20 November 2019
EMA/527554/2019
Stakeholders and Communication Division

Meeting summary – Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations

20 November 2019, 09:00hrs to 16:00hrs

Co-Chairs: J. Garcia Burgos (EMA), K. Immonen (PCWP), U. Jäger via Adobe (HCPWP)

Welcome and introduction

J. Garcia Burgos (EMA) welcomed participants to the first meeting with all eligible organisations since 2017 and taking place under the new PCWP/HCPWP mandate for 2019-2022, with the newly elected co-chairs, K. Immonen (PCWP) and U. Jaeger (HCPWP).

M. Carr (EMA) thanked all eligible patient, consumer and healthcare professional organisations for their support and contribution throughout the past years and shared the outcome and key messages from the analysis of the public consultation on the Regulatory Science Strategy to 2025 specifically on:

- ATMPs and precision medicine;
- Developing scientific advice/assessment pathways;
- Optimising evidence including RWD for decision making and communication;
- Clinical trials, digital therapeutics and modelling & simulation;
- Reinforcing patient relevance in evidence generation;
- Developing research partnerships with academia;

1. EMA in 2020 and beyond

1.1 Addressing future challenges and key priorities for EMA

The EU medicines regulatory network, including EMA, are adapting to accommodate changes in science, technology and legislation. G. Rasi (EMA) presented EMAs future proofing, which includes an in-depth review of its organisation to face the new challenges (see presentation).

1.2 From relocation towards a business recovery pathway

N. Wathion (EMA) provided an update on EMA's business continuity plan (BCP), how the Agency is emerging from this period of transition, highlighting the successful handover of the permanent EMA

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building on 15 November 2019 (see presentation). The move to the permanent building is scheduled between 9 Dec '19 and 10 Jan '20 to minimise disruption of Committees work. In the context of Brexit preparedness, it was noted that with each additional extension of the Brexit deadline, the Agency needs to make impact analysis and update its processes accordingly.

N. Wathion also provided an update on EMA staff retention figures and recruitment planning to address staff loss and to meet new demands. In defining its work programme for 2020 and beyond, EMA will focus on the core activities identified in the last phase of business continuity as a baseline and then prioritise additional activities dependent upon the available resources

1.3 Move to permanent premises

T. Freitas (EMA) provided an overview of the new EMA building and informed there will be an *Orientation guide prepared for patients and healthcare professionals* (see presentation).

The audience asked about shortages in the post-Brexit United Kingdom (UK) and the UK patients' and healthcare professionals' role in the EU framework after Brexit. EMA responded that currently there is no confirmation of any potential shortages of critical medicines after Brexit. However, this will continue to be monitored.

Speakers commented that National Authorities can contribute to EMA's transition towards business re-initiation by contributing to priority setting at the Management Board and by nominating national experts at EMA.

Actions:

- Further details on the new structure of EMA will be shared after EMA Management Board meeting in December 2019;
- Members will be kept updated on any further developments associated with Brexit;
- EMA work programme 2020 will be circulated once published;
- Orientation guide for patients and healthcare professionals, including information on the EMA building and how to reach it is being prepared;
- Next PCWP/HCPWP meeting will be held at EMA's permanent location in Amsterdam.

2. EMA role in the implementation of new legislation

2.1 Veterinary medicines

J. Torren Edo (EMA) gave an overview of the new Veterinary regulation (NVR) coming into effect on 27 January 2019 (see presentation). He presented the Agency's role in the implementation of NVR with special attention to Antimicrobial Resistance (AMR).

During the discussion the importance of a responsible use of antibiotics given to animals to avoid the transmission of resistance to humans was stressed.

- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)
- EMA webpage: https://www.ema.europa.eu/en/veterinary-regulatory/overview/implementation-new-veterinary-medicines-regulation

Actions:

- Members will be kept updated by EMA on the implementation of AMR-related provisions.

