1 December 2017
EMA/757232/2017
Stakeholders and Communication Division

Meeting summary

Patients and Consumers Working Party (PCWP) meeting with all EMA eligible patient/consumer organisations

22 November 2017, 09:00hrs to 17:00hrs – meeting room: 3E

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

1. Relocation preparedness

- *Relocation preparedness; next steps*

G. Rasi (EMA) and N. Wathion (EMA) presented updates on relocation plans following the Council's decision to relocate the Agency to Amsterdam. He informed the participants that the Agency's move to Amsterdam has to be completed by 30th March 2019 and that the EMA and Dutch delegations are already in contact to initiate the work.

Priorities will be assessed on an on-going basis according to the business continuity plans and all stakeholders will be kept updated. The PCWP and the HCPWP will continue to be regularly updated through their meetings and the website will be kept up-to-date on the relocation progress.

Action: All organisations will be kept informed on EMA's relocation plans.

2. Patient/consumer involvement in EMA activities

- *Highlights of 2017*

M. Mavris (EMA) presented an overview of EMA activities involving patients and consumers so far during 2017. She highlighted some new activities, such as involvement within the CHMP and the HMPC, the adoption of principles to involve young people and the expansion of the annual training day (see presentation).

A discussion on EMA training resources and methodologies followed and it was agreed that will be a further reflection during 2018 involving PCWP on how to streamline and make training to patients more strategic.

Action: All activities involving patients, consumers and healthcare professionals will be detailed in the 2017 annual report which will be published 2Q 2018 (link to page).

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3. MA's first public hearing

N. Bere (EMA) presented the process and outcome of the first public hearing held by EMA in September 2017 on valproate and the risk in pregnancy (see presentation). The summary report and video recording of the hearing are available on the EMA website (link).

Public Hearings are considered on case-by-case basis based on agreed criteria and they complement other engagement methods already in place at EMA.

A 'lessons learnt' report will be published once finalised. The initial feedback received from PRAC members and participants after the public hearing is very positive. The public provided some very valuable inputs which will contribute to the assessment of valproate.

The PRAC assessment report on its recommendations following the review of valproate will highlight how the information from the public hearing has been considered.

Action: EMA will share the 'lessons learnt' report once available.

4. New EMA shareable communications

M. Bensetter (EMA) presented some new communication materials which EMA has prepared, highlighting the use of images and infographics specifically for engaging with the public (see presentation). She encouraged patient/consumer organisations to use these materials and to forward any suggestions regarding social media to raise awareness about EMA, its work and the involvement of patients.

Participants highlighted the importance of being involved in the preparation and user-testing of these materials. It was clarified that it is not always possible to share everything in advance,

The current construction of EMA's new website was also highlighted.

Actions:

- A presentation of the new website will be included in the next meeting.
- EMA will discuss and reflect how to best identify those situations which would benefit from sharing, consultation and/or user-testing during their preparation with PCWP or a subgroup of PCWP members/experts

5. Highlights from committees

- *CAT*

K. Breen presented the work of the CAT, explaining the different types of advanced medicinal products and the priorities for 2018 (see presentation).

- *CHMP*

H. Enzmann updated on the most recent discussions from the CHMP since September and highlighted the involvement of patients in oral explanations (see presentation).

A discussion followed regarding how best to gather input from the patient community during benefit-risk evaluations and it was suggested to convene a small drafting group to further analyse current experience to define best practice and recommendations as necessary. H. Enzmann agreed to lead the drafting group.

Action: A call for expression of interest to participate in a drafting group will be sent out shortly.

- *COMP*

D. O'Connor presented the activities of the COMP, highlighting a workshop on prevalence taking place in December and a project regarding the publication of the Orphan Maintenance Assessment Reports (see presentation).

- *HMPC*

S. Bager explained that the herbal committee prepares guidelines and monographs for herbal products. The committee invited patients as observers during several of its meetings this year and their feedback will be shared with the HMPC in January.

Action: Regular involvement of patients in the HMPC will be discussed in the first quarter of 2018.

- *PDCO*

D. Athanasiou gave an update from the Paediatric Committee (see presentation). He emphasised the need to reduce off-label use as this is still quite prevalent in the paediatric population. He also encouraged patients to get in touch with ethics committees and explain the need for the paediatric population to participate in clinical trials.

- *PRAC*

M. Greco presented the work of the PRAC. He presented the most relevant procedures taking place currently and invited the participants to proactively check the work of PRAC and contact the secretariat in case they would like to give any inputs (see presentation).

6. Pharmacovigilance

- *Big data and real world evidence*

A. Cave (EMA) gave a presentation on big data and real world evidence, focusing on the shift in the regulatory paradigm, the current data landscape and the acceptability of big data for regulatory decision making (see presentation). She also introduced an upcoming workshop at EMA on data anonymization in which patients will be represented and heard.

Action: A session on big data and real world evidence is planned for the next PCWP meeting.

7. Information on medicines

- *EMA Action Plan following Commission's recommendations on product information*

J. Garcia-Burgos (EMA) gave a brief update on the EMA action plan to improve product information for EU medicines. Among the different actions, work on the use of digital media to facilitate access to product information will be prioritised, for which a mapping exercise of the ongoing initiatives will be started and a workshop will be organised in the upcoming year together with all stakeholders.

Actions:

- A multi-stakeholder workshop on product information will be organised in 2018.
- The action plan will be disseminated to the participants.

- *Changes to the EPAR summary (now called medicine overview)*

E. Scanlan (EMA) presented updates to the EPAR summary, which will now be called 'medicine overview'. She highlighted the important role of the patient / consumer reviews in the preparation of these documents (see presentation) and how their input is used to shape changes to the document.

The template has been updated based on feedback received from patients who have been reviewing the EPAR summaries and those who attended training sessions at EMA.

8. Members voice

- *We are here for our fellow patients*

A. Deschamps (EUomo) gave a presentation on the organisation European Prostate Cancer Coalition (Europa Uomo) and how they changed to a "managerial driven" approach (see presentation).

The take-home messages were that a "business approach" is possible in non-for-profit organisations, that "judgement" of projects should be based on "most benefit" (not profit) and finally that this approach can be seen as best practice by their stakeholders.

- *Proposal for EU network of patients acting as contact point for pharmacovigilance*

F. Houyez (EURORDIS) gave a presentation on a proposal for a new role for patient advocates as contact points for pharmacovigilance in each patient organisation, which would be an equivalent of the QPPV in pharmaceutical industry (see presentation).

The proposal was positively received by participants; however further discussion is needed over several aspects of its practical implementation.

Actions:

- F. Houyez (EURORDIS) took note of some of the issues raised, will consider these and and will share more information with all participants in due time.
- The topic will be revisited at the next PCWP meeting.

9. Looking ahead

- *PCWP and HCPWP work programmes for 2018/19*

I. Silva (EMA) presented the joint work programme for PCWP and HCPWP for 2018/2019. She explained that the aim is to have a single work-plan covering a two-year period but which could also set the direction beyond this.

The final draft is to be sent for consultation during December to the drafting group and in January this will be shared for final review and endorsement by both working parties.

Action: The final draft will be circulated for feedback, and final adoption is expected in January 2018.

- *PCWP and HCPWP topic groups*

N. Bere (EMA) gave an update on the current topic groups; "involvement of young people" and "digital media and health" (see presentation).

Action: Anyone interested in joining the current topic groups should contact N. Bere.

10. AOB

I. Natsis (EPHA) highlighted the publication of a set of recommendations for increasing the transparency of Scientific Advice.

Action: I. Natsis will forward his paper to be shared with the meeting participants.