12 November 2018
EMA/717794/2018
Stakeholders and Communication Division

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

25 September 2018

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

Introduction and points for information

- ***Update since April 2018***

Juan García Burgos (EMA) gave an update on activities since April 2018, including the Public hearing on quinolones and fluoroquinolones held in June 2018, the Stakeholders Engagement report for 2017, the new streamlined process for annual re-evaluation of eligibility of organisations, the meeting held with civil society representatives in EMA committees and the revision of PCWP/HCPWP mandates and rules of procedure (see presentation for more details).

- ***EMA preparedness on Brexit and relocation – impact in PCWP and HCPWP activities***

He also updated the group on EMA's business continuity plan which enter the third phase on 1 October 2018 and which will address the move to Amsterdam and manage staff losses (see press release).

He informed that there will be no physical meetings of the working parties until June 2019 but two virtual meetings with all eligible organisations will be organised to provide updates on Brexit/Relocation related activities. Elections for the new PCWP/HCPWP co-chair will be postponed until Q3 2019 (see presentation).

PCWP/HCPWP members will be kept up to date and were advised to use the general email for PCWP and HCPWP secretariats (PCWPsecretariat@ema.europa.eu and HCPsecretariat@ema.europa.eu) for any specific questions.

Post meeting update: First virtual meeting with all eligible organisations to take place on **Thursday 13 Dec 2018,** from **14h-16h** (UK time).

1. EMA perception survey

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- ***Results of 2017 EMA perception survey***

E. Scanlan (EMA) presented the key findings from a perception survey on EMA communications to the public, conducted among partners, stakeholders and web visitors in May 2017 aimed to identify challenges and areas for improvement (see presentation for full details).

PCWP/HCPWP members suggested that it would be interesting to receive feedback from patients and healthcare professionals that have not used the EMA website before, and also from different groups of healthcare professionals (e.g. GPs, hospitals).

2. EMA regulatory science to 2025

- ***Background to the initiative and future consultation process***

A. Humphreys (EMA) gave a presentation on 'EMA regulatory science to 2025' highlighting the work done so far, including a baseline report to identify science and technology trends prepared in consultation with committee chairs and stakeholders outreach.

He informed that a multi-stakeholder workshop will be organised on 24 October 2018 (broadcast live) and a report/consultation document is expected to be published in Dec 2018 (see presentation and press release).

Action:

– EMA to share report / consultation document once published (expected Nov/Dec 2018).

3. Pharmacovigilance

- ***Feedback from the 12th Stakeholder Forum on Pharmacovigilance***

H. Sundseth (EIWH) and R. Anderson (PGEU) gave a brief update on the 12th Stakeholder Forum on Pharmacovigilance that took place on 24 September 2018:

- H. Sundseth (EIWH) explained that the meeting focused on what has been achieved since the implementation of the new Pharmacovigilance legislation; P. Arlett (EMA) gave an overview of the work of the last 6 years. Some highlights included the creation of PRAC, the new Eudravigilance system, allowing for direct patient reporting of side effects and public hearings. The meeting also looked at challenges for the next 5 years with complex medicines being developed. Marco Greco (PRAC) encouraged national Regulatory Agencies to include patients in their work and provide training. The involvement of young people in the regulatory processes was considered a positive step forward.
- R. Anderson (PGEU) explained how the meeting focused on engagement as a way to build trust. He presented a session on the Valproate referral as a case study, to demonstrate the need to involve all stakeholders throughout the process.

Action:

– EMA to distribute presentations and multimedia with PCWP/HCPWP members once published.

- ***Updates on Good Pharmacovigilance Practices (GVP), in particular GVP III – pregnancy/breastfeeding, CVP IV – paediatrics and GVP V – geriatrics***

P. Bahri (EMA) gave an update on GVPs in Paediatrics, Geriatrics and Pregnancy and Breastfeeding (see presentation).

PCWP/HCPWP members were asked to give input on the GVP module covering population-specific considerations for geriatrics, specifically on the following points:

- What do those representing geriatric patients expect to be addressed in this GVP module?
- What do geriatric clinical specialists expect or may contribute from their expertise?
- What contributions can pharmacoepidemiological researchers make from their experience?

A draft of the GVP module covering population-specific considerations on pregnancy and breastfeeding is expected to be published in late 2018 early 2019.

Actions:

- PCWP/HCPWP members to give input on GVP module covering population-specific considerations on geriatrics by **31 March 2019**;
- EMA to keep PCWP/HCPWP informed on GVP module updates.

- ***Highlights from the PRAC Pharmacovigilance Impact project work on engagement of patients and healthcare professionals, in particular a proposed conceptualisation of engagement in pharmacovigilance and feedback from a case study on valproate***

P. Bahri (EMA) reported on PRAC work on measuring impact of engagement with patients and healthcare professionals within pharmacovigilance. This project also includes Valproate as a case study (lessons learnt from the Public hearing and preliminary recommendations).

4. Digital media and health

- ***Follow up by PCWP/HCPWP topic group on digital media and health***

D. Singer (EACPT) provided an update on the PCWP/HCPWP topic group on Digital Media and Health, which had a series of TCs and a day themed around digital media and health during the last Joint PCWP/HCPWP. He highlighted that the topic group is generating a user's Q&A document intended to clarify aspects related to use of patient data in real world evidence (RWE) and patient registries. PCWP/HCPWP members were asked to provide comments on the Q&A (see presentation).

Once meetings resume, the European Commission will be invited to present on the use of mobile Health (mHealth).

