and quality assurance of SmPCs could best respond to healthcare professionals' information needs; b) how to promote consistency between SmPC and therapeutic guidelines/ prescribing recommendations; c) interaction with drug bulletins.

The topic group on information on medicines is a joint initiative between the HCPWP, EMA, CHMP and PRAC. The key objectives include:

- Setting the scene and summarising identified challenges;
- Discuss the target audience(s) of the different information on medicines produced by EMA (e.g. healthcare professionals, those treating patients, bodies preparing therapeutic guidelines, or, journals/drug bulletins/other information providers);
- Discuss healthcare professional organisations' role in the information chain, e.g. for communicating regulatory information or therapeutic guidelines/prescribing recommendations;
- Identify ways to facilitate input from healthcare professionals into the preparation and update of regulatory information;
- Prepare recommendations to EMA and to healthcare professional organisations on:
  - how to use available resources to maintain high quality of product information throughout the lifecycle of the medicine whilst ensuring it reflects as much as possible clinical practice reality (with proposals for concrete pilots);
  - how to use or improve current EMA information outputs to support clinical practice;
  - how to bridge regulatory outputs with therapeutic guidelines/prescribing recommendations.

2.8. Academia, learned societies and healthcare professionals' organisations

EMA interactions involving healthcare professionals range from information and consultation to participation in the scientific activities of the Agency and its committees, and review of information intended for the public. In December 2011, the Agency's Management Board endorsed a framework of interaction between the Agency and healthcare professionals that particularly focused on the interaction with their professional organisations.

The Agency is also developing collaboration with academia with a framework expected to be endorsed by end of 2016. The topic group on academia, learned societies and healthcare professionals' organisations consists of HCPWP members and relevant EMA staff.

The key objectives include:

- Map organisations' current practices/ initiatives intended to promote involvement in regulatory activities and raise awareness of that involvement amongst their members

- Brainstorm around group Vs individual approaches in relation to interaction with EMA
- Support development of the EMA framework of collaboration with academia
- Reflect on the need to review the EMA framework of interaction with healthcare professionals
- Prepare recommendations to EMA and to healthcare professional organisations intended to raise awareness of how the EU Medicines Regulatory Network functions (by Q4/2016)

3. Key milestones/activities and outcomes

A number of concrete steps were achieved with the contribution of the topic groups. Some have already had a direct impact in EMA activities carried out in the reporting period. Others have paved the way for further implementation and reflection in the years ahead. Figures 1-8 provide a timeline highlighting key milestones and outcomes for each topic group.

Figure 1. Key activities of the PCWP topic group on training and related outcomes

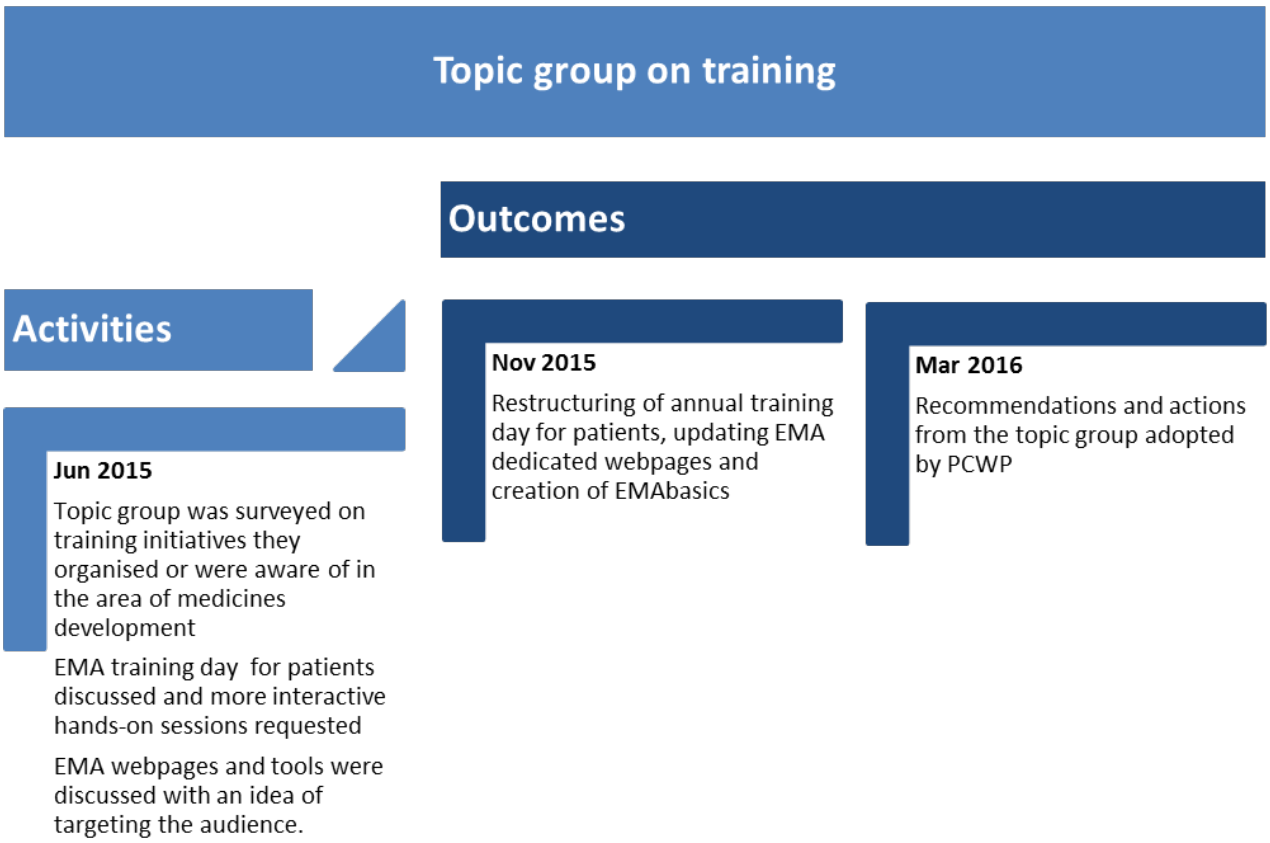


Figure 2. Key activities of the HCWP topic group on academia, learned societies and HCPs' organisations and related outcomes

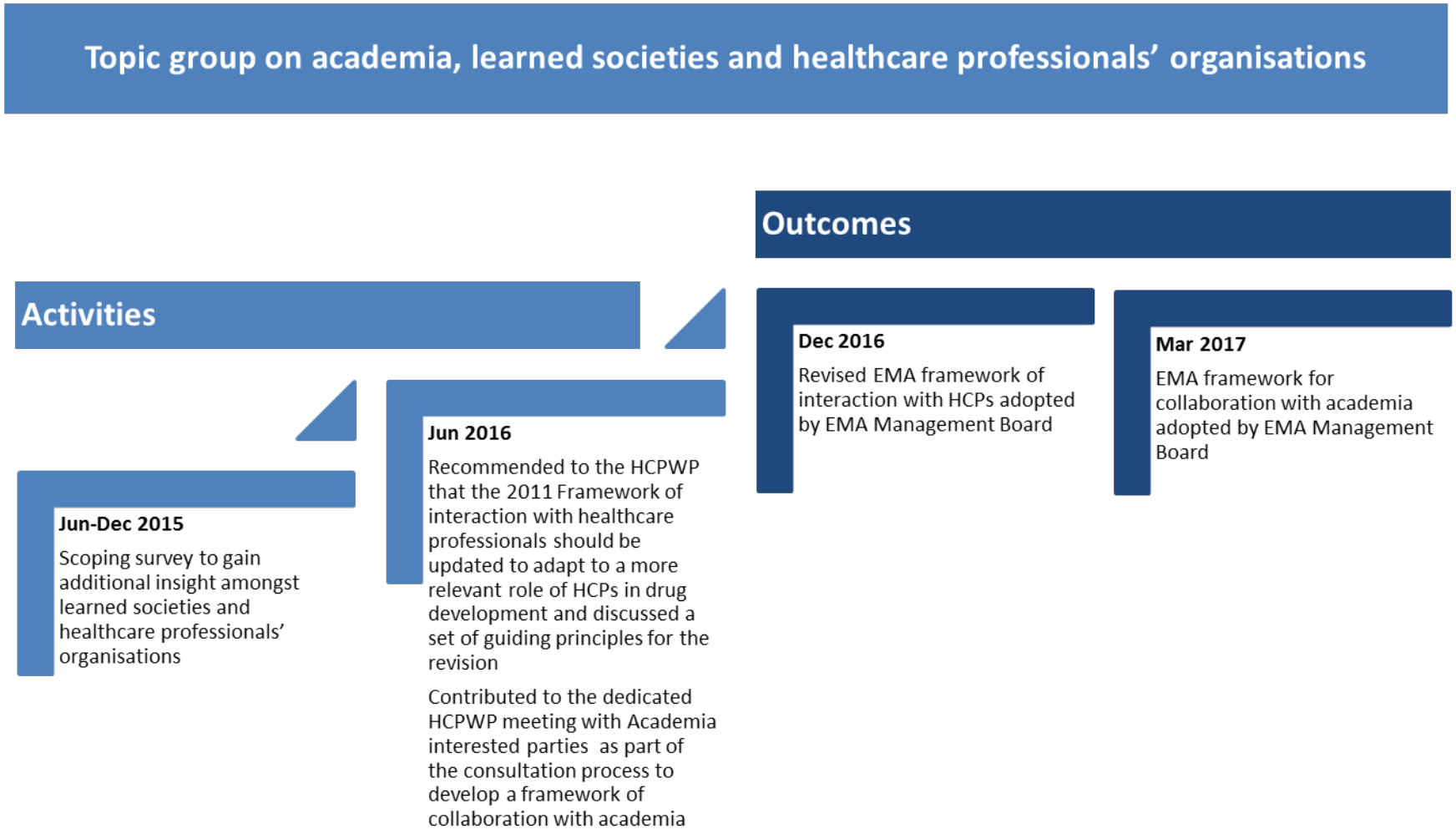


Figure 3. Key activities of the PCWP topic group on acknowledgment/promotion of visibility of patient input in EMA activities and related outcomes

