15 April 2014
EMA/155728/2014
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

25 February 2014 - chaired by Isabelle Moulon

Present

Representatives from Healthcare Professionals' Organisations: European Association for Clinical Pharmacology and Therapeutics (EACPT), European Aids Clinical Society (EACS), European Association of Urology (EAU), European Association of Hospital Pharmacists (EAHP), European Federation of Internal Medicines (EFIM), European League Against Rheumatism (EULAR), European Society of Cardiology (ESC), European Society for Medical Oncology (ESMO), European Society of Radiology (ESR), European Union Geriatric Medicine Society (EUGMS), Pharmaceutical Group of the European Union (PGEU), Standing Committee of European Doctors (CPME), The European Specialists Nurses Organisations (ESNO), United European Gastroenterology (UEG)

Representatives from Patients' and Consumers' Organisations: AGE Platform Europe (AGE), Alzheimer Europe (AE), Europa Uomo-The European Prostate Cancer Coalition (EUomo), 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 Public Health Alliance (EPHA), Health Action International (HAI), International Diabetes Federation Europe (IDF Europe)

Representatives and observers from the Agency's Scientific Committees: Committee for Advanced Therapies (CAT), Committee on Herbal Medicinal Products (HMPC), Committee for Medicinal Products for Human Use (CHMP), Committee for Orphan Medicinal Products (COMP), Pharmacovigilance Risk Assessment Committee (PRAC)

Observers: Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), EMA Management Board (MB), European Food Safety Authority (EFSA), European Forum for Primary Care (EFPC), European Hematology Association (EHA), Medicines and Medical Devices Agency of Serbia (ALIMS)

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. Introduction

The chair welcomed all participants to the joint meeting and gave an overview of the topics to be addressed.

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

The agenda was adopted with no additions.

1. Involvement in EMA activities

1.1 Funding of organisations

Juan Garcia (EMA) presented an overview of the latest updated proposal regarding the evaluation of financial information from patient/consumer and healthcare professional organisations for assessment of EMA 'eligibility' following extensive previous discussions within the PCWP/HCPWP. This now incorporates feedback received from all eligible patient/consumer organisations in December 2013.

It was made clear that eligibility of an organisation to work with the agency allows them to be involved in discussions on general topics, but that eligibility is not sufficient for involvement on specific product related activities. When involving individual patients, consumers or healthcare professionals on specific product related activities, the 'EMA policy conflicts of interest applies'.

The main changes relate to the limitation to the amount of funding which can be received from a single pharmaceutical company, the publication of yearly financial accounts and the adherence to a 'code of conduct/rules with regards to the relations of an organisation with industry'.Regarding the latest, one member asked which code of conduct/rules should be used? The EMA explained that they could not recommend or endorse any particular one and that it was up to individual organisations, to either develop their own or adhere to for example an existing one which is already in place and used by some organisations (to be further developed within the context of the EUPATI project).

The proposals and text were agreed by all organisations.

1.2 Update on supply shortages activities

Andrea Taft (EMA) presented an update on the current work progress of the sub-groups dealing with shortages of medicinal products due to manufacturing and quality defects. This was a follow up to the presentation given to the working parties in June and September 2013.

The EMA, together with member states developed an initiative in order to prevent and coordinate with supply shortages more efficiently (Shortages). A reflection paper and associated implementation plan 2012 – 2015 has been prepared outlining a plan to prevent, mitigate and manage shortages of important medicines. It includes a number of activities to encourage a more active risk management by the pharmaceutical industry, and to ensure effective communication with all concerned parties, including patients and healthcare professionals.

The EMA held several meetings with industry associations, which are planned to continue throughout the year. Input from patient and healthcare professional organisations will be sought when applicable. Furthermore, international cooperation amongst regulatory authorities will also be strengthened.

Andrea explained that the agreed papers on decision tree for escalation of shortages from a national to the European level, as well as the classification criteria for "critical" medicinal product have already

been applied and used in several cases with positive feedback. The effectiveness of the proposed processes will be evaluated in 2015, when more experience is available.

The EMA also held a workshop on this topic in October 2013, in which the representatives of patients and physicians actively participated along with industry and regulatory authorities (presentations and video are available online).

A drafting group of patient and healthcare professional organisations prepared a common position paper from their viewpoint, including proposals for shortage prevention, communication and management.

