25 August 2015
EMA/167556/2015
Stakeholders and Communication Division

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)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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)

Introduction

I. Moulon (EMA) welcomed all participants, including the observer from the Food and Drug Administration (FDA), and gave an overview of the topics to be addressed.

No conflicts of interests were disclosed in relation to the agenda items.

The agenda was adopted with two additional points to be covered under A.O.B. – EMA survey to stakeholders in relation to the publication of clinical data on medicines and EMA workshop on shortages.

1. Update on EC activities

1.1. European Commission study on off-label use

B. Mentré (EC) provided an update on the Commission's requested study to understand the ramifications of off-label use of medicinal products. In June 2014, PCWP and HCPWP were invited to comment on some elements of the terms of reference of this study. A tender was subsequently launched and the successful consultant was selected in January 2015. This is a consortium composed of the Netherlands Institute for Health Services Research (NIVEL), in cooperation with the Netherlands National Institute for Public Health and the Environment (RIVM) and the European Public Health Alliance (EPHA).

The study, which is a stock taking exercise covering both scientific (public health/patient safety-efficacy) and legal (regulatory framework) aspects related to the off-label use of medicines, will run for 14 months and its conclusions will be further assessed by Commission services and discussed with the Member States.

The project team will contact different stakeholders and Member State representatives to conduct interviews in order to provide the European Commission with a clear description of existing and potential future off-label use as well as an analysis of all parties' positions towards existing measures and tools to regulate this practise. This will be followed by group brainstorming sessions.

The Commission would welcome participation of organisations representing patients, consumers and healthcare professionals in the study.

PCWP and HCPWP welcomed the study and will encourage their organisations to take part.

2. Involvement in EMA activities

2.1. 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.

2.2. Update on EU Clinical Trial Portal and Database

F. Sweeney (EMA) updated participants on progress made since March 2015, emphasising that the public will be able to access, via the EU clinical trial portal and database, extensive details of each trial including the major characteristics of the trial, the start and end of recruitment, end date of the trial and substantial modifications to the trial.

These details will be made public as they occur; starting with the decision on the trial. A summary of results and lay summary will be published 12 months after the end of the trial. For those trials included in a marketing authorisation application in the EU, clinical study reports will also be published 30 days after the procedure for granting the marketing authorisation has been completed or the application has been withdrawn.

The Regulation requires that the clinical trial database shall be publicly available unless one or more of the following exceptions apply:

- protection of personal data;
- protection of commercially confidential information, in particular taking into account the marketing authorisation status of the medicine, unless there is an overriding public interest;
- protection of confidential communication between Member States in the preparation of their assessment;
- protection of the supervision of clinical trials by Member States.

The stakeholders' views on EMA's proposed options for the application of these exceptions were sought in a public consultation concluded in February 2015. In order to facilitate a system for publication of data and documents that is simple, predictable and automatic, clinical trials are proposed to be grouped into three categories: 1) pharmaceutical development; 2) therapeutic exploratory and confirmatory; and 3) therapeutic use. Taking into account such categorisation, time of publication is then defined by specific events (i.e. decision on the trial; end of trial; 12 months after end of the trial; 30 days after marketing authorisation (MA) decision or withdrawal; fixed period of years after the trial in the absence of MA by that time).

Following further assessment of the outcome of the public consultation the EMA, in close collaboration with the Member States and the European Commission will revise the choices to be made on publication of information. The agreed rules will be submitted for endorsement in the October 2015 Management Board meeting.

One participant requested clarification in relation to information to be made public on the clinical trial investigator, namely how economic interests and institutional affiliations that might influence impartiality would be disclosed. There was a suggestion that investigators could be asked to complete a declaration of interests as already occurs for experts involved in EMA activities. F. Sweeney explained there was a need to have more concrete guidance on how this will be implemented and that this was a matter yet to be discussed with Member States and the European Commission.

Another participant inquired about who would be monitoring the summary of results of the trial and the laypersons summary as well as enforcement of the 12 months rule. F. Sweeney clarified that it is the responsibility of the clinical trial sponsor to submit the summaries; there is no capacity to review these documents as volume is very high but guidance and templates will be developed in order to establish common grounds of what should be included (please refer to the PCWP meeting of 3 June 2015 for a specific presentation on Guidelines on the summary of clinical trial results for laypersons).

PCWP and HCPWP members will continue to be updated on aspects related to the implementation of transparency rules and the EU clinical trial portal and database.

3. A.O.B

3.1. EMA survey on aspects related with the publication of clinical trial data

I. Moulon (EMA) informed that an EMA survey to stakeholders will be circulated to PCWP and HCPWP members after the meeting to ascertain views and preferences on format/search aspects of the public website of the clinical data publication project.

3.2. EMA workshop on shortages

B. Cuddy (EMA) briefed PCWP and HCPWP members on the plans to organise on 9 October 2015 a workshop on product shortages due to manufacturing/GMP and quality issues to follow up on progress made since 2013. The EMA would like to invite a smaller group from PCWP and HCPWP to take part in the shaping of the workshop programme.

A call for expressions of interest to join such group will be circulated shortly after the meeting.

The chairpersons thanked the participants for their contribution and participation in the meeting.

Close of meeting

Workshop on risk-minimisation measures: 16 September 2015

Next PCWP/HCPWP joint meeting: 17 September 2015