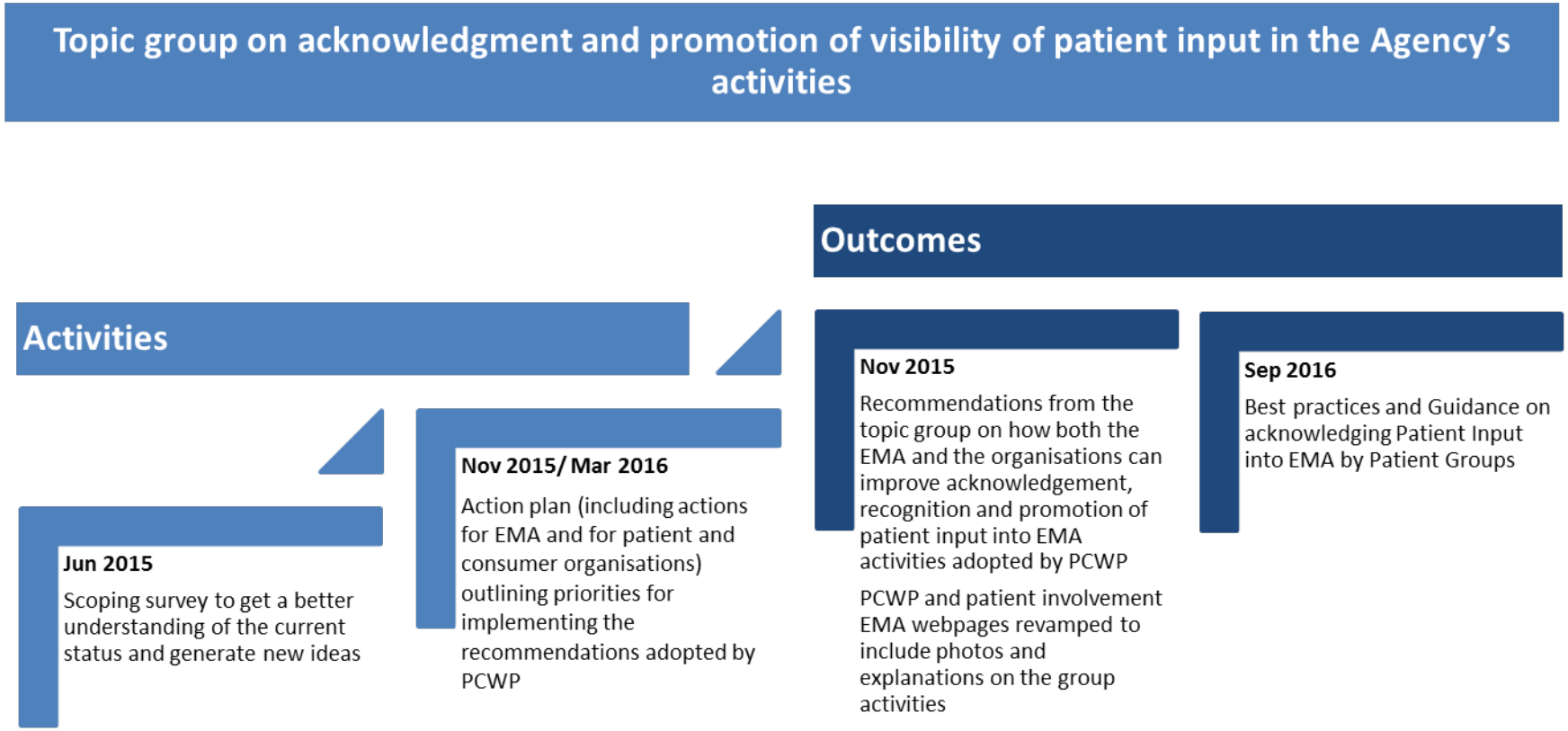


Figure 4. Key activities of the HCPWP topic group on EMA/CHMP/PRAC projects on information on medicines and related outcomes

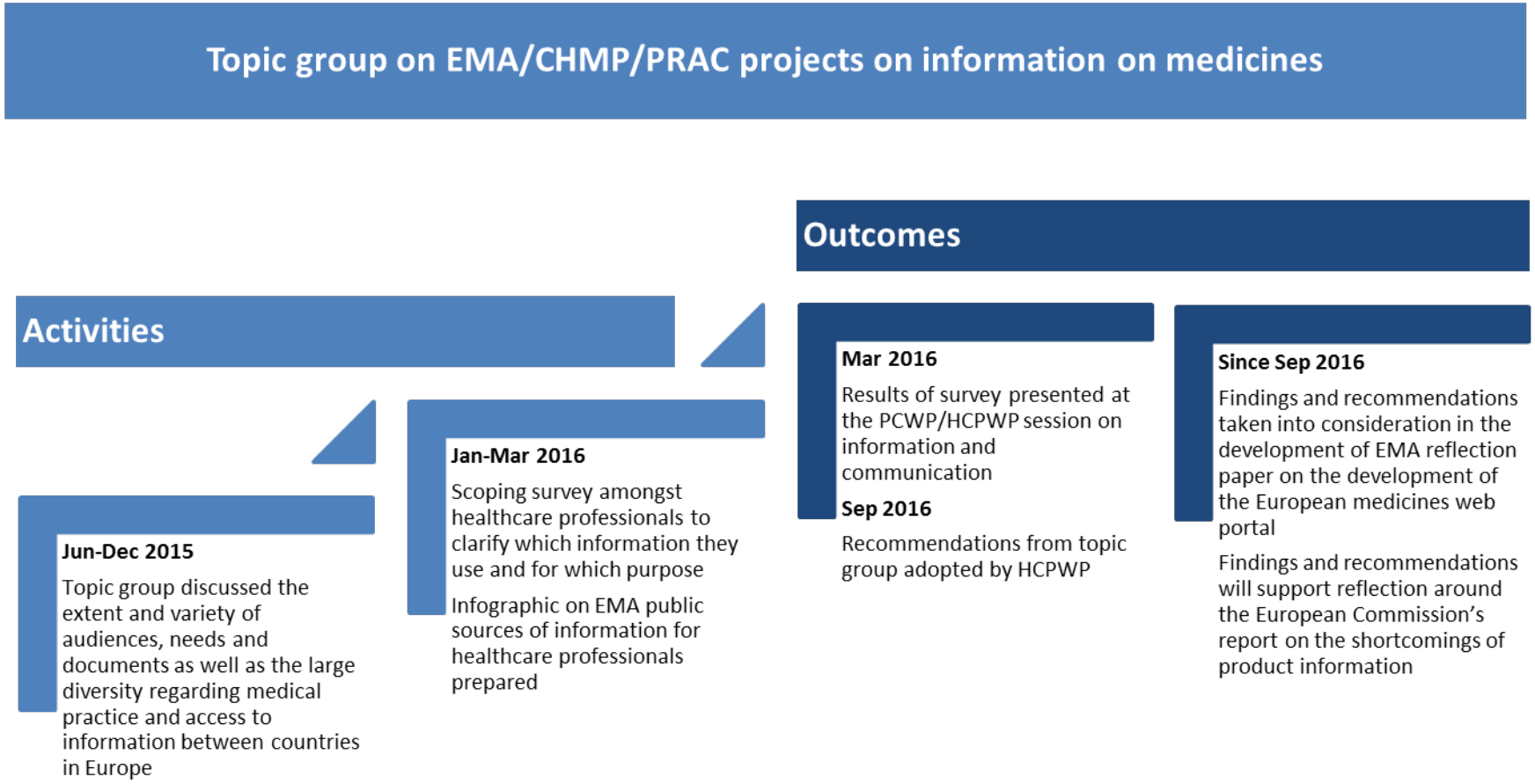


Figure 5. Key activities of the PCWP topic group on measuring impact of patient involvement in EMA activities

