25 July 2014
EMA/335623/2014
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

3 June 2014 – 09:00hrs to 16:30hrs, meeting room 4A - chaired by Isabelle Moulon (EMA) and David Haerry (PCWP)

Role	Name
Co-chairs:	Isabelle Moulon (EMA) and David Haerry (PCWP)
Present:	**PCWP members:** 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 Heart Network (EHN); European Institute of Women's Health (EIWH); European Organisation for Rare Diseases (EURORDIS); European Patients' Forum (EPF); European Public Health Alliance (EPHA); Health Action International Europe (HAI Europe); International Alliance of Patients' Organizations (IAPO); International Diabetes Federation European Region (IDF Europe); International Patient Organisation for Primary Immunodeficiencies (IPOPI); Patients Network for Medical Research and Health (EGAN) **HCPWP members**: European Academy of Paediatrics (EAP); European Aids Clinical Society (EACS); European Association for Clinical Pharmacology and Therapeutics (EACPT); European Association for the Study of Diabetes (EASD); European Association of Hospital Pharmacists (EAHP); European Association of Urology (EAU); European Federation of Neurological Societies (EFNS); European League Against Rheumatism (EULAR); European Society for Medical Oncology (ESMO); European Society of Cardiology (ESC); European Society of Endocrinology (ESE); 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 the Agency's Scientific Committees**: Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Role	Name
	Products (COMP); Pharmacovigilance Risk Assessment Committee (PRAC) **Observers:** EMA Management Board; Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)); European Academy of Allergology and Clinical Immunology (EAACI); European Forum for Primary Care (EFPC); International League Against Epilepsy (ILEA)

Introduction

I. Moulon (EMA) welcomed all participants, including observers from the European Academy of Allergology and Clinical Immunology (EAACI), the European Forum for Primary Care (EFPC), and the International League Against Epilepsy (ILAE). She then provided an overview of the topics of common interest to be addressed.

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

The agenda was adopted with an additional update on the 'common position between patients', consumers, and healthcare professionals' organisations on supply shortages of medicines' to be covered under A.O.B.

1. Involvement in EMA activities

1.1. Update on EMA's clinical-trial data policy - principles for redaction of clinical study reports to be published

N. Wathion (EMA) provided an update on the EMA draft policy for the proactive publication of clinical-trial data.

Further to the public consultation phase in mid-2013, the Agency carried out a final round of targeted consultations with key stakeholders (i.e. patients'/consumers' organisations and healthcare professionals' organisations; pharmaceutical industry associations including small and medium sized enterprises; and representatives from academia, research bodies and medical journals) in May 2014, following discussions at its December 2013 and March 2014 Management Board meetings.

The aim of such consultations was to provide an update on progress made since the end of the 2013 public consultation, to inform on the envisaged amendments to the draft policy (in order to address concerns related to the concept of commercially confidential information (CCI) and the protection from unfair commercial use; protecting patient confidentiality; and the concept of raw data), and in particular, to consult on the characteristics of the managed publication process (including technical measures to make the data available under the policy including their terms of use (ToU)), and the principles for possible redaction of the clinical study reports (CSRs). These targeted consultations showed broad support for the policy, but highlighted concerns over a proposed view-on-screen access to the data. The concerns raised will be addressed and put to the consideration of the EMA Management Board at its meeting of 12 June 2014.

N. Wathion pointed out that the policy had been shaped in the absence of any specific legal provision mandating the EMA to publish documents submitted to the Agency by third parties. Consequently, a balanced approach was needed taking into account different stakeholders' competing interests, within the limitations of the current legal framework. This compromise allows access to clinical data, but at the same time aims to discourage unfair commercial use of the data.

The policy sets out clearly that the majority of data in clinical study reports is not CCI and provides a common understanding with applicants on what information can be considered as CCI. CCI is defined, for the purpose of the policy, as '*any information contained in the clinical reports submitted to the Agency by the applicant/marketing authorisation holder (MAH) that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH'.*

The policy provides redaction principles which will ensure a clear and transparent understanding of the redactions the Agency is prepared to consider. The starting point of the redaction principles is that CSRs do not, in general, contain CCI. However, there might be some CCI in exceptional cases where the Agency is prepared to consider the justifications for redactions, as is clarified in the policy. It is for the Agency to take the final decision on what is and is not to be redacted. The extent of what the Agency will redact will always be visible in the final documents that the Agency makes available.

