EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 April 2018
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Stakeholders and Communication Division

Meeting summary

Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

17-18 April 2018

Co-Chairs: Juan Garcia Burgos (EMA), Kaisa Immonen (PCWP) and Gonzalo Calvo (HCPWP)

Digital media and health
The joint meeting started with a full day themed around digital media and health with presentations covering three main topics: real world evidence (RWE); mHealth and social media (see presentations). The main goal of the day was to inform about recent learnings, trends and ongoing initiatives within the European medicines regulatory network and allow for a rich exchange of views with members of the working parties.
Actions: A number of points were identified where communication around RWE, mHealth and social media by regulators and patient and healthcare professional organisations require attention. These will be further discussed by the PCWP/HCPWP topic group with an update to be provided at the PCWP/HCPWP meetings in September.
Electronic product information
Members were updated on the work being carried out by EMA and Heads of Medicines Agencies (HMA) to implement the EC recommendations from the EC report on product information, in alignment with the EMA action plan to improve product information. For the moment EMA is focusing on the fifth recommendation of developing an electronic PIL. This was prioritised as there were many different forms of e-PILs being developed by various stakeholders and there was a need for harmonisation. There will be a multi-stakeholder workshop in November 2018 to develop the key principles on the use of electronic product information. A mapping exercise to establish what tools are currently available is underway and will help inform discussions at the workshop (see presentations).

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Actions: PCWP and HCPWP representatives will be invited to the multi-stakeholder workshop to be held in November 2018. In the meantime, a call for participation in a face-to-face meeting with EMA/HMA to discuss the outline of the workshop will be circulated and further discussion will take place at the PCWP/HCPWP meetings in September.

General update on actions arising from previous meetings

- *Actions from previous meetings*

Information regarding the upcoming public hearing on quinolone and fluoroquinolone antibiotics was shared with participants. The public hearing will take place on 13 June 2018 and the aim is to hear the views of the general public on the persistence and severity of side effects reported with this group of medicines

Participants were informed of the new streamlined eligibility re-assessment process that will be implemented in 2018. The aim of this new system is to simplify the process for both the eligible organisations and EMA whilst retaining the same standards and criteria.

Currently a revision of mandates and rules of procedure for both the PCWP and HCPWP is being undertaken. EMA is proposing a single document for the rules of procedure for both working parties. Separate documents for the mandate and composition of the working parties will be retained. EMA will endeavour to present these documents in the September joint meeting.

"The role of patients as members of the European Medicines Agency human scientific committees" document is being revised and will now encompass patients and health care professionals. The document will be circulated to PCWP and HCPWP members for information.

The European Organisation of Specialist Nurses (ESNO) has produced a guide to biosimilars for nurses. The document was circulated to all participants prior to the meetings. ESNO invited interested parties to endorse this document.

Actions: Organisations to disseminate information regarding the public hearing to their networks.

Implementation of streamlined re-assessment to commence in June.

EMA to present revised rules of procedure for working parties in September if available. EMA to circulate this revised document to PCWP and HCPWP members for information.

- *Draft proposals open for consultation*

A proposal from EMA to organise annual meetings with all eligible organisations, including healthcare professionals is being prepared.

Action: EMA to circulate this proposal to PCWP and HCPWP members for comment

- *Outcome of written procedures*

The joint PCWP/HCPWP work-plan 2018/2019 was endorsed by all EMA scientific committees and have now been published on the EMA website. Key dates for events involving patients, consumers and healthcare professionals in 2018 were presented for information and are included in the joint work-plan.

- *Annual Report of Activities 2017*

The Public Engagement Annual Report 2017 is currently being finalised and will be presented to the management board in June. Participants were shown the "Patients, consumers, healthcare professionals key figures 2017" infographic ahead of its publication on the EMA website.

Action: EMA to circulate link to annual report to member organisations once published.

Members to share and disseminate this.

- *EMA regulatory science strategy*

Participants were briefly informed of the EMA regulatory science strategy. EMA wishes to work closely with all stakeholders, including patients, consumers and healthcare professionals in the development of this strategy. Stakeholder involvement will occur in different phases, and will include a multi-stakeholder workshop in October 2018 and a public consultation planned for 1Q 2019.