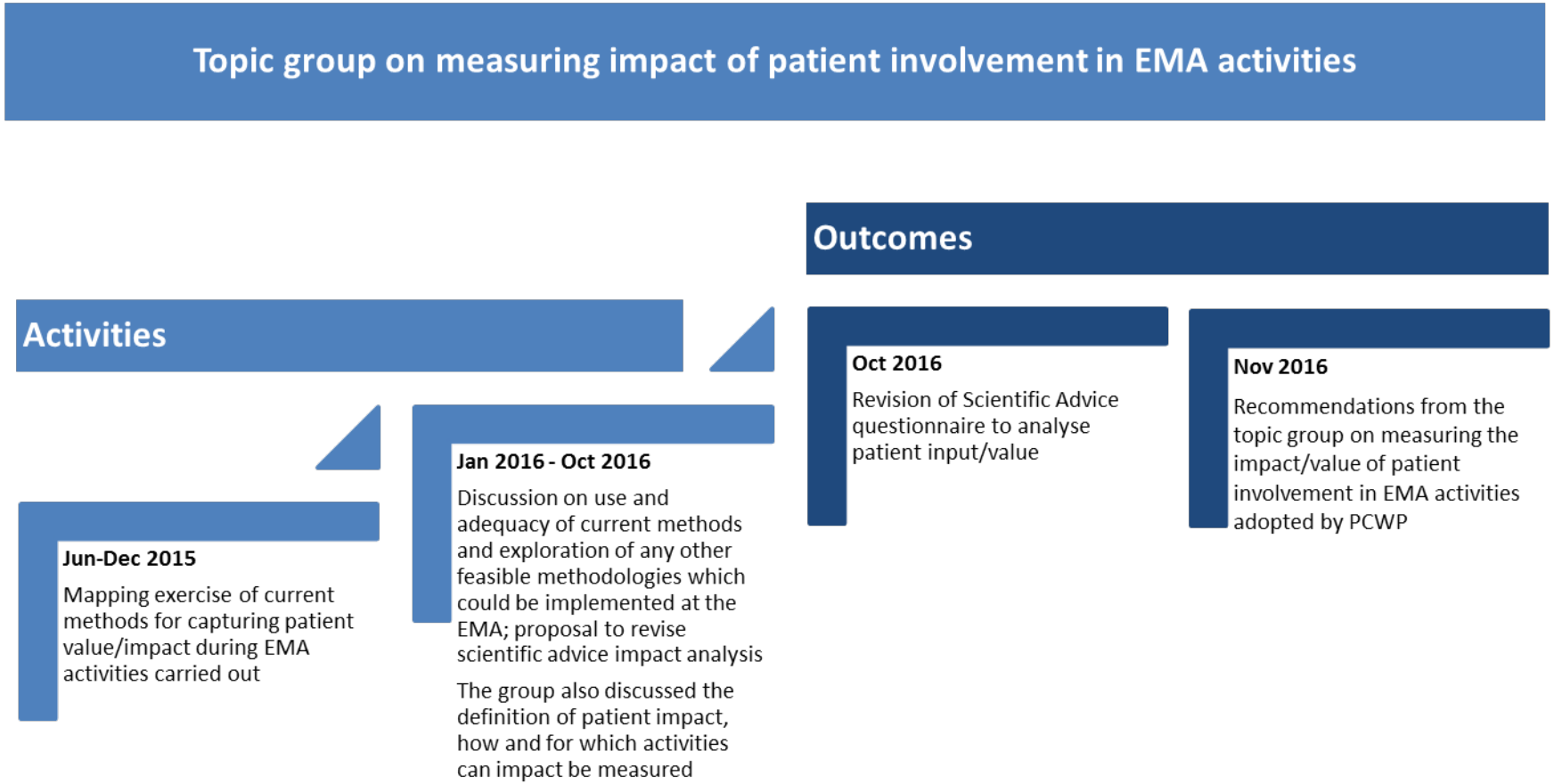


Figure 6. Key activities of the HCPWP topic group on risk minimisation measures and assessment of their effectiveness and related outcomes

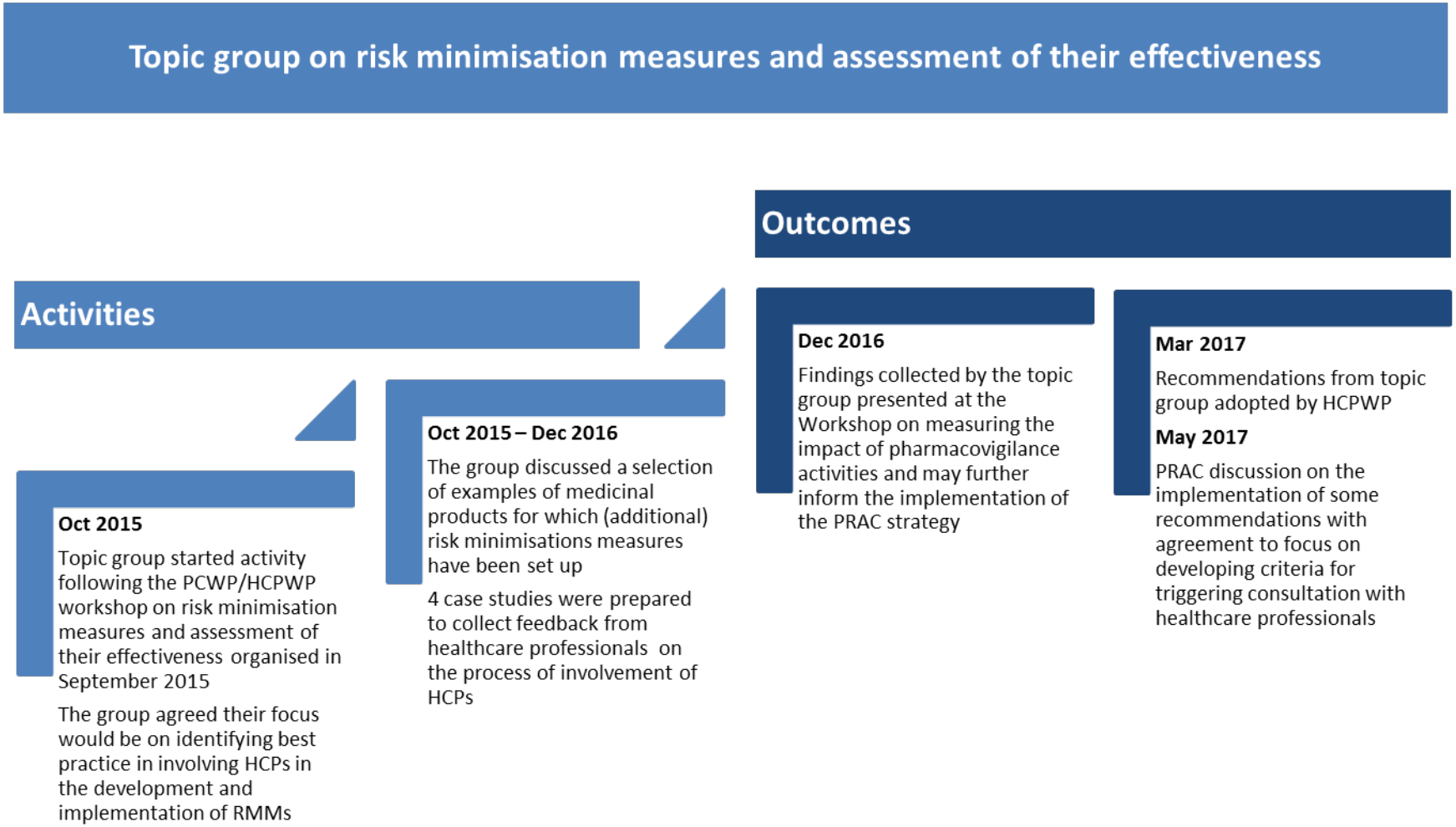


Figure 7. Key activities of the PCWP/HCPWP topic group on social media and related outcomes