2.2 Medical devices and in vitro medical devices

Z. Frias (EMA) provided an update on EMA's role in the implementation of new legislation for medical devices (MDR) and in vitro diagnostics (IVDR), which is aimed to increase medical device's safety and

effectiveness across the EU while adapting to technical and scientific developments (see presentation). Q&As on the implementation of the new regulations were published February and October 2019.

EMA will be consulted by notified bodies on companion diagnostics and medical devices composed of substances and will provide opinions to the European Commission on borderline products.

The MDR has a transition period of three years and will fully apply from 26 May 2020. The IVDR has a transition period of five years and will fully apply from 26 May 2022.

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- EMA webpage: https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices

Action:

- Following the public consultation on the EMA draft guideline on quality requirements for medical devices in combination products, EMA is now planning a workshop in March 2020. More details will be provided once available.

2.3 Clinical trials

- A. Marcal (EMA) highlighted the key changes introduced by the CT Regulation and how it differentiates from the existing CT Directive. She presented EMA's role in its implementation including the development of the Clinical Trials Information System (see presentation). She explained which information will be included within the database and gave a demonstration of the developing system itself. Various user-training options will be available before and once the system goes live. The system is being developed in close collaboration with the European Commission, member states and relevant stakeholders including sponsors, CROs, HCPs and patient representatives. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance
- EMA webpage: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation

Action:

- EMA/PCWP/HCPWP co-chairs to explore suggestion to include virtual CTs, eConsent and eSources as a topic to be addressed in an upcoming PCWP/HCPWP meeting.

3. Antimicrobial resistance

3.1 Findings from ECDC's survey on healthcare workers' knowledge and attitudes about antibiotics and antibiotic resistance

In his presentation, J. Kinsman (ECDC) shared the methodology and results on a survey of healthcare workers' knowledge, attitudes and behaviours on antibiotics, antibiotic use and antibiotic resistance in the EU/EEA, as well as the lessons learned from the survey results (see presentation).

ECDC webpage: https://www.ecdc.europa.eu/en/news-events/first-its-kind-survey-reveals-gaps-european-healthcare-workers-knowledge-and-attitudes

Action:

- Members to share any comments on the findings of the survey directly to ECDC

3.2 EMA communication campaign for EEAD 2019 and discussion on focus for 2020

A. Faia (EMA) presented the campaign for the 2019 European Antibiotic Awareness Day (EAAD) that includes several targeted info-cards addressed to patients and to healthcare professionals (see presentation). In the development of the info-cards emphasis was given to the role and responsibility of each stakeholder.

- EMA webpage: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/antimicrobial-resistance#public-awareness-section

Action:

- EMA welcomes dissemination of the info-cards by PCO and HCP organisations as well as subequent feedback from on interactions: e.g. shares, likes, comments, mentions, messages;
- Re-send email with set of info-cards in all EU languages;
- New survey to decide 2020 campaign themes will be circulated during Q1.

4. Training strategy

4.1 Introduction

M. Mavris (EMA) presented the current state of play regarding training at EMA, together with some objectives and future ideas for expanded training. With the objective of revising the training strategy for patients to include healthcare professionals (see presentation). She raised questions that were discussed in 4 breakout sessions and the outcomes subsequently reported back to the plenary.

Patients and healthcare professionals agreed that an EMA training strategy is necessary.

Emphasis was made on the following topics

- Role of EMA
- EMA's role within the European Medicines Regulatory Network
- Role of organisations/individuals at EMA
- How to prepare/participate in EMA activities
- Description of the different authorisation pathways
- Activities of each EMA scientific committee
- Updates on regulations update – clinical trials, medical devices, veterinary

Participants felt that blended learning was the best approach (using both face to face and online tools)

It was agreed to explore accreditation of time spent on training.

Action:

- A revised training strategy will be prepared using feedback collected during the breakout sessions and will be presented at a future PCWP/HCPWP meeting.

AOB

No AOB topics

End of meeting