In relation to the envisaged implementation of the policy, N. Wathion explained that the Agency had chosen a stepwise approach where the publication of CSRs will occur in a first phase and then, in a second phase, the Agency will endeavour to find the most appropriate way to make individual patient data (IPD) available, in compliance with privacy and data protection laws. This will involve consultation with stakeholders on the concept of IPD. More information on this consultation process will be provided at a later stage.

A number of questions were asked from the floor namely focusing on the relationships between the policy and the new Clinical Trials Regulation as well as on how the policy will not prejudice citizens' rights and public interest.

It was clarified that the new Regulation provides, for the first time, a direct legal basis for the release of clinical trial results. The policy will serve as a useful complementary tool ahead of the implementation of the Regulation when it comes into force no sooner than May 2016, and is without prejudice to the provisions within the Regulation. Furthermore, the policy is without prejudice to the access to documents legislation. There will be no difference in the understanding of commercially confidential information and how it is applied to documents held by the Agency that are requested through 'access to documents' or that will be proactively published by the Agency.

Post-meeting note:

On 12 June 2014, EMA's Management Board agreed the policy on publication of clinical trial data, together with more user-friendly amendments proposed by the EMA that will give the possibility to download, save and print the trial data for academic and non-commercial research purposes. In light of discussions at the Board, the wording of the policy, including practical arrangements for academic and non-commercial research users, will now be finalised with a view to its adoption by the Board through written procedure by mid-July 2014.

1.2. European Commission's study on off-label use

I. Moulon (EMA) introduced the topic by summarising the scope of the new pharmacovigilance legislation which now includes in its definition of adverse reaction those arising from the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors.

B. Mentre (EC) then gave a presentation on the context and scope of a European Commission's study on off-label use. Off-label use relates to situations where a medicine is intentionally used for a medical purpose not in accordance with the authorised product information. The study is intended to cover both

scientific (public health/patient safety) and legal (regulatory framework) aspects related to the off-label use of medicines in order to understand the ramification of the issue and identify any potential need for coordinated action at EU level.

The EC is drafting the terms of reference for the study and would like to gather the views from members of the HCPWP and PCWP on some elements of these terms. Once available, input will be requested within two weeks.

A participant remarked the importance of considering the concept of individualised/personalised medicines as well as patients' heterogeneity for a single condition when addressing off-label use of medicines.

Another participant asked whether the study would also explore the place of compassionate use and off-label use in the regulatory path for drug approval. B. Mentre explained that the study has a legal perspective aimed at analysing off-label use versus compassionate use.

Future collaboration of HCPWP and PCWP members with the consultants that will carry out the study would be welcome.

1.3. Update on the new clinical trials regulation

F. d'Atri (EC) provided an overview on the new Regulation on clinical trials (see presentation), focusing on the requirements for the authorisation procedure of clinical trials to be conducted within the EU. F. d'Atri underlined the aim of the regulation which is to facilitate and speed up the authorisation procedure of clinical trials in order to make the European Union more attractive for clinical research and to invert the decreasing number of investigations of medicines in humans conducted in the EU, while maintaining the high standards of patient safety. Whilst Member States will continue to make their independent decision, the regulation establishes that a single application will be sufficient for conducting clinical trials in several Member States. Under the previous legislation an application had to be submitted to each Member State where the clinical trial was to be conducted.

After several questions from the audience, the following clarifications were provided:

- the reporting Member State (responsible for coordinating the assessment of a clinical trial application) is decided amongst all Member States involved in the clinical trial; an advisory group led by the European Commission will be set up to identify the selection rules for a reporting Member State (Clinical Trials Coordination and Advisory Group – CTAG);
- a Member State can refuse a multinational clinical trial to be conducted in their territory under specific justification which will be made public; in the case of a negative opinion by a national ethics committee, the Member State in question can refuse authorisation to conduct the clinical trial in its territory; the clinical trial can nonetheless go ahead in the other Member States for which there was a positive opinion by the respective national ethics committees;
- although the original proposal was to include 'patients' in the composition of ethics committees, this was not consensual amongst Member States during the legislative procedure and the adopted Regulation foresees the inclusion of a 'lay person';
- taking into account the need to translate results of clinical trials into real life, the Regulation requests companies/sponsors to justify the exclusion of a particular population group; the grounds for such exclusion will be considered by the assessor evaluating the application;
- in a scenario where something may go wrong with a clinical trial, the concerned Member State can suspend the trial and oblige the sponsor to take corrective action;

- the CTAG will meet regularly to monitor the implementