



4 October 2019
EMA/546723/2019
Stakeholders and Communication Division

Meeting summary - Patients and Consumers Working Party (PCWP) meeting

24 September 2019

Co-Chair: Juan García Burgos (EMA)

Tour de table and presentation of all members

J. García Burgos (EMA) welcomed the 4 new PCWP member organisations:

- European Liver Patient Association (ELPA)
- Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)
- Thalassaemia International Federation (TIF)
- United Parent Projects Muscular Dystrophy (UPPMD)

1. Election of PCWP co-chair

1.1 PCWP co-chair election proceedings

N. Bere (EMA) presented the process of elections

- 3 candidates expressed interest and submitted their motivation letters.
- Election was by secret ballot. There was quorum of members in the room eligible to vote. Two proxy votes were assigned:
 - PRAC to EURORDIS
 - COMP to EPF
- Kaisa Immonen (EPF) was re-elected as PCWP co-chair by absolute majority of the members during the first round of elections.

A member of the EMA legal department, who was present, endorsed the election procedure.

1.2. Nomination of observers to the HCPWP

HCPWP Observers (alternating):

Kathi Apostolidis (ECPC) and Marilena Vrana (EHN)



2. EMA Regulatory Science to 2025

2.1 PCWP engagement in the strategic reflection - workshop in November 2019

A. Humphreys (EMA) presented the results of the preliminary analysis of the public consultation on the [EMA draft 'Regulatory Science to 2025' strategy](#), which is a plan for advancing EMA's engagement with regulatory science over the next five to ten years, covering both human and veterinary medicines (see [Strategic Reflection](#) document). EMA published its draft Regulatory Strategy in December 2018 for a six-month public consultation. The draft strategy incorporates feedback from two workshops with stakeholders in 2018. A. Humphreys' presentation focused on the feedback from individual members of the public, Patient and Consumer Organisations and advocacy groups and presented the overall aggregate ranking of core recommendations.

Actions:

- Upcoming EMA Workshop on Human (November 18th-19th) and Veterinary (December 5th-6th)
- Consultation results, along with the outputs from the workshop, will be published as soon as possible following the workshops.
- Finalisation of the RSS to 2025 is scheduled for 1Q 2020
- PCWP to discuss a common approach to RSS 2025

3. CIOMS "Guidance on patient involvement in the development and safe use of medicines"

3.1 Update from CIOMS Working Group XI

I. Moulon (EMA) and F. Houyez (EURORDIS) presented the CIOMS "Guidance on patient involvement in the development and safe use of medicines" (see [presentation](#)). Since April 2018, the [CIOMS Working Group XI](#) is developing this guidance which objective is to formulate pragmatic "*Points to Consider*" in patient involvement by providing a comprehensive overview of present knowledge and existing initiatives. The guidance will also address a wide range of remaining challenges and practice gaps in patient involvement.

Actions:

- Topic to be further discussed at the PCWP/HCPWP joint meeting of March 2020