3 March 2016
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Stakeholders and Communication Division

PCWP/HCPWP topic groups

Consolidated interim report for the PCWP/HCPWP joint meeting of 9 March 2016

In March 2015, both PCWP and HCPWP agreed to set up a number of smaller groups to brainstorm on specific topics between plenary meetings. The table below lists the topic groups for which aims and objectives were endorsed in June 2015. Key milestones/activities and next steps are also identified with the intention to feedback to the working parties, identify potential areas of synergy/overlap across groups and adjust accordingly.

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
Acknowledge and promote visibility of patient input in the Agency's activities	PCWP	• Explore how to raise awareness and visibility of patients/consumers work at the EMA. • Explore how to best acknowledge	The topic group decided to prepare a survey to get a better understanding of the current status and generate new ideas; the survey was distributed to the 13 topic group members.	A work plan including priorities for implementing the recommendations will be discussed in the 2nd	Acknowledgement and promotion of patient input into EMA activities could be improved via social media.

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Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
Co-leaders: Isabel Proano (PCWP)/ Isabelle Moulon (EMA)		patient/consumer input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups. • Make recommendations.	On the basis of the outcome of the responses to the questionnaire, the topic group agreed on some preliminary recommendations on how both the EMA and the organisations can improve acknowledgement, recognition and promotion of patient input into EMA activities. (Annex 1)	quarter of 2016. The topic group is expected to conclude its activities in June 2016. **For March meeting:** Discussion of implementation of recommendation related to provision of meeting certificates – gain better understanding of different needs for a certificate	
Training Co-leaders: Richard West (PCWP)/ Maria Mavris (EMA)	PCWP	• Explore synergies with existing training initiatives. • Discuss and explore further training methods and tools for patients involved in EMA activities • Make recommendations	The topic group was surveyed on training initiatives they organised or were aware of in the area of medicines development. EMA training day discussed and more interactive hands-on sessions requested. Revised format of EMA Training day took place in November 15 EMA webpages and tools were discussed with an idea of targeting the audience.	The group will aim to finalise recommendations in the 2nd quarter of 2016. The topic group is expected to conclude its activities in June 2016. **For March meeting:** Discussion of Recommendations (Annex 2)	Social media could be used to raise awareness of the existence of Training and Workshops providing information on medicines. Consider future training sessions for young people (once initiative has begun) Could consider that future academics page will also have link to

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
					Resources (as with HCP)
Involvement of young people / children in EMA activities Co-leaders: Rafal Swierzewski/ (PCWP)Nathalie Bere (EMA)	PCWP	• 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 7 October 2015	The group contributed to the planning of an EMA 20th anniversary activity with the paediatric committee which took place on 7 October 2015 and included a young person (18 years) in a lunch panel discussion together with two youth group leaders and the chairs of both the PDCO and the PRAC. The group is currently reaching out within their members/ organisations to try and locate patient youth groups within the EU with the aim to establish a 'network' of youth groups.	The group will endeavour to locate and contact EU youth groups to establish a network. The group will discuss and propose areas of EMA's work where young people could be involved and set up rules of procedure to do so, as appropriate – to be presented in September 2016.	Synergy with training topic group, for future training sessions for young people (once initiative has begun)
Measure the impact of patient involvement in EMA activities Co-leaders: Kaisa Immonen-Charalambous (PCWP)/ Nathalie Bere (EMA)	PCWP	• Explore how to measure the benefit/value of patient input within EMA. • 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	An overview of the current methods for capturing patient value/impact during EMA activities has been prepared. The group is discussing whether these methods are sufficient and whether there are any other feasible methodologies which could be implemented at the EMA. There have also been discussions on the	The group will prepare an overview with potential recommendations, if any, by the 2nd half of 2016, also taking into account other initiatives in this area (e.g. CIRS). Continuation of the topic group will be re-assessed	Potential synergies with the Visibility topic group to be explored.

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
		for monitoring and reporting purposes.	definition of patient impact, how and for which activities can impact be measured.	in June 2016	
Social Media Co-leaders: Donald Singer (HCPWP)/ Ivana Silva (EMA)/ Maria Mavris (EMA)/	PCWP/ HCPWP	• 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 • Identify topics and speakers for a PCWP/HCPWP workshop on social media to be organised in 2016.	A scoping survey amongst the 65 eligible patient, consumer and healthcare professional organisations was carried out to gain a better understanding of their social media usage and how well EMA social media channels are known. (Annex 3) - Based on the findings of the survey, a SWOT (strengths-weaknesses-opportunities-threats) analysis was proposed to understand what organisations feel their strengths are and what they still want to learn in order to shape the workshop's programme. The group has learnt about EMA's use of social media and plans for a social media strategy. It has also learnt about the ongoing IMI project WEBRADR.	Proposal of objectives, content, format and potential speakers for the dedicated workshop on 19 September 2016. Drafting of recommendations addressing aspects related to social media usage to amplify communication on medicines information and to gather data. Recommendation to continue topic group beyond September with a wider focus on digital media and health (looking into real world research and big data); the possibility to evolve into an EMA expert group will be investigated. **<u>For March meeting:</u>** SWOT analysis to all WPs	Synergy with the RMM topic group – consider using one example to test communication of a particular risk minimisation message.