Action: EMA to organise follow up webinar with interested PCWP and HCPWP members to explain the strategy in more detail and how they can be involved.

EMA Relocation

- *Update on business continuity and EMA relocation*

N. Wathion (EMA) presented updates on Brexit related business continuity planning (BCP) and the Agency's relocation plans from London to Amsterdam. Participants were shown the tracking tool for the relocation that is available on the EMA website.

Priorities will be assessed on an on-going basis according to the business continuity plans and all stakeholders will be kept updated.

N. Wathion also shared details of the Agency's temporary premises in Amsterdam, the Spark Building.

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

European Immunisation Week

- *Update on EMA communication activities*

EMA activities planned for the European Immunization week (EIW) were presented. The EIW aims to raise awareness and increase rates of immunisation against vaccine-preventable diseases in Europe. Several participants at the meeting took part in a video entitled "What gives you confidence in vaccines?". EMA will share this video, along with a statement from Executive Director Guido Rasi on the EMA website and social media accounts. In the discussion that followed it was agreed that more collaboration between EMA and the eligible organisations is needed to co-ordinate efforts in this area. Participants were asked to keep EMA informed of any vaccine related initiatives or campaigns.

Actions: EMA will share the video and other visuals with eligible organisations.

Organisations to promote the Agency's EIW campaign through their own social media and websites.

Transparency and Clinical Trials

- *EMA Clinical Data Publication- experience since Oct 2016 and Technical Anonymisation Group (TAG)*

Members were updated on the experience to date with clinical data publication (CDP). From October 2016-2017 data from 54 procedures was published (see infographic). This included over 3000 documents. At present individual patient data is not published but this will be implemented at a later stage. An annual report of CDP in 2017 will be published on the EMA website. Participants were also informed of the work of the technical anonymisation group (TAG), an expert group established by EMA to help further develop best practices for the anonymisation of clinical reports. TAG encourages applicants to use alternative anonymisation techniques such as data transformation in lieu of redaction to ensure the data published is meaningful and useful.

Action: EMA to circulate annual report of CDP to PCWP and HCPWP members

- *Implementation of Clinical Trial Regulation (CTR)- update on EU-CT portal and database*

An update on the implementation of the CTR and on the EU-CT portal and database was provided (see presentation). This regulation will streamline and ensure harmonisation of clinical trial authorisation requirements across the EEA. The EU-CT portal and database will be publically accessible and will contain the information uploaded by the clinical trial sponsor, or if the results are used as part of a marketing authorisation procedure, by the applicant regardless of the outcome. Participants were also shown a live demonstration of the use of the database.

Participants raised concerns about the possibility to delay the publication of certain documents relating to a clinical trial by the sponsor. EMA explained that some trials, such as phase I trials, contain commercially sensitive information and this is the rationale behind the possibility to defer. Participants were invited to read the transparency addendum available here for more details on the reasons behind potential deferrals. She also clarified that the main characteristics of the trial such as the trial name, phase and countries it is being conducted in would still be publically available.

Participants also inquired about the possibility to migrate the data from Eudra CT published under policy 70 to the EU-CT portal. Participants were informed that this is under discussion but a definite way forward has not yet been defined. Eudra CT will be live and functional after the EU-CT portal and database is launched.

Pharmacoviligance

- *Findings of the EMA survey on awareness of the 'additional monitoring' concept and next steps*

An overview of the results of a survey launched by EMA in September 2017 to gauge patients and healthcare professionals understanding of the additional monitoring concept was presented. The results of this survey will form part of a report from the European Commission to the European Parliament and Council on the additional monitoring list.

In the discussion that followed participants raised concerns about the overall awareness of this concept by patients and healthcare professionals in the EU. It was suggested that this issue needs to be addressed at a European and national level and that information around the additional monitoring concept should be permanently available on the websites of all national competent authorities. The vital role that patient and healthcare professional organisations can play in raising awareness in this area was also discussed.

EMA corporate website

- *Relaunch of EMA corporate website*

Members were informed about the relaunch of the EMA corporate website. The new website will have an improved search function, a fresh 'look and feel' with improvements to usability and new, 'meaningful' URLs. Meaningful URLs will improve search results both on the website and on external search engines. The appearance of the website on mobile devices will also be improved. The Agency is aiming to launch the new website in H2 2018.