Action:

- PCWP/HCPWP members to provide comments on the Patient data Q&A document **by 25 October 2018.**

C. Enachioiu (EMA) explained that EMA is happy to consider requests to support social media campaigns from patient/consumer and healthcare professional organisations, provided that they are aligned with EMA communication priorities. She also highlighted that EMA would welcome organisations support on EMA campaigns; to aid this, EMA will inform organisations in advance, giving them key messages and timelines, visuals and pre-drafted messages with hashtags (see presentation).

PCWP/HCPWP members wishing to get EMA support with a public health campaign are encouraged to contact EMA in advance via press@ema.europa.eu (and cc: PCWPSecretariat@ema.europa.eu / HCPSecretariat@ema.europa.eu), with the following information:

- key messages of the campaign, objectives and audiences, relevant visual items, any quotes,

hashtags and timelines.

Action:

– EMA to organise a follow up conference call with topic group on digital media and health in October 2018.

Post meeting update: follow up conference call will be organised in December/January.

5. Electronic product information

- ***Update on ongoing work***

A. Skarlatos (EMA) gave an update on work being carried out by EC/EMA/HMA on improving product information in the EU, in particular the electronic Product Information (ePI) (see presentation).

An international survey was launched to document all projects and initiatives/systems around ePI; responses were discussed during a meeting in Madrid in July 2018 with representatives of national authorities, EC, industry and patient and healthcare professional organisations.

A multi-stakeholder workshop will take place on 28-29 November 2018, to agree on key principles on the use of the ePI, to be followed by a Public Consultation end 2019.

The need to create a technical sub-group was highlighted for further collaboration with stakeholders to help describe use and features for ePI to explore points for consideration for the November meeting. A call for expression of interest was launched among PCWP/HCPWP members.

Participants expressed concerns on the speed of updating paper and electronic versions of Product Information (PI) and highlighted that ePI should not substitute paper PI but rather be complementary with the aim to improve accessibility to information.

- ***EC/HMA/EMA multi-stakeholder workshop – feedback by PCWP/HCPWP participants at preparatory meeting, draft programme and points for discussion***

C. Cabrita (BEUC) provided feedback from the Madrid meeting and highlighted some of the concerns raised by stakeholders: such as which portal will be used and who will manage it, especially the quality of the information. She also highlighted that patients without digital access or literacy should not be excluded from receiving information. She emphasised the importance of improving the package leaflet.

I. Silva (EMA) shared the draft Agenda of the upcoming EC/HMA/EMA workshop on electronic Product Information (ePI) (28-29 November 2018). It will be broadcast live.

She explained that purpose of the workshop is to bring together national competent authorities, patient/consumer organisations, healthcare professionals, academics and industry to discuss and agree on a set of common EU key principles for the use of ePI (and look at the opportunities offered by electronic formats and how ePI fits in the EU and in the global context).

The key principles generated from this workshop will then be put for public consultation.

Actions:

– EMA to circulate a call for participation in the multi-stakeholder workshop of 28-29 November 2018; PCWP/HCPWP members to respond by **5 October 2018**;

– Proposed principles will be shared with members once published for consultation.

Post meeting update: Agenda of the workshop has been condensed into one single day and will take

place on 28 November 2019.

6. Access to medicines

- ***Update on availability of authorised medicines***

M. Dias (EMA) updated on the ongoing work on the Brexit impact on the availability of medicines and the initiative to improve how shortages are managed.

In relation to Brexit EMA wants to ensure that pharmaceutical companies have plans in place to comply with the EU legal requirements once UK becomes a third country in March 2019.

EMA carried out a survey, launched in January 2018, to obtain information on timelines for submission of the necessary regulatory changes and to identify CAPs potentially at risk of supply shortages. EMA is tracking all necessary submissions for changes and continues to work directly with the marketing authorisation holders (MAH) to address any outstanding issues. It will also discuss relevant mitigation measures with its scientific committees, including recommendations on possible therapeutic alternatives to which patients could be switched if necessary (see press release).

PCWP/HCPWP members will continue to be updated through EMA Press Releases and during the November workshop.

E. Martínez (EMA) updated on EMA-HMA Task Force on Availability of Authorised Medicines, mainly on thematic group 2: Supply Chain Disruption. The group developed a draft on the definition of shortages as well as guidance for MAHs to detect and report shortages to authorities. The group also developed metrics for measuring shortages. The task force published a work programme in August 2018 and will co-host the HMA/EMA workshop in November 2018.

PCWP/HCPWP members were asked to provide comments on a draft definition of shortage (see presentation).

Action:

- Comments on draft definition of shortage to be sent in writing by **5 October 2018**.

- ***Preparation for the HMA/EMA multi-stakeholder workshop on availability of authorised medicines – contribution from PCWP and HCPWP***

I. Abed (EMA) introduced the multi-stakeholder workshop on 9 November 2018, which will be an opportunity to bring together all stakeholders involved in medicines shortages. She provided background information on EMA/HMA Task Force as well as the objectives of the workshop and highlighted the importance of involving patients and healthcare professionals, to bring awareness and search for solutions (see presentation).

I. Silva (EMA) showed the draft Agenda for the workshop. The meeting will be broadcast.

The aim of the workshop is to inform stakeholders about the activities of the task force, to give an update and gather feedback on the progress of its working including the impact of Brexit in medicines availability, how to address shortages and how to improve information on medicines availability.

Action:

- A call for participation in multi-stakeholder workshop on 9 November 2018 to be circulated; PCWP/HCPWP members to reply **by 5 October 2018**.