12 November 2018
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Stakeholders and Communication Division

Meeting summary - EMA Human Scientific' Committees Working Party with Patients' and Consumers' Organisations (PCWP)

25 September 2018

Co-Chairs: Juan García Burgos (EMA) and Kaisa Immonen (PCWP)

1. Patient involvement and visibility in EMA activities

- ***Patient engagement along the regulatory lifecycle***

N. Bere (EMA) presented an overview of patient involvement, showing how patients are involved within the different stages along the regulatory lifecycle. The presentation also highlighted the categories of patient representation and flexibility needed in terms of engagement methodologies, the number of patients involved during 2017 and how they are selected and provided with support and training to aid and optimise their contribution. Some specific challenges were identified with proposals to address them. Finally a brief update on the second Public hearing on Quinolone and Fluoroquinolone medicines that took place in June 2018 was also given (see presentation).

A discussion followed on how to find suitable patients (sometimes with tight deadlines) and the importance of ensuring that EMA training resources are available and easily accessible. EMA explained that a variety of training materials are available on EMA website. It was agreed that EMA will include a list of ongoing medicines evaluations within the monthly newsletter. EMA is currently developing a training strategy that will be circulated when finalised. Members also agreed to share information at a future meeting(s) regarding the methods they use to identify patients so that other organisations can benefit from experience already gained.

Actions:

- EMA to share list of ongoing medicines evaluations with PCWP members on a monthly basis (within the Human Medicines Highlights Newsletter);
- EMA to develop a training strategy for patients;
- PCWP members to share patient identification methodologies during future meetings (members' voice section).

- ***Visibility of patient input throughout scientific procedures***

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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M. Mavris (EMA) gave an update on the visibility of patient input throughout scientific procedures and the tools used by EMA to communicate (annual reports, infographics, press releases, EMA website, specific landing pages for patients, social media, targeted emailing, online and face-to-face training activities, meetings and workshops) (see presentation).

She also took this opportunity to inform that, in view of Brexit and Business Continuity Plans, EMA will not produce a Stakeholder Engagement report for 2018. She also explained that in the future EMA will produce a more streamlined report. In this respect working party members were invited to work with M. Mavris to identify and select which information is likely to be most relevant for the organisations.

M. Mavris will coordinate a group of volunteers to meet (virtually) to help identify the objectives of the next Public Engagement report. A survey will be prepared to gain a better understating of what members expect from the annual report, how they use it and which sections/content is considered essential to include in a future version.

Actions:

- Working party members to inform M. Mavris (Maria.Mavris@ema.europa.eu) if they wish to join the working group;
- Feedback from the working group and results of follow-up survey will be presented at a future meeting.

- ***Relaunch of EMA website***

A-C. Schmidt (EMA) presented the upcoming launch of new EMA corporate website (live on Thursday, 27 September 2018) and explained the reasons behind the update, how the website will look, and the new features to improve user experience and how to navigate (see presentation).

It was also mentioned that the website's content and structure remain unchanged and although the site's URLs are new, URLs from the previous website will continue to work for every page and document, thanks to one-to-one redirects. Although these redirects will be available for an indefinite period, EMA encourages users who have bookmarked any URLs to consider updating them.

It was highlighted that the work on EMA's corporate website will continue, even after the Go-live date, and PCWP members were encouraged to test it and provide feedback (problems or suggestions for improvement).

During the discussion that followed, PCWP members raised questions on website accessibility standards (better contrast and change of font size), the possibility to receive email alerts on topics of interest, a login functionality for members of PCWP and how/where to find particular information on the new website.

Action:

- PCWP members to provide general feedback (problems or suggestions for improvement) on the new EMA corporate website via AskEMA form or newwebsite@ema.europa.eu.

2. Committee feedback

- ***COMP – Description of Article 8.2***

D. O'Connor (COMP) gave an update on Article 8.2 (a provision whereby the period of marketing exclusivity can be reduced from 10 to 6 years). He also highlighted a recent COMP paper, which defines orphan conditions in the context of the European orphan regulation. Furthermore, he explained

that two new EC documents have been recently published to reflect changing science, and there is also an EMA infographic with an overview of EU's orphan designation programme and a Q&A on "Rare diseases, orphan medicines. Getting the facts straight." (see presentation).

Action:

– COMP paper "Defining orphan conditions in the context of the European orphan regulation: challenges and evolution" to be shared with PCWP members.

- ***CAT***

K. Breen (CAT) gave an update on CAT activities including the progress and development of the use of CAR T cells (the next generation of immunotherapy for the treatment of cancer). He informed that two products were approved by EMA/EC in August 2018 (Yescarta and Kymriah) and presented the challenges in the context of post approval in the UK (approval for reimbursement). He also highlighted the CAT work plan for 2018 and the increasing number of ATMPs being assessed by the CAT and of products being submitted for marketing authorisation (see presentation).

- ***CHMP***

C. Prieto (CHMP) gave an update on patient involvement in CHMP activities (scientific advisory /ad hoc expert group meetings and oral explanations) and highlighted the need to identify areas to expand patient participation in CHMP (new areas and new ways of participation).

- ***PDCO***

D. Athanasiou (PDCO) highlighted the difficulties facing the patient members in the committees as they are participating as volunteers without any external support. He also explained the differences between a patient representative and patient expert and the challenge to involve young people in PDCO processes.