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
				member organisations	
EMA/CHMP/PRAC projects on information on medicines Co-leaders: Joan Peppard (HCPWP)/ Laurent Brassart (EMA)	HCPWP	• Setting the scene and summarising identified challenges • Discuss the target audience(s) of the different information on medicines produced by EMA • Discuss healthcare professional organisations' (HCPOs) role in the information chain • Identify ways to facilitate input from healthcare professionals into the preparation and update of regulatory information • Prepare recommendations to EMA and to HCPOs	The group discussed the extent and variety of audiences, needs and documents as well as the large diversity regarding medical practice and access to information between countries in Europe. The group recommended carrying out a survey within Healthcare Professionals to clarify which information they use and for which purpose. The scoping survey amongst healthcare professionals was carried out in January with the support of 44 HCPOs and reached over 500 respondents. In parallel, the group agreed to develop an infographic combining available sources of information for healthcare professionals that are produced throughout the regulatory pathway and depict how these are used through the clinical journey. This should be supplemented with a glossary. The group has also identified the main themes around which recommendations should be developed: ease of use; place of regulatory information among other information on medicines; and	The survey findings will be presented at the 8 March workshop. The group will aim to prepare potential recommendations in the 2nd half of 2016. Continuation of the topic group will be re-assessed in September 2016	

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
			healthcare professionals' input to EMA documentation.		
Risk minimisation measures and assessment of their effectiveness Co-leaders: Jamie Wilkinson (HCPWP)/ Michael Berntgen (EMA)	HCPWP	• 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 related to product life cycle support, 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	The group started activity in October, following the PCWP/HCPWP workshop on risk minimisation measures and assessment of their effectiveness organised in September 2015. The group agreed their focus would be on identifying best practice in involving HCPs in the development and implementation of RMMs. The group has discussed a selection of examples of medicinal products for which (additional) risk minimisations measures have been set up. The goal was to identify examples that cover/impact different clinical settings and/or professional groups and compile information on how was involvement of HCPs organised, what worked well and whether there were elements of it that could have been done differently to optimise the final outcome. The group has identified a set of questions, applied to the selected examples that would benefit from the wider HCPWP input to adjust focus of the	The group will recommend a set of criteria to be put to the consideration of PRAC for HCPs' involvement in RMM development and implementation. Continuation of the topic group will be re-assessed in September 2016. **<u>For March meeting:</u>** A working lunch will be organised on 8 March to brainstorm on issues emerging from the analysis of the selected examples and additional questions identified by the group, to subsequently launch a wider consultation amongst HCPWP members.	Synergy with Information on medicines – use of DHPCs; communication on changes to the SmPC, etc. Synergy with the Social Media topic group – consider using one example to test communication of a particular risk minimisation message. Synergy with HCPOs/Academia & Learned Societies topic group - explore the possibility of advocating for the inclusion of risk minimisation measures / tools into HCPs' continuing education and/or CPD activity

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
		communications and prepare recommendations as appropriate.	group's work.		
Academia, learned societies and healthcare professionals' organisations Co-leaders: Rosa Giuliani (HCPWP)/ Sergio Bonini (EMA)	HCPWP	• Reflect on the need to review the EMA framework of interactions with HCPs. • Support the development of the EMA framework for collaboration with Academia. • Identify current practice with involvement in regulatory activities. • Discuss areas for improvement and foreseeable changes.	The group recommended that the 2011 Framework of interaction with healthcare professionals should be updated to adapt to a more relevant role of HCPs in drug development and monitoring and align it with the foreseen framework of collaboration with academia. The group has also discussed which initiatives could enhance relationships with Academia and recommended to focus on the following: • More active involvement in regulatory policy initiatives • Increased representation in EMA Committees • Early involvement in the authorization process of medicines • Joint workshops on specialized topics • Cross-learning programs and reciprocal participation in scientific events	Discuss revised text of framework of interaction with healthcare professionals by the 2nd quarter of 2016. Follow up developments on the consultation with academia on the establishment of a specific framework of collaboration. Contribute to the dedicated HCPWP meeting with Academia interested parties on 15 June 2016. Continuation of the topic group will be re-assessed in September 2016.	

Topic Group	Working Party	Key objectives	Activities to date	Next steps	Synergies/ overlaps
			• Involvement in drafting of documents and guidelines • Joint research • Exchange of personnel (visiting research scientists at EMA and visiting EMA staff at academic institutions). The group was kept updated on the EMA work leading to the launch of a public consultation on collaboration with Academia.		

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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.

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

→ 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.

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→ 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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WORKING DOCUMENT – TO BE DISCUSSED AT PCWP/HCPWPJOINT MEETING 09.03.16

Annex 2

Recommendations and Actions from the PCWP topic group on Training.

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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a. 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.

b. 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.

c. 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

d. 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.