17 December 2015
EMA/670072/2015

Annex 1

Extract from the published minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

4 June 2015 – 08:30hrs to 12:00hrs, meeting room 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA), David Haerry (PCWP) Gonzalo Calvo Rojas (HCPWP) (apologies)
Present:	**PCWP members**: AGE Platform Europe (AGE); Alzheimer Europe (AE); European AIDS treatment Group (EATG); European Cancer Patient Coalition (ECPC); European Consumers' Organisation (BEUC); European Federation of Allergy and Airways Diseases Patients' Associations (EFA); European Federation of Neurological Associations (EFNA); European Heart Network (EHN); European Institute of Women's Health (EIWH); European Multiple Sclerosis Platform (EMSP); European Organisation for Rare Diseases (EURORDIS); European Patients' Forum (EPF); European Prostate Cancer Coalition (EUomo); Health Action International - Europe (HAI); International Alliance of Patients' Organizations (IAPO); International Diabetes Federation European Region (IDF Europe); International Patient Organisation for Primary Immunodeficiencies (IPOPI) **HCPWP members**: European Academy of Neurology (EAN); European Academy of Paediatrics (EAP); European Aids Clinical Society (EACS); European Association for Clinical Pharmacology and Therapeutics (EACPT); European Association of Hospital Pharmacists (EAHP); European Association of Urology (EAU); European Federation of Internal Medicines (EFIM); European League Against Rheumatism (EULAR); European Society for Medical Oncology (ESMO); European Society of Endocrinology (ESE); European Society of Radiology (ESR); Standing Committee of European Doctors (CPME); United European Gastroenterology (UEG) **Representatives from the Agency's Scientific Committees**: Committee for Advanced Therapies (CAT); Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Pharmacovigilance Risk Assessment Committee (PRAC)

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Role	Name
	European Commission via teleconference **External speakers**: Medicines and Healthcare Regulatory Agency (MHRA) **Visiting expert representative:** Food and Drug Administration (FDA), USA **Observers**: EMA Management Board; Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMDh); Spanish Agency for Medicines and Health Products (AEMPS); European Forum for Primary Care (EFPC), European Society of Oncology Pharmacy (ESOP); Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe); Pain Alliance Europe (PAE)

EU Network Strategy to 2020

I. Moulon introduced the topic underlining that the EU Network Strategy to 2020 was developed in close collaboration between the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). The proposed strategy was then presented and commented on by N. Wathion and M. Dias, on behalf of EMA, and by J. Mogford, Director of Policy at the MHRA, on behalf of the HMA.

N. Wathion (EMA) outlined the main steps of the preparation of the strategy, which was released for public consultation in March 2015. Once the consultation is concluded and its outcome is analysed and discussed between EMA and HMA, all contributions will be published in the form of an overview together with the action to be taken.

In parallel to the public consultation, the EMA was also gathering comments from EMA staff, Scientific Committees and the PCWP and the HCPWP. A discussion followed on the key themes covered by the draft strategy. The document was welcomed with comments pointing to some areas that could be further explored or clarified as summarised below:

- use the opportunity of a joint strategy to stimulate patient involvement at national level;
- explore the possibilities of having an HMA observer at the level of the PCWP and interacting with the HMA network via its annual meeting;
- provide more information on what the performance indicators used to measure success will be;
- include references to WHO when possible (e.g. WHO priority medicines report; WHO drug surveillance work);
- continue to balance the handling of conflicts of interest with identifying the best available expertise to promote academia involvement in EMA activities;
- elaborate further on what will be the expected uptake by EMA of more sophisticated tools to support research in regulatory science, how will these be shared with HMA and how will they be explained to the public;
- some concerns were expressed around terms used in the document such as 'innovative medicines', 'unmet medical needs', 'convergence' that might create misconceptions and would benefit from additional clarification; it was also remarked that some areas of the document were more detailed than others where the text was very general.

The comments will be further assessed and considered by EMA and the HMA.

It was clarified that the proposed text had been agreed by consensus. Although in some parts of the document more general statements were included, additional detail would be provided by EMA and HMA within their respective multi-annual work-programmes.

In light of some specific comments made in relation to falsified medicines and international surveillance around quality of medicines crossing EU borders and beyond as well as aspects related to international collaboration at the level of regional Agencies and TTIP negotiations, it was suggested to revisit this at a future PCWP/HCPWP meeting. It was also suggested to address the topic of antimicrobial resistance and use of antibiotics in food producing animals at an upcoming meeting.

Participants were invited to submit their written comments to the public consultation by 30 June 2015.