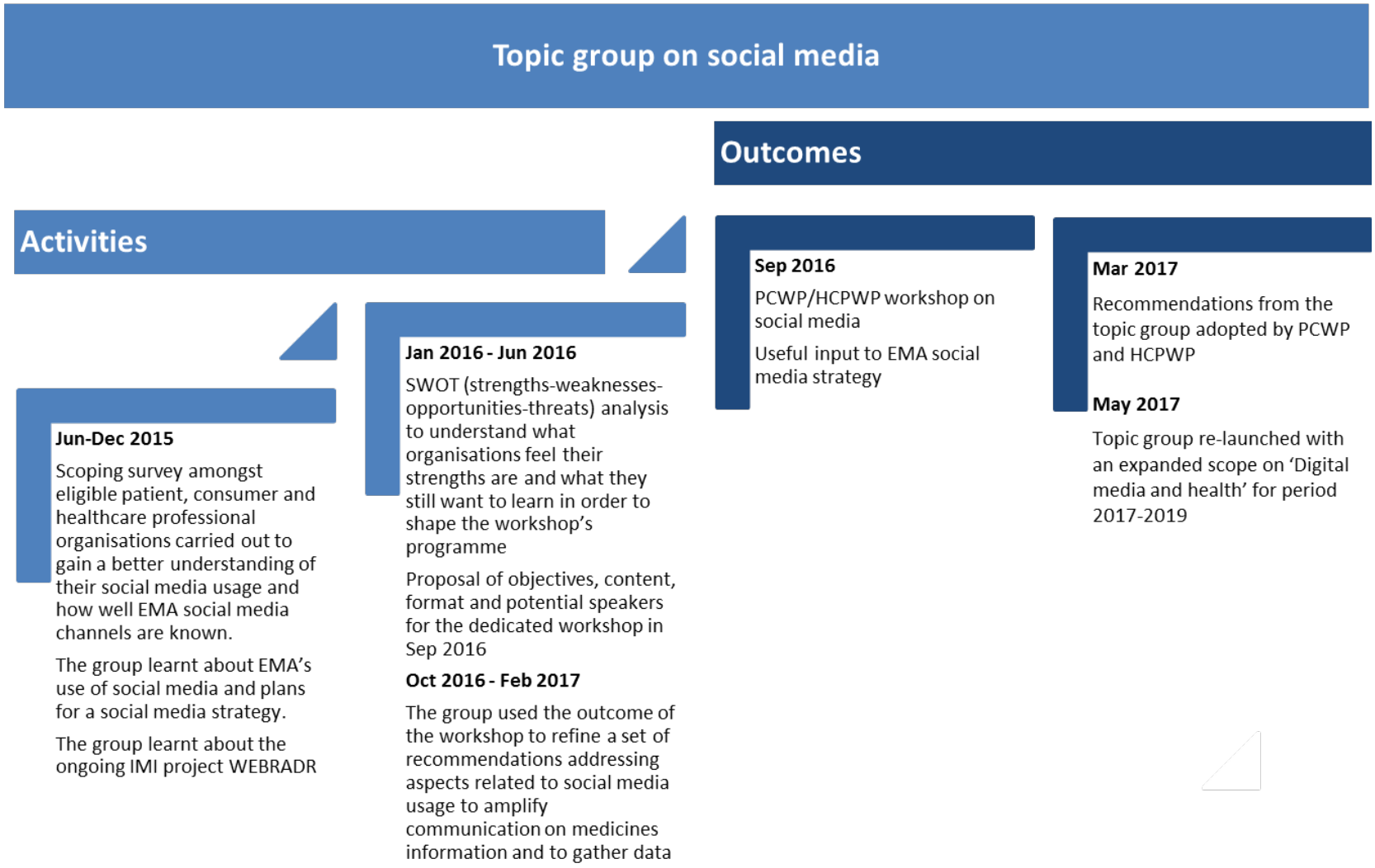
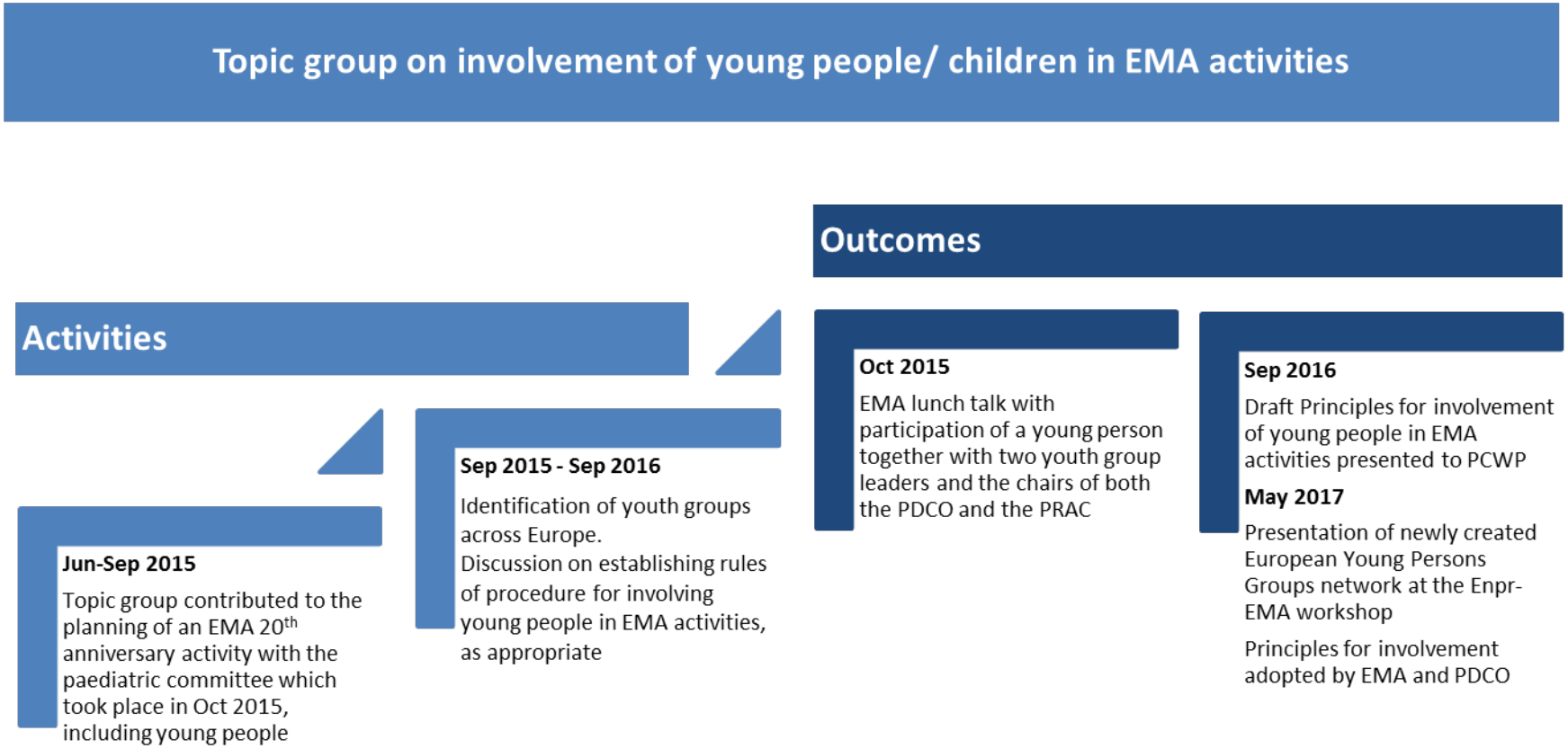


Figure 8. Key activities of the PCWP topic group on involvement of young people / children in EMA activities and related outcomes



4. Conclusion

Some topic groups achieved their objectives and were closed, with the option to reactivate them if and when needed, others are ongoing and adapting and refining their scope. These include the PCWP topic group on involvement of young people / children in EMA activities and the expanded PCWP/HCPWP topic group on digital media and health (former topic group on social media).

New topic groups may be created, as needed, in the context of activities identified within the PCWP/HCPWP work plan for 2018-2019.

5. References

Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 4 March 2015

http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2015/06/WC500188370.pdf

Minutes of the EMA Human Scientific Committees' Working Party with Patients and Consumers' Organisations (PCPWP) meeting with all eligible organisations – 26 November 2015

http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2016/02/WC500200863.pdf

European Medicines Agency (EMA) Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 9 March 2016

http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2016/06/WC500209272.pdf

Minutes of the EMA Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) meeting – 15 June 2016

http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2016/08/WC500212112.pdf

Developing a framework of collaboration between the European Medicines Agency (EMA) and academia Report of the workshop hosted by the Healthcare Professionals' Working Party (HCPWP) – 15 June 2016

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/08/WC500211452.pdf

Framework for collaboration between EMA and academia – March 2017

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/03/WC500224896.pdf

Annual Report 2015

http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2016/06/WC500209168.pdf

6. Acknowledgements

Measure impact of patient involvement in EMA activities

Francois Houyez (Eurordis), Kaisa Immonen-Charalambous (EPF), Ancel.La Santos (HAI), Ken Mastris (Europa Uomo), Ilaria Passarani (BEUC), Paola Baiardi (PDCO Alternate), Albert van der Zeijden (IAPO), Roberta Savli (EFA), Sarah Masefield (ELF), Hildrun Sundseth (EIWH), Nathalie Bere (EMA)

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Academia, learned societies and healthcare professionals' organisations

Angeles Alonso Garcia (ESC), Jamie Wilkinson (PGEU), Gonzalo Calvo (EACPT), Michel Delvaux (UEG), Riccardo Riccardi (PDCO), Lorenzo Dagna (EFIM), Olivier Clement (ESR), Roberto Frontini (EAHP), Rosa Giuliani (ESMO), Marianne de Visser (EAN), Karin Plass (EAU), Sergio Bonini (EMA), Monica Ensini (EMA), Ivana Silva (EMA)

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Annex 1

Recommendations from the PCWP topic group on acknowledging and promoting visibility of patients' input in the Agency's activities

Adopted on 26 November 2015

As part of its activities, the PCWP identified the need to raise awareness of the involvement of patients, consumers and their organisations in the work of the EMA and also to further acknowledge the value of their input.

The topic group was created to:

- Explore how to raise awareness and visibility of patients/consumers work at the EMA;
- Explore how to best acknowledge patient/consumer input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups;
- Make recommendations.

In order to get a better understanding of the current status and generate new ideas, the 2 co-leaders prepared a survey which was distributed to the 13 topic group members.

9 organisations answered. The questionnaire is attached in annex.

On the basis of the outcome of the questionnaire, the topic group agreed on the following recommendations:

Organisations acknowledge and promote recognition: Pre-requisites

- EMA to provide clear guidance on "confidentiality versus transparency" boundaries (organisations refrain to communicate on patients' involvement to avoid breach of confidentiality);
- EMA and organisations acknowledge that patients may refuse to be named (risk of stigma) and protection of private data has to be respected.