Access to medicines

- *EMA-HMA collaboration on shortages and availability of medicines: stakeholder input*

R. Gonzalez-Quevedo (EMA), A. Byrholt Hansen (DMA) and Y. Knudsen (NOMA) presented recent developments with the EMA-HMA collaboration on shortages and availability. This collaboration is working towards preventing the occurrence of shortages and, when they do occur, mitigating their impact. A key aspect of this collaboration is the improvement of communication around shortages within the network of medicines agencies and to external stakeholders.

A face to face task force meeting will take place in June 2018. A stakeholder workshop on shortages is planned for 8-9 November 2018 where working party members will be able to give their input and feedback. EMA will update the working parties on the progress of the task force in the September working party meetings.

In the discussion that followed participants highlighted their respective organisations' work in this area and also collaboration between organisations on this topic.

Actions: EMA to contact participants to obtain information on existing initiatives in this area.

Stakeholder workshop on shortages to take place in November 2018

- *EMA-EUnetHTA collaboration: mutual learning concerning practices for engagement with patients and healthcare professionals in assessment activities*

A Willemsen and C. Guilhaume (EUnetHTA) gave participants an overview of patient involvement in EUnetHTA activities, which is part of the EUnetHTA joint action 3. Patients may be involved in work package WP4 and WP5 activities. EUnetHTA has identified several approaches for patient engagement such as open calls, interviews, focus groups and attendance at meetings. Healthcare professionals may be involved in WP4 activities. Open calls and continuous Q&A are methods of healthcare professional involvement being explored by EUnetHTA.

Participants highlighted that interviewing one patient for an assessment at national level may not be representative of an entire patient group or population. Participants also emphasised the need for clarification on conflict of interest rules for participation in EUnetHTA activities.

Committee Feedback

- *COMP*

L. Greene gave an update of COMP activities including highlights from the strategic review and learning meeting (SRLM) in March 2018, the commencement of publication of orphan medicine assessment reports and the recent Q&A document published by EMA entitled "Rare diseases, orphan

medicines. Getting the facts straight".

- *CAT*

K. Breen gave an overview of the CAT experience in examining CAR-T therapies. Currently two CAR-T products are being considered by the CAT for marketing authorisation. He also highlighted two EMA workshops on this topic which took place in November 2016 and February 2018.

- *PRAC*

R. Anderson updated participants on recent PRAC activities. These included the outcome of the Valproate Referral, information on the public hearing as part of the Fluoroquinolone/Quinolone Referral (Art 31) and the announcement of Referral (Art 31) on Methotrexate.

- *CHMP*

F. Ventura gave an update on the most recent discussions from the CHMP from October 2017 to March 2018 and gave an overview of the interactions between CHMP and patients and healthcare professionals (see presentation). H. Enzmann discussed the drafting of a reflection paper on expanding patient reported outcomes and quality of life input within regulatory submissions. He thanked the working party members who have contributed thus far and will keep working party members updated with progress on this.

Action: EMA to share draft reflection paper with members once progressed.

- *PDCO*

V. Giannuzzi gave an update on the steps being taken to involve young people in the activities of the PDCO. At present the committee is discussing the stage at which young people could be consulted, how they could contribute and what steps the committee need to undertake to achieve this. The next steps the PDCO will take are to identify some PIPs where young people could potentially be involved and to gather feedback from those pilots to learn what works well and what can be improved or modified to ensure the interaction is mutually beneficial.

Members voice

- *Online training for MS nurses project, MS Nurse Professional*

A. Antonovici (EMSP) presented the "MS Nurse PROfessional" which is a training programme led by the European Multiple Sclerosis Platform (EMSP) in collaboration with the International Organisation of Multiple Sclerosis Nurses (IOMSN) and Rehabilitation in MS (RIMS). It is a foundation course targeted at nurses beginning their careers in the field of MS and is focused on the core competencies of MS nurses. It consists of six modules, is available in 11 languages and can be accessed for free. EMSP is now examining ways to measure the impact of the training course on patient care.

AOB

None

End of meeting