During the Q&A session, Andrea clarified that although there are other causes for shortages, e.g. distribution issues, these are not in the EMA's remit; the Agency is empowered to coordinate shortages resulting from manufacturing and quality defects. It was mentioned that the EMA catalogue on shortages should include when shortages occur related to national medicines, however it was previously agreed that the Agency would publish information on shortages in relation to centrally authorised medicines or those, which were escalated to the European level (CHMP or PRAC), as others are dealt with at member state level.

1.3 Overview of HCP involvement in EMA activities during 2013 and opportunities for EMA awareness raising

Ivana Silva (EMA) provided an overview of the involvement of healthcare professionals and their organisations during 2013 (see presentation). The key achievement being the formal establishment of the EMA Healthcare Professionals Working Party (HCPWP), and the election of Isabelle Moulon and Gonzalo Calvo as co-chairs, as well as an increased involvement of individual HCP experts across many EMA activities. The future steps will be the assessment of current involvement and to identify room for improvement, increase awareness on the involvement of HCPOs in EMA activities and explore ways to further recognise the experts involved in EMA activities.

After the presentation a participant highlighted that there are challenges to find suitable experts, without conflicts of interest who are available within sometimes short deadlines. The EMA responded that they were aware of these difficulties and wherever possible provide as much prior notice as possible.

Nathalie Bere (EMA) then gave a short presentation highlighting where EMA staff members have been invited to speak at organisation events during 2013/2014 to highlight patient and healthcare professional involvement in EMA.

The Agency aims to increase external awareness of the involvement of these stakeholders in its work. To increase visibility of this interaction organisations are asked to identify any relevant European events which would merit EMA presence and to suggest other means for increasing awareness within organisation networks, e.g. articles, interviews, posters, internal meetings? Increasing awareness will lead to extended outreach and improve understanding of EMA's work.

1.4 Feedback from Scientific Committee Members

Jane Ahlqvist Rastad (PRAC) gave a presentation on the committees' activities, specifically focusing on recent safety referrals.

This was followed by Dinah Duarte (CHMP) who gave an overview of CHMP opinions Sept-Dec 2013 with concrete examples of patient/healthcare professional involvement.

Harald Enzmann (CHMP) then verbally introduced a proposal to initiate a pilot phase within the CHMP, whereby patients would be invited to participate in some oral explanations, where it is felt that they can provide useful complementary information in terms of real life experience to the benefit/risk discussions. Patients are already involved in benefit/risk discussions through scientific advice and scientific advisory group meetings and this proposal is a step forward in ensuring a patients voice can be obtained along the medicines lifecycle. It is proposed to invite two patients, with experience of the condition under discussion, accompanied by a more experienced patient (PCWP member) and the pilot phase would last for at least one year to be able to fully assess feasibility of the project. This will be presented at the CHMP meeting in March.

Daniel O'Connor from the COMP, Olli Tenhunen from the CAT and Steffen Bager from the HMPC also gave short updates from their respective committees.

2. Pharmacovigilance

2.1 Proactive pharmacovigilance – signals detection

Georgy Genov (EMA) presented an overview of the new processes related to signal detection and Management (see presentation). The new pharmacovigilance legislation includes four key topics in this area; Collection of key information on medicines, better analysis and understanding of data and information, regulatory action to safeguard public health and communication with stakeholders. Georgy gave a detailed summary on the definition of a signal, where the information comes from and how it is studied and handled, and how all concerned stakeholders are involved throughout. He also provided recent statistics and some examples of signals discussed at the PRAC. He finalised with an explanation on the increased transparency through the public communication of ADR information and outcomes.

Following the presentation a few questions were asked from the floor; such as how does the EMA prioritise requests for EudraVigilance Data analyses? Georgy responded that large requests (e.g. research request by Academia) are dealt stepwise manner and so far the EMAs well able to agree pragmatic approach with requesters and there has not been the need to reject/postpone and that requests have been answered accordingly.

It was also asked whether all countries report ADRs? Georgy explained that there was a difference in the level of reporting between MS.

Members highlighted to need to look at the transparency of data; more access and awareness, and the need to look how to stimulate an increase in overall reporting of ADRs.

2.2 Guidance on ADR reporting

Nathalie Bere (EMA) provided an update on the final version of the "Guidance for patients on direct reporting". This has been prepared in collaboration with patient organisations and has been presented to the PCWP/HCPWP in 2013.

The key information is presented on the first page with additional information included on the reverse in the form of 'Frequently Asked Questions'.