How to improve acknowledgement and promotion of patient input into EMA activities by EMA

- EMA to provide a certificate of attendance to meetings;

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- EMA to send thank you letters and update the participant on the outcome of his/her involvement;
- Increase visibility of patients' involvement in EMA annual report highlighting what patients' involvement has brought to EMA activities;
- Acknowledge patients' involvement in various EMA Web pages or create an acknowledgement page;
- Make PCWP and patient involvement pages friendlier: include photos of PCWP and explanations on the group activities;
- Press release/case studies on patient involvement highlighting the value of patient involvement;
- Create a Facebook page, use social media;
- "Easy to read summaries" /vignettes/ EMA basics to make information more attractive and patient-friendly. (be careful with acronyms);
- Write articles to better explain potential ways to input, progress made and how this is making a difference at EMA and national level;
- EMA to participate in Patients' organisations workshops/conference;
- Open PCWP beyond "closed club": explore more work in topic groups involving all eligible organisations, broadcast PCWP to all eligible organisations, circulate agenda and minutes to all eligible organisations;
- Promotion of Patient groups' input can be done through training.

How to improve acknowledgement and promotion of patient input into EMA activities by the organisations

- Celebrate a "patient involvement day";
- Report on patient involvement during Workshop / tutorials / advisory committees/ board meetings/ annual congress;
- Formal acknowledgement through Annual report, newsletter;
- Organise "summit" with those involved;
- Encourage PCWP members to submit posters/abstracts and attend conferences to explain their involvement at EMA level;
- Disseminate and share information/experience through blogs, Newsletters, Twitter. Publish personal example of involvement (short story) on organisation's website, linkedin… to increase knowledge and awareness and point people back to EMA;
- Regular conference calls between those involved to share topics of common interest, experiences, issues and get support;
- Specific EMA section on organisation's website;
- Use material developed by EMA (see previous section) to increase knowledge and awareness;
- Develop patient ambassador programme delivering personalised certificate;
- Promotion of Patient groups' input can be done through training.

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Annex 2

Recommendations and Actions from the PCWP topic group on Training

Adopted on 9 March 2016

As part of its activities, the PCWP identified the need to increase awareness of the Agency's mandate and activities and to review all training provided by the Agency. In addition, training initiatives in the area of medicines development have already been developed by eligible organisations and collaborative projects and one aspect of this group was to explore synergies with these initiatives.

The topic group was created to:

- Explore synergies with existing training initiatives;
- Discuss and explore further training methods and tools for patients involved in EMA activities.

Explore synergies with existing training initiatives

Organisations that work with the EMA have recognised the importance of preparing their members and volunteers for interactions with the Agency (either European or national) on issues related to medicines. For this reason, the Training topic group provided information on relevant training materials and initiatives that were either prepared by their own organisation or that they have attended. A compilation of materials from the EMA and organisations was made.

One recommendation was to extend the request of materials to all eligible organisations. This invitation was extended during the November 2015 meeting with all eligible organisations.

A reflection was undertaken on how best to demonstrate these training synergies. One recommendation was to refer to these trainings on the EMA website. The updated webpages (described below) now include links to three of the identified initiatives (EUPATI, Eurordis Summer School and EPAP). In addition, representatives were invited to present these initiatives during the meeting with all eligible organisations in November 2015 in the context of the Training topic group.

Discuss and explore further training methods and tools for patients involved in EMA activities

Taking comments and discussions with the working party members into consideration, updates and new measures for providing information on the activities of the EMA were put into action as follows:

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Annual EMA training day

Based on feedback from previous participants and an internal recognition of a need to move towards a more interactive hands-on format for annual training day, a new format was introduced in November 2015. As patients are involved all along the lifecycle of a medicine, minimal presentations and breakout sessions were used to illustrate the role of patients and the expectations of the Agency for various activities from involvement in pre-submission and evaluation phases to post-authorisation.

In addition, while EMA colleagues have always presented during the Training day, the new format involved the in the break-out sessions providing more contact and exchanges with the participants. Positive feedback was received from the participants and the trainers in the follow up survey.

Webpage update

To support the Training initiative, all Patients' and Consumers' webpages have been updated. The Training and Support webpages have been renamed to Training and Resources to reflect the training and materials provided by the EMA.

The EMA Training Overview document, describing the activities of patients at the EMA and the training and support available for these, will be updated to reflect the recent changes.

The EMA YouTube channel provides video links to previous training sessions and workshops however these have been an underutilised source and now has a more prominent position on the updated pages.

In addition to the existing content, new shorter 'video's entitled EMABasics were created.

EMA Basics

The purpose of the short videos is to provide short 'digestible' information on the activities of the EMA, the centralised procedure, the role of patients and other topics of relevance and interest to patients and the general public.

The EMABasics are short versions of the information provided during the 2014 Training day videos on the YouTube channel. For individuals looking for more in-depth presentations, the longer versions are easily located via the Training and Resources page.

Currently there are 6 online in English (along with downloadable pdfs of the slides and text); these include:

- The European Medicines Agency;
- The centralised procedure;
- Involvement of patients;
- The Patients' and Consumers' Working Party;
- Pharmacovigilance;
- How the EMA works with healthcare professionals.

Members' voice

In the spirit of 'learning from each other', a new section has been systematically introduced into each working party meeting entitled Member's Voice. In this section, members present activities and initiatives, relevant to the remit of the EMA, ongoing in their organisations with a view to informing, motivating and providing stimulation for other organisations and potential collaboration.

Conclusion

The Training topic group has achieved the objectives agreed upon and also extended itself to create a new Resources page for the Healthcare Professionals, which also includes the EMABasics and workshops of interest.

The topic group is anticipated to wrap up in June having achieved its objectives and once the Training overview document is updated.

For individual patient experts invited to participate in EMA activities, the one-to-one individual support and training provided is ongoing and updates to all webpages described above contribute to a deeper understanding of the role of the Agency and the role of patients within regulatory decisions.

Together with the PCWP, the EMA will continuously ensure that its training materials are up to date and relevant and take feedback from participants into consideration.

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Annex 3

Recommendation from the HCPWP topic Group on information on medicines

Adopted on 20 September 2016

Executive summary

The Topic Group has been asked to prepare recommendations on how to maintain high quality of regulatory information throughout the lifecycle of the medicine to support clinical practice. After analysing current information and performing a survey among healthcare professionals, the group notes that regulatory information on medicines is nowadays comprehensive and of utmost importance both for clinical practice and preparation of therapeutic guidance, but not easily accessible. The group therefore recommend optimising the ease of use of regulatory information through improved online access, readability and communication.

The EMA HCPWP Topic Group on information on medicines has been asked to prepare recommendations to EMA and to healthcare professional organisations on:

- how to use available resources to maintain high quality product information throughout the lifecycle of the medicine whilst ensuring that it reflects as much as possible clinical practice reality;
- how to use or improve current EMA information outputs to support clinical practice;
- how to bridge regulatory outputs with therapeutic guidelines/prescribing recommendations.

After sharing their experiences, performing a survey on the use of medicines' information among Healthcare Professionals throughout Europe, and, discussing its challenges with the EMA Healthcare Professionals and Patients Working Parties, the Topic Group made the following observations:

- Healthcare Professionals use many sources of information, including regulatory information, medicines databases, prescribing support tools, clinical practice guidelines and medical journals. Over time, the amount of information on medicines has switched from being scarce to becoming overwhelming. Information overload makes it challenging to ensure access and uptake of reliable and relevant information by the right target group at the right time in the right format. The main challenge is finding a quick answer to a query during a busy healthcare professional working day.

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- Provision of regulatory information is comprehensive and of utmost importance both for clinical practice and preparation of therapeutic guidance, but not easily accessible (e.g., because of the many resources available on the EMA website). The summary of product characteristics (SmPC) stands out as the regulatory document of reference on a medicine. Quick and easy access to the latest efficacy and safety information is also necessary in clinical practice. This includes information on new medicines, new indications and new safety issue or risk minimisation measures for a product or a class of products.
- Regulatory information is often seen as the best available information at the time of the initial authorisation. However, all information may not be available at the time of licensing and timely updating of information needs attention in view of faster communication in conferences, medical journals or other publications. Communications of changes face several challenges at the same time; these include: the collection of robust evidence, the need to avoid unnecessary alarming or promising messages, the demand for transparency on uncertainties and the variability among users on how early they should receive new safety or efficacy information.
- The approach of EMA documentation focusses on one medicinal product while in practice information on the drug class is also used. Class information is particularly important for placing medicines within their current therapeutic contexts and assessing their added therapeutic value.
- The SmPC and clinical practice guidelines are key information sources. Targeting consistency between regulatory information and therapeutic guidelines currently represents a challenge since the latter are numerous, prepared by different bodies (ranging from local to international) and professional societies may differ from one place to another and be quickly evolving.
- Differences in licenses between different manufacturers of products with the same active substance (generics) were seen as unhelpful. Examples include different indications, cautions and contraindications.
- Healthcare professionals' organisations can act as mediators in communicating EMA information or providing expertise in their review. Although there are some limitations due to different constructs of the societies within and between countries, their role in multiplying information at local level is well recognised and could still be expanded.

On this basis, the Topic Group first recommends to optimise EASE OF USE of regulatory information on medicines, with:

- Priority given to the quality of information rather than the quantity of information;
- Better online access to the existing information:
  - Through a single portal with easy navigation and optimal search functionality, offering a one stop shop for comprehensive regulatory information on the medicines authorised in EU;
  - Allowing individuals to select what suits their needs:
    - On a medicine (based on generic and proprietary names) or in a therapeutic area or clinical speciality

      (e.g. using the Anatomical Therapeutic Chemical (ATC) classification system, or, a classification per particular system of the body or aspect of medical care as used in medicines formulary such as the British National Formulary);
    - Providing quick information for clinical practice in all European languages:

    - including the SmPC, communication on risk minimisation and information on important recent changes;
    - SmPCs should be directly accessible on their own, since the SmPC is the document of reference on a medicine.
  - to more comprehensive information aimed at, e.g., preparation of therapeutic guidelines or research (where information can be in English only).

