27 August 2015
EMA/377881/2015
Stakeholders and Communication Division

# Minutes of the EMA Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) meeting

4 June 2015 – 13:30hrs to 16:15hrs, meeting room 3E

| Role | Name |
|---|---|
| Chair: | Isabelle Moulon (EMA) |
| Present: | **HCPWP members**: European Academy of Neurology (EAN); European Academy of Paediatrics (EAP); 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)<br>**Representatives from the Agency's Scientific Committees**: Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Pharmacovigilance Risk Assessment Committee (PRAC)<br>**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); Patients' and Consumers' Working Party (PCWP) |

## Introduction

I. Moulon (EMA) welcomed all participants and presented apologies on behalf of Gonzalo Calvo, co-chair of the HCPWP.

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

# 1. EMA framework of collaboration with Academia

## *1.1. Current state of affairs*

I. Moulon (EMA) presented the purpose of developing an EMA framework of collaboration with Academia, which is mainly intended to structure and shape such collaboration. She pointed to the fact that of all products approved through the centralised procedure, 17% of these products are initially developed by academia, which is not a negligible figure. It is also important to note that most of advanced therapy products that are presented to the EMA originate from academia or spin-off companies from universities, with a similar scenario also identified for orphan medicines. There are many designations for orphan medicines and certifications for advanced therapies; however the great majority does not translate into actual marketing authorisations, which raises the need to identify the root of the problem, by further collaborating with the academic community.

As part of the process of developing such framework, initial steps have already been taken in the sense of gathering information on current interaction by interviewing and carrying out an internal survey amongst some EMA colleagues who interact with academia in the course of their EMA activities. The preliminary results of this exercise were presented in order to stimulate a free discussion and capture the HCPWP members' ideas on this topic together with a number of EMA colleagues who also contributed to the discussion.

## *1.2. Discussion on the key components of the framework*

I. Silva (EMA) facilitated the brainstorming session, covering the following areas:

- Current collaboration, unmet medical needs and scientific progress, translation of scientific advance into drug development and drug utilisation;
- Drug development and pre-authorisation/ 'Incentives' (regulatory support) / Advise on protocols and methods/ Research networks;
- Drug utilisation and post-authorisation/ safety and efficacy studies/ patient registries;
- Communication/Awareness/Visibility/ Reaching out to academics.

The open discussion provided very rich input, which will be captured in a working document aimed at supporting the drafting of the framework. Overall, the main elements emerging from the discussion revolved around the following points:

- Overall positive feedback on EMA's initiative to develop a framework of collaboration with academia;
- Need to do an exercise (similar to what has been done internally with EMA colleagues) to collect the unmet needs/gaps on the academic side of the professional organisations/learned societies to find out what they do not know about the EMA and where mutual benefit from interactions could be identified;
- Identify and target specific audiences with tailored mechanisms of interaction to enable meaningful collaborative approaches - four possible groups with whom the Agency needs to develop interaction (which have different needs and would require different approaches) could be the following: 1) centres striving for excellence in education and research (pure academic centres); 2) groups focusing on translational sciences (public research organisations at member state level); 3) academics organised in learned societies; 4) professional associations (acting and performing research in primary and secondary care);

- Use existing conferences, training courses and educational programmes to integrate and foster knowledge about the EMA and the regulatory environment;
- Take a strategic approach to communication, moving away from the purely regulatory style and using available platforms and know-how within learned societies to appeal more to practicing clinicians and clinical academics;
- Start small and expand progressively.

Comments gathered during the brainstorm session will inform the drafting of the framework and once a draft document is prepared this will be circulated to the HCPWP.

## 2. HCPWP topic groups

I. Silva (EMA) gave an overview of the drivers, key objectives and proposed high-level plan of action for each of the following topic groups:

- Social media;
- Risk minimisation measures and assessment of their effectiveness;
- EMA/CHMP/PRAC projects on information on medicines;
- Academia, learned societies and healthcare professionals' organisations.

As a follow up action from the discussions under the previous agenda item, it was agreed to include a survey to gain additional insight amongst learned societies as part of the HCPWP topic group on academia, learned societies and healthcare professional organisations.

It was clarified that each organisation can nominate different members to ensure participation in as many groups as they wish.

Kick-off teleconferences will be organised in June/ July to agree in detail on the working methodology and plan of action as well as to identify the co-leads from the side of the professional organisations. Regular progress reports will be provided in the course of upcoming HCPWP meetings.

There was general agreement with the proposed direction of travel.

## 3. A.O.B

There was no other business.

The chairperson 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