It aims to inform patients that they can report directly, explaining why they should report and how they can report; here we refer them to the PL, their doctor/pharmacist or to consult their national website (link attached includes same info as given within the PL).

This does not imply NCAs have standard web forms available for patient reporting, but informs that various methods may be available according to the national system.

This guidance has been approved by relevant teams within the pharmacovigilance project coordination group. The next steps are to present it to the PRAC, Inform all Heads of Medicines Agencies, translate in all EU MS languages (translations will be sent to PCWP for comments) and to publish on EMA website and disseminate to EMA eligible patient/consumer/HCP organisations and make available to all MS for use as required.

2.3 Action Plan Medication Errors

Thomas Goedecke (EMA) gave an update on the medication error action plan (see presentation). Medication error refers to any unintended error in the prescribing, dispensing or administration of a medicine and the new legislation obliges reporting of ADRs associated with medication errors to the EudraVigilance database. The EMA held a workshop on medication errors early in 2013 including regulators, patient safety agencies, patient and healthcare professional representatives, academia and the pharmaceutical industry (report: http://Medication Errors workshop). The workshop resulted in several recommendations leading to specific actions which were then proposed to Heads of Medicines Agencies in November 2013 who agreed the deliverables be completed by Sept 2015 and Member States to provide input via existing development frameworks.

The final action plan with milestones is expected to be published on the EMA website in April 2014 and the PCWP/HCPWP are encouraged to comment via the public consultation.

3. Transparency initiatives

3.1 EMA conflicts of interest policy for scientific committee members and experts

Frances Nuttall (EMA) presented an overview of the revision of the EMA conflicts of interest policy. The Agency held a workshop in September 2013 to elicit the views and concerns of stakeholders on the Agency's conflicts-of-interests policy for experts and has used the information gathered from this workshop for the proposed revision.

Frances explained that the revision will provide a more clear and practical policy with a risk-based approach to implementation; the highest risk given to decision making parties. There will also be a detailed guidance which will be published including continued professional development. The review will be robust and will ensure the policy is fit for purpose.

After the presentation, a participant enquired about general meetings with industry which are not product related, but are included within 'consultancy' which entails restrictions for involvement? Frances explained that the agency is trying to capture the right balance between involving relevant experts whilst ensuring public confidence in our system. Consultancy is considered a direct interest because usually money is involved and there are also intellectual conflicts to consider. It was highlighted that these kinds of examples could potentially be included within the guidance.

The revision will be presented to the MB for agreement in March.

3.2 Publication and access to clinical-trial data

Frances Nuttall also provided an update on the development of the publication of clinical trial data.

The Agency has been releasing clinical-trial reports on request as part of its access-to-documents policy since late 2010 and is now working towards publishing clinical-trial data proactively for the medicines it has assessed. As part of this process, the EMA released a draft policy on the publication and access to clinical-trial data in June 2013 for a three-month public consultation. During the consultation over 1200 comments were received, especially relating to private and commercially confidential data. The Agency is now defining what personal/private data is and preparing the format for future reports to be automated. It is important to prevent misuse of the information elsewhere and terms of use will be prepared. Patient raw data is not going to be available; this is likely for a later stage. The draft policy will be presented to the EMA Management Board in March.

Following the presentation it was mentioned that the EudraCT register does not currently include information for patients regarding the trial site location or contact person, to enable them to potentially volunteer. Frances agreed to take this comment on board for future consideration.

It was also asked whether the results of the public consultation will be available, the EMA replied that this will first be discussed at the level of the MB. Finally one member also emphasised that raw clinical trial data should be made available; there followed a discussion on the feasibility of anyone having access to this data without the knowledge to analyse such information.

Frances explained that the outcome of the on-going court case will also determine the way forward.

3.3 Principles for publication of agendas and minutes of EMA scientific committees

Isabelle Moulon showed the participants where the Agency systematically publishes all of the committees' minutes and agendas on its website.

4. AOB

4.1 Change of next meeting date

Due to unexpected circumstances, the next meeting date has been moved to 3 June (from 18/19 June).

4.2 Experts on secondment

The EMA has launched a new call for expression of interest for two "experts on secondment" to join the Agency; one for academia/HCP involvement and one for patient/consumer involvement. This would be for one year, renewable (see rules and job descriptions: Recruitment). Members were encouraged to circulate the call.

The Chair thanked all participants and closed the meeting.