- Concise, reliable and ready to use information:
  - The SmPC should not become more extensive, or, it should be considered to complement it with a summary;
  - Package leaflets should be improved, with a less rigid template, more patient-friendly information on benefits, and, side effects could be matched with how to manage them. Experience gained with the European Public Assessment Report summary should be used as an example for communicating information on key benefits and risks to patients;
  - The complexity and size of the public assessment report (EPAR) was seen as a disadvantage.
- Communication and training:
  - On which, and how, regulatory information is prepared (covering aspects such as assessment, transparency, the type of marketing authorisations and links between EMA and National Agencies);
  - Improve clarity on which information is not available (e.g., added-therapeutic value, new non-validated safety signal or off-label use);
  - Offer tailored subscription to EMA news, e.g., per clinical specialty;
  - With an alert system for new and important changes (per clinical specialty, if appropriate);
  - Promote and disseminate information in partnerships with National Competent Authorities and healthcare professionals' organisations;
  - Use new technologies and social media.

In terms of consistency between medicines regulatory information and therapeutic guidelines, the Topic Group recommends to investigate this matter with a pilot exercise in a specific therapeutic class to further assess how one influences the other over time, and, which are the most common related issues in practice.

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Annex 4

Recommendations from the PCWP topic group on measuring the impact/value of patient involvement in EMA activities

Adopted on 30 November 2016

The EMA has developed a robust system for involving patients, consumers and their representative organisations in its activities including the development of policies, regulatory guidance, and product related evaluation.

Quantitative and qualitative feedback on the impact of patient input on particular activities is regularly provided as well as an analysis of feedback from patients (survey) on their satisfaction as seen within the annual report of interaction with patients, consumers, healthcare professionals and their organisations.

The Agency is frequently asked to further quantify the impact of patient involvement in its activities. There is a need to review the adequacy of the current methodology to determine if and how it could be improved and/or expanded.

The topic group was created to:

- Explore how to measure the value/impact of patient input on regulatory outcomes;
- Explore the impact that involvement in EMA activities has on empowerment of PCOs;
- Establish a system for regular cross-Agency collection of quantitative and qualitative data for monitoring and reporting purposes.

The objectives of the group as described above encompass bidirectional effects of patient involvement in regulatory processes; impact of patient input in regulatory outcomes and by virtue of this experience, whether there has been an empowering effect on those involved.

The third objective involved establishing a system for collection of data for monitoring and reporting and in this respect we could consider modifying existing methodologies and/or creating measurement of different aspects of patient involvement in Agency activities.

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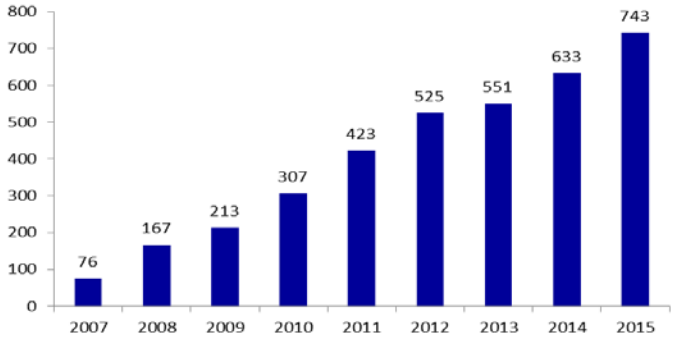
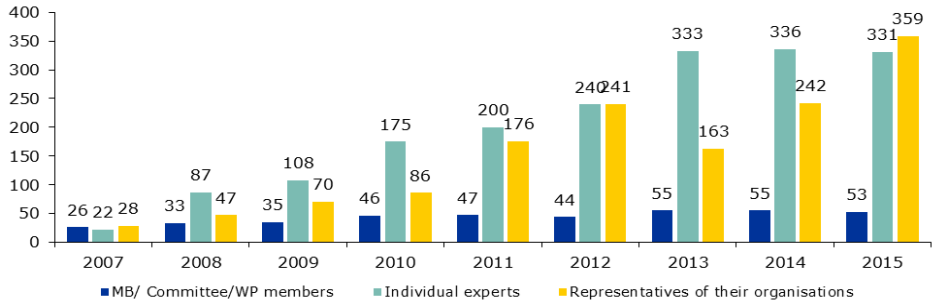
Approaching impact from a holistic perspective

Looking at patient input from a more holistic view enables a shift from a rather narrow (quantitative) "measuring of impact" to a wider approach that highlights and identifies the added value of patient involvement, which includes qualitative methods.

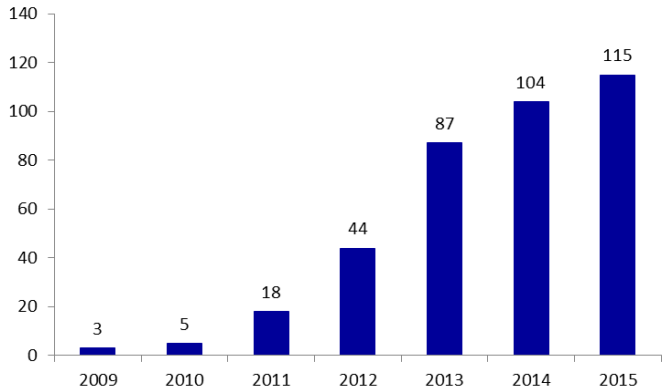
Over the more than 20 years that the Agency has engaged with patients, we have seen an increase in numbers of patients involved in EMA related activities; the graphs below show the progression from 2007-2015.



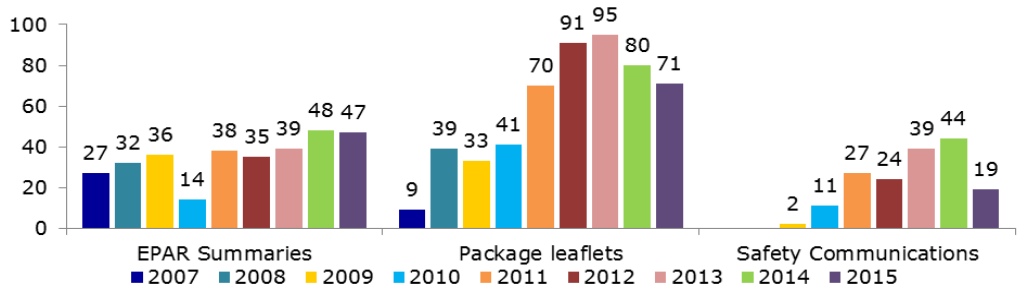
Similarly the range and type of activities where patients and consumers are involved has diversified over this time. Patients have been included in the EMA management board, scientific committees and working parties, and increasingly involved as individual experts in scientific consultations or as representatives of their organisation in workshops and other activities.



The number of workshops where patients and consumers are involved has increased over the years and their involvement has moved from attendee to speaker and chair on numerous occasions.



As a result of the working party and requests by patients, more information is produced for the public which is reviewed by patients prior to publication. Below is a graph indicating some of the documents that are produced by EMA and reviewed by patients.



The involvement of patients in EMA activities has had a positive impact and as such has resulted in an extension of the range and type of activities where patients are involved and hence an increase in numbers of patients involved.

NB: The decrease observed in 2014/2015 reflects the decrease in the numbers of authorised medicines.

Measurement of the benefit/value of patient input on regulatory outcomes

Although there has been an overall increase in patient engagement across Europe, and we are starting to see some research aiming to highlight the value of such engagement through *quantitative* assessment, there is not as yet a great deal of data available.

European Medicines Agency

As shown in the graphs above there has been an increase in requests for patient input and more areas where patient input is required within scientific evaluations as well as workshops and review of documents. This is a direct result of the successful involvement and unique perspective and experience provided by patient representatives in the various activities.

The Annual Reports of EMA interactions with Patients, Consumers, Healthcare Professionals and their organisations provides an overview of the strength of the involvement of all of these stakeholder groups as well as highlighting the increasing diversity of the activities where they are involved. This overview also provides detailed qualitative evidence of the value and benefit of individual patient input within specific activities.

The added value and benefit of involving patients in EMA activities can also be evidenced by the creation of the Department of Patients and Healthcare Professionals in 2014, dedicated to identifying, involving, supporting, and training patients and healthcare professionals in the activities at the Agency.

External impact

Other EU Agencies have also increased the involvement of patients in their activities as demonstrated in the survey conducted in 2015 and several agencies have approached the Agency to learn from EMA experiences of patient engagement. The survey showed that almost all Agencies felt involving patients was beneficial to their work, however different Agencies where at different stages for these interactions. There is a general awareness that mutual trust, understanding of regulation, resources and experience are needed to build these relationships.

A fellowship exchange was organised whereby staff members from both the EMA and the US Food and Drug Administration (FDA) agency spent time in each other's agency to experience and exchange best

practices. This very fruitful exchange then resulted in the establishment of a formal EMA/FDA 'cluster on patient engagement'.

