29 November 2018
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Stakeholders and Communication Division

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

26 September 2018

Co-Chairs: Juan Garcia Burgos (EMA)

1. Advances in clinical practice – scientific and regulatory challenges

I. Silva (EMA) invited HCPWP members to reflect on what has been done in the previous years and what can be done in the future with a particular focus on how the group envisages to further contributing to EMA activities. She highlighted some areas for shaping up HCPWP discussions for 2020-2025 building on the results of the survey circulated in advance of the meeting to explore priorities/directions (see presentation).

A discussion followed on the importance and value of HCPWP position/reflection papers, the uniqueness of the working party as a platform for gathering different views and the opportunity to use the organisations' journals to publish these papers as well as proceedings from EMA workshops. It was suggested to create small topic groups on the basis of activity clusters to develop such reflections but this should be preceded by establishing a common methodology. HCPWP members also discussed the importance of registries data collection, developing further interaction on guidelines, the importance of continuing to have joint discussions with patient organisations, the participation in focus groups and the relevant role of organisations in selecting experts.

Participants also expressed an interest to use HCPWP meetings for more practical discussions whilst using other channels to communicate/update the working party on EMA activities.

Action:

– Set up a call for expressions of interest for a small group to define a methodology for prioritising and addressing topics in the form of reflection papers, workshops and discussion points at HCPWP meetings.

- ***Visibility of healthcare professional input throughout scientific procedures***

M. Mavris (EMA) gave an update on the visibility of healthcare professionals' input throughout scientific procedures and the tools used by EMA to communicate (annual reports, infographics, press releases,

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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.

2. Members voice

- ***Invite members to present on how they are including regulatory sciences in fellowships and young researchers training***

- K. Plass (EUA) presented the European Association of Urology Associates training programme. The programme started in 2012 with the aim to train young clinicians (Associates) in systematic review methodology, initially for the development of clinical guidelines . This programme has evolved over the years into a leadership programme; by exposing Associates to a variety of scenarios, including industry and regulators, empowering them to be critical thinkers and become future leaders in their fields (see presentation).
- W. Marrocco (EFPC) gave a presentation on FIMMG (Italian Federation of General Practitioner) initiatives for regulatory education. This derived from a lack of structured information aimed at GPs. FIMMG developed and online course and a 3-day resident course for School of Research in General Medicine and Drug Management. Participation in the first one is mandatory for the second. The main aims were authorisation procedures and pharmacovigilance activities (speaker authorised by AIFA). This is proposed to be repeated in the following year and expanded to postgraduate GP training (see presentation).
- J. Peppard (EAHP) presented the Statement Implementation Learning Collaborative Centres (SILCC) programme that allows hospital pharmacists to visit hospitals from other member countries to learn about pharmacy procedures linked to the 44 European Statements of Hospital Pharmacy in a hospital that has achieved a high implementation level in the statements being demonstrated. The programme was launched in March 2018 and some of the topics discussed are management of availability of medicines, pharmacovigilance and methods and systems to improve reporting of medication errors and involvement in clinical trials (see presentation).
- D. Sereni (EFIM) presented an insight on the Clinical Research Seminar, a masterclass of three days for young researchers who have already experience in clinical research, which is organised and supported by the European Federation of Internal Medicine and the Foundation for Internal Medicine in Europe. He explained that normally they have 15 participants each year and presented the objectives of the seminar, the programme for the seminar that took place in July 2018 and

shared what participants find most valuable (see presentation).

- F. Ventura (CHMP) gave a presentation on Infarmed's experience with training, which is divided in two parts: *a basic training* on the principles of the EU regulatory system for medicines and on the available sources of relevant information and *on-the-job training*, where the trainee participates in the day-to-day activities of the training area (e.g. management of marketing authorisations, post-marketing authorisations, management of clinical trial applications). She informed on the increase number of trainees, the type of interaction with national and EU regulators, the added value for participants and presented lessons learnt (see presentation).
- In the discussion that followed it was highlighted the importance of this initiatives and on developing training on medicines regulation and it was suggested to include this in the HCPWP work programme and to explore training for healthcare professionals. It was agreed EMA will give a presentation on EU Network Training Centre at a future HCPWP meeting.

Action:

- EMA to give a presentation on EU Network Training Centre at a future HCPWP meeting.

M. Ensini (EMA) took this opportunity to update HCPWP members that the selection procedure for the coordination and support action (CSA) titled "Strengthening regulatory sciences and supporting regulatory scientific advice", topic on the 2018-2019 health work programme of Horizon 2020, was successfully completed. The successful project, which was awarded to a consortium formed by a pull of National Competent Authorities, will kick start in January 2019 and run for 3 years. A crucial objective is to complement, coordinate and/or harmonise efforts among Member States and at European level in order to support the main target group: academic clinical scientists. The aim is to reach these researchers very early in the planning process for relevant grant applications. A further aim is to strengthen regulatory knowledge in general by reaching clinical scientists during professional training and qualifications. More details and information will follow once the project will officially start early next year.

3. Committee feedback

- ***COMP***

D. O'Connor (COMP) gave a presentation on the importance of a valid orphan condition. He highlighted a FDA paper that was published last year He also highlighted the COMP paper on defining the orphan condition that was published last month regarding some of the challenges when delineating an orphan condition, explaining COMP decisions in the context of the EU orphan drug regulation and providing some discussion points to help future sponsors. Furthermore, he informed on the changes on EC's definition of similarity on medicinal products and the Q&A document that was made available to explain the changes. He also noted EMA's infographic with an overview of the EU's orphan designation programme (see presentation).

- ***CHMP***

F. Ventura (CHMP) gave an overview on CHMP activities, from April to September 2018, in particular the new medicines approved, which includes orphan medicines. She also highlighted the changes in the Product Information for Viekirax and Xofigo and informed on the ongoing review of Valsartan medicines, from Zhejiang Huahai Pharmaceuticals, following the detection of an impurity. She also presented the figures for scientific advice and protocol assistance and informed on the products that have received PRIME eligibility (see presentation).

4. A.O.B.

- ***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 HCPWP members were encouraged to test it and provide feedback (problems or suggestions for improvement).

Action:

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