Recommendation is to look at the *impact* of patient involvement in EMA activities from a holistic viewpoint and to consider it as 'added value' rather than 'impact'. The progression over the years in terms of areas of involvement, increased occasions of interaction and also increased external interest to 'learn from patient engagement at EMA' is in itself a demonstration of the value of engagement.

Impact of involvement in EMA activities on patients and consumers

The patient and consumer groups that are involved in EMA activities have recognised a need to raise awareness within their communities of the work of the regulatory agency as well as their role within the development of medicines.

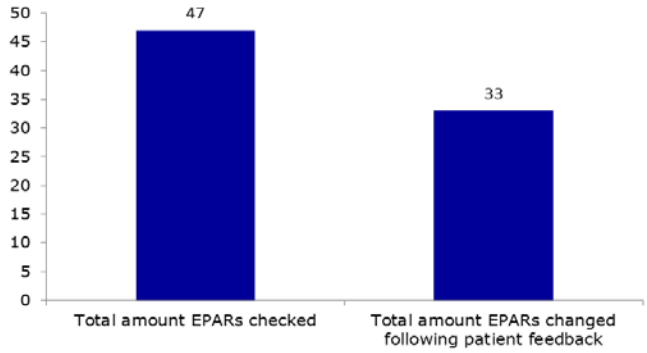
In order to support these activities, several patient groups have developed training specifically focused on the development of medicines and the role of patients to ensure that they understand the entire process of medicines development, regulation, access and reimbursement. This then enables patients to be better equipped to be involved in Agency activities whenever they are called upon and in turn empowers them by virtue of the increase in knowledge but also by giving them a voice in the decisions. EMA actively supports and contributes to external training and awareness initiatives.

A survey conducted with alumni of the EURORDIS Summer School (one of the training initiatives developed by a patient organisation) showed that of the 79 responses, 10% were subsequently involved in an EMA Scientific Committee, EMA working parties (10%), EMA expert consultations (25%), involvement with other European institutions/organisations (34%), national medicines agencies (23%) and national HTA bodies (11%).

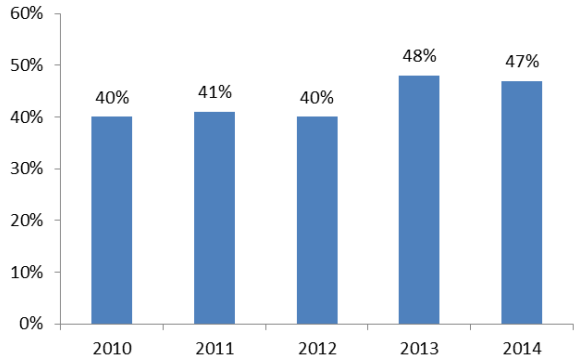
Recommendation is to continue to contribute and support external patient training initiatives while developing more training for patient involvement at EMA (in conjunction with the Training topic group)

System for regular collection of quantitative and qualitative data for monitoring and reporting purposes

Currently impact of patient input at the EMA is measured quantitatively within the review of documents whereby feedback is provided to each reviewer on if, and how their comments are incorporated into the final document and this is then evaluated as an overall percentage (see graph below); 70% of suggestions made by patients were introduced into the final document.



An additional area where quantitative feedback is also obtained on patient input is within scientific advice and protocol assistance procedures. Here the evaluation of impact relates to whether or not the patient's contribution during the procedure had an impact (was included) in the final advice provided to the pharmaceutical sponsor as seen in the graph below.



However it became apparent that this type of data collection is too narrow. Patient input in scientific advice can vary from agreement with the suggestions proposed by the sponsor to contributing on meaningful endpoints, likelihood of compliance and factors impacting recruitment due to methodology or selection criteria, respectively. Some patients provide a broad overview of their disease community, concomitant treatments and other factors affecting quality of life, while other patients provide specific details on some of the issues highlighted above. In both cases, an added value could be perceived even if not a specific impact on the final advice letter. In light of the above the current questionnaire used to collect feedback on impact has been revised to include the broader contributions; not only whether input 'changed' the final document. This will also assist in the qualitative measure of patient input.

Recommendation is to continue to assess the impact in the review of written documents but to revise the current questionnaire for gathering feedback within scientific advice and protocol assistance procedures and also to use this as a pilot which, if successful could then also be extrapolated to other areas, such as SAG /ad-hoc expert meetings and scientific committees.

Overall conclusion

The topic group was established to explore the impact that patient input has within EMA activities, how this is (and can be) captured within the EMA but also for those organisations and patients involved. The research undertaken by this group highlighted that this is not a straightforward question to answer and as such the co-chair of the group suggested that rather than speak of 'impact' that we describe and measure the 'added value'.

It was concluded that there is little research on methodologies in this area that could be extrapolated and used to measure patient input within EMA activities, as yet, but that this would continue to be monitored. It was also felt that the current methods of qualitative collection and reporting of the value of patient input at the EMA is very useful in its own right (e.g. detailed within annual reports) and that the quantitative collection of similar information should continue as is within the review of documents. For information on 'added value' within scientific advice procedures this has been revised and broadened, the feedback will be re-analysed after 6 months and if useful will then be used within other EMA meetings where patients are involved, such as SAG/ad-hoc expert meetings.

'Measuring' the 'impact' or value of any given interaction with patient(s) is subjective and needs to be approached with caution; patient experts should not be subjected to scrutiny which is ultimately not exercised on other experts. Nevertheless it is important to be able to highlight the overall benefits and value that patient contributions bring to the regulatory arena.

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Annex 5

Recommendations from the HCPWP on Additional Risk Minimisation Measures (aRMMs)

Adopted on 15 March 2017

Background

As part of its activities, the HCPWP identified the need to reflect further on the development and implementation of additional risk minimisation measures.

A topic group was created with the following objectives:

- To discuss current practices/experience (regulator and healthcare professional perspectives) in the development and implementation of additional risk minimisation measures, using concrete examples of risk minimisation tools;
- In the context of the PRAC activities, brainstorm on how to facilitate input from healthcare professionals (HCPs) into the feasibility, information and evaluation of risk minimisation measures; explore aspects around product-specific issues, therapeutic class and overall therapeutic environment and prepare recommendations as appropriate;
- To discuss how to better inform HCPs about ongoing activities and initiatives within the EU regulatory network related with post-authorisations Efficacy and Safety studies, registries, medication errors, RMP summaries and safety communications and prepare recommendations as appropriate.

Findings and recommendations

The topic group was asked to prepare recommendations for consideration by PRAC/ EMA and HCPs on the implementation and adherence to additional Risk Minimisation Measures (aRMMs). Following the selection of four concrete case studies of aRMMs, a survey was conducted of healthcare professionals across Europe. The group notes that there are several barriers and facilitators to the implementation and adherence to aRMMs. Therefore, the group makes the following seven recommendations concerning the development process, the content and the communication of aRMMs, both from a regulatory perspective, as well as in practice.

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Recommendations for consideration by PRAC/ EMA:

Involve HCPs earlier on in the development process of additional risk minimisation measures

Rational: Early involvement would serve two purposes

- To investigate appropriateness and feasibility of having aRMMs;
- To gather frontline practice-based input into the type of aRMM, the messages to be conveyed and nuances of practice affecting their success.

Feedback from HCPs suggests the use of a scientific advisory group (SAG) was beneficial. However several further suggestions / gaps were identified by consulting HCPs at a later stage which could have been included in the aRMM materials pre-launch.

Involve HCPs earlier on in the development of routine risk minimisation measures.

Rational: Early involvement would also serve two purposes

- Reduce / prevent risk of potential medication errors and;
- Early involvement may also potentially reduce the need for subsequent aRMMs.

Feedback from HCPs suggests that early involvement could facilitate appropriate package design, labelling and SmPC content at the point of routine RMM design, rather than at the point of aRMM design or review.

Guides / checklists should cover all HCPs involved in medication use

Rational: Ensuring guides / checklists include all relevant HCPs better reflects the medication's "journey" from manufacture, distribution, prescribing, dispensing and supply, administration and disposal (if relevant).

Feedback from HCPs indicated that the final HCP dealing with the patient and the medication may not be a physician, but could be a nurse or a pharmacist.

Information provided to patients could be better balanced / articulated e.g. include side effect frequencies, info on risk of other medicines in same class / alternatives

Rational: Well-articulated and balanced information for educational material for patients has two benefits

- Better understanding of and ability to follow the aRMMs in patients with varying levels of health literacy;
- Balanced material would avoid discouraging the use of the medication.

Feedback from HCPs suggested that the use of size, colour and plain language / catchy slogans was considered valuable. However, wording including size effect frequencies (as in the SmPC) could be used to better articulate risk in aRMM materials.

HCPs also stated that including text that alternatives to the medication may also have (similar) potential adverse effects would help balance the materials.

Consider making information available on the outside of the package and in the SmPC, as a summary / prompt / removable card to facilitate dialogue with patients

Rational:

- Single-issue or limited-issue materials provided to HCPs in practice can often run-out quickly, get lost in the surgery, ward or pharmacy;
- There may be uncertainty as to where they can be re-ordered;
- A summary / prompt / removable card, which is available on the outside of the package would increase the chances that the aRMM message reaches the patient.

Feedback from HCPs suggested the use of a removable card or succinct summary on the outside of the box to trigger a dialogue with the patient upon dispensing the medication.

Additionally, the messages in materials are "forgotten" where use / administration occurs infrequently, and HCPs reported that systematic distribution of materials at the time of each use was not possible. It was also noted that materials may be missed in practice due to staff turnover, shift patterns, absences and locums.

Feedback from HCPs also suggested considering adding a checklist to be completed by patients, to be sure that the use of the medication / operation of the device is well understood.

Target communications with appropriate tool(s) and to appropriate audience(s), using mixed media channels

Rational:

- Traditional methods of communication are now being complemented by a range of electronic, online and mobile technologies;
- Patients', consumers', academic / learned societies and healthcare professionals' representative bodies are also increasingly utilising online / digital media to communicate with their members, which could also include information on aRMMs.

Feedback from HCPs recommended the use of websites would be beneficial when concerning disease areas with a high prevalence in the population for a chronic disease.

Additionally, the use of wider electronic communications for younger HCPs and patients should be considered as they are likely to be using more often.

Consider also the use of scientific publications / communications / events for dissemination

Rational:

- The EMA enjoys a tradition of collaboration with patients', consumers' and healthcare professionals' representative bodies at European level within the PC/HCP WP. Many of these organisations publish scientific journals and/or host events for their members;
- Leveraging further collaboration within the PC/HCP WP and in the future also with academic / learned societies could increase awareness of aRMMs.

Feedback from HCPs suggested that dissemination (of information on aRMMs) in scientific publications could be very useful, for example via their in-house journals or publications.

As already mentioned, feedback from HCPs recommended the use of websites would be beneficial when concerning disease areas with a high prevalence in the population for a chronic disease.

Reflections for consideration by HCPs

As a result of both the open and closed question responses of the survey, the following reflections have been identified for consideration by healthcare professionals:

- Incorporation of RMMs into Institutional protocols / guidelines;
- Incorporation of RMMs into the education of HCPs' (i.e. Continuing Education and Continuous Professional Development);
- Widening access to shared eHealth records (with indications / diagnoses / reported ADRs or side effects);
- Encourage multi-professional collaboration & shared responsibilities.

Additionally, reflection on dissemination practices concerning RMMs for European level stakeholder / representative bodies could also be considered.

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Annex 6

Recommendations from the PCWP/HCPWP topic group on Social Media

Adopted on 15 March 2017

Background

As part of its activities, the PCWP and the HCPWP identified the need to stimulate discussion around what are the opportunities and the challenges for medicines development, evaluation, surveillance and information emerging from social media.

The topic group was created to:

- Map current practices in the digital world that are shaping clinical research and clinical care;
- Prepare recommendations to EMA and to patients', consumers' and healthcare professional organisations:
  - on how to use their communication channels (internet and social media) more widely, to ensure easy, consistent and timely access to authoritative, reliable and understandable information on medicines;
  - intended to raise awareness of how data and information related to the real use of medicines is being collected and used for research and/or other purposes and call for actions, as appropriate.
- Identify topics and speakers for a PCWP/HCPWP workshop on social media to be organised in 2016.

Findings and recommendations

The topic group carried out a scoping survey in 2015 amongst EMA eligible organisations to understand how they use social media to find information and to communicate information to their members as well as to determine how well EMA social media channels are known to this group. A SWOT analysis in 2016 amongst these organisations further evaluated attitudes towards social media. Results were presented at the PCWP/HCPWP workshop on social media on 19 September 2016.

On the basis of the findings of the scoping survey and the SWOT analysis as well as of the outcome of the PCWP/HCPWP workshop, the following recommendations are proposed:

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Recommendations for EMA to action:

As EMA is developing its Social Media strategy, the following recommendations could be taken into consideration:

- Engage EMA stakeholders in different social media channels (as conduits and advocates for important messages) by collaborating in content creation, tagging each other, retweeting content of partners and potentially where relevant by defining and disseminating key topics together;
- Information produced by EMA is to be prepared in a neutral voice and must be scientifically / technically correct and adapted to be relevant to lay audiences, medical professionals or other stakeholders. This would require multiple versions of key messages to be produced;
- The use of visual aids, infographics, videos and links should be considered and are strongly recommended as they stimulate interactions and are more likely to be 'favourited' and shared by others;
- A clear distinction should be made between communications linked to an 'alert' situation and those for information only e.g. urgent safety communication versus strategic public consultation;
- Content and tone of message as well as communication channels are suitable differentiators;
- EMA should emphasise to its stakeholders that it welcomes the sharing of its messages as broadly as possible with an understanding that they may need to be adapted for their audience;
- EMA should also consider appointing some senior staff or certain departments to act as ambassadors online, thus making the EMA more personal.

Recommendations for patient, consumer and healthcare professional organisations to action:

- A repository is to be created containing:
  - EMA policy on social media (i.e. data protection, data mining, privacy considerations …);
  - A general good practice document:

    Indicate reputable sources of information on how to set up accounts for Twitter, Facebook, LinkedIn and other trusted media;

    Indicate or supply brief user guides for consideration;

    EMA stakeholders can be requested to point to such information (potentially available).
- Social media should not replace the use of more traditional communication channels, but should be used to reach groups otherwise difficult to contact, enrich existing means of communication, as well as offer new opportunities for interaction. Currently, social media are amongst the most 'instant' means of communication however there is a lack of effective control for some channels: an important consideration when deciding to use social media or not.
- A formal **social media strategy** may be helpful (if not already in place) to support the use of social media as a communication tool:
  - Social media should be an integral element of media strategy, not just for campaigns, but also in the case of crisis communication, as effective tools for reaching a broad audience in a short time-frame;

  - List the right social media channel to disseminate information that will best fit the intended message and target audiences;
  - List the level of expertise/time/cost to invest for each option;
  - Advise to prioritise activities, and start with a manageable option which can be built on after gaining experience;
  - Engage a social media expert (community manager) with logistical/operational experience to complement subject expertise to focus on content;
  - A certain level of monitoring and moderation will be required for selected social media channels. Monitoring responses will be helpful in making informed decisions, and also to allow for revising strategies.
- Network building is key to success, as is creating a ´brand´. National and international organisations should engage their own network in this process. Keeping a focus on the particular community and tailoring the message towards the intended audience, is crucial for success;
  - this goes both ways. Also important to reuse/adapt relevant content of others. This way interaction will improve, which will help in expanding your network).
- EMA messages should serve as a reference for the stakeholder groups to use as a basis for their onward communication. Stakeholders should have the option to slightly adapt EMA messages (translate, or co-brand). Depending on the target audience, translation may be unavoidable;
- **Analyse, evaluate and improve**
  - As for all standard/old-fashioned activities: planning is a crucial component to success. Ensuring that all components are in place well ahead of time will enhance the potential of success, bearing in mind geographical differences in social media update and the need to consider staggering timing of messages where different time zones are involved.

Actions for EMA, patients, consumers and healthcare professionals

In order to adapt approaches and optimise interactions:

- Stakeholders should be encouraged to monitor replies to their social media output, provide timely feedback and share findings with EMA;
- EMA social media metrics may be of interest for their partners.

Next steps

Due to the rapidly changing nature and terminology used for Social Media in particular with health and medicine (e.g. medicine 2.0, health 2.0, eHealth, mobile health (mHealth), personalised health (pHealth), user-generated content, big data), the group **recommends** altering its name from 'Social Media' topic group to '***Digital media and health***' with a view to continue to work on the following three pillars over the period 2017-2019:

Social media

Expected outcome: Raise awareness of social media practices amongst PCWP/HCPWP and EMA, with a particular focus on promoting interactions and exchange of information.

Work to be developed:

- Continue to share practices and experiences of organisations with social media; identify training activities to build up organisations' capacities for social media outreach; follow development of EMA social media strategy, etc.;
- Use the 'member's voice' section of PCWP/HCPWP joint meetings to share practices and experiences of effective case studies in use of social media;
- Explore how to raise awareness of existing training resources prepared by patient and healthcare professional organisations.

mHealth

Expected outcome: identify questions that need reflection at PCWP and HCPWP level

Work to be developed:

- Follow up on outcome of WEBrADR and other relevant projects;
- Gain a better understanding of European Commission policy on mHealth (e.g. Code of Conduct on privacy for mHealth apps, mHealth assessment guidelines working group and medical devices guidance document on qualification and classification of stand alone software) with a view to identifying areas of relevance for medicines evaluation and monitoring;
- Share information on mHealth apps for real world clinical use (e.g. apps for capturing clinical end points):
  - Identify points of concern from patients and healthcare professionals around mHealth apps for real world clinical use (e.g. validity, reliability, transparency, interoperability, safety, effectiveness and efficacy);
  - Reflect on the need for a guideline for patients on how to assess open mHealth apps and solutions? Privacy, transparency, usability.

Real world evidence

Expected outcome: promote a better understanding of how real world evidence is incorporated into the evaluation of medicines (collection, use, interpretation for regulatory purposes, curation) in a language that is meaningful to patients and healthcare professionals

Work to be developed:

- Follow up on outcomes of the EMA workshops on patient registries, big data and adaptive pathways and other relevant projects;
- Gain a better understanding of how real world evidence supports lifecycle regulatory decision-making;
- Identify points of concern from patients and healthcare professionals around generation and use of real world evidence (e.g. validity, reliability, transparency, security, ethics) in the evaluation and supervision of medicines;
- Reflect on how to address identified concerns and best communicate to patients and healthcare professionals in a clear and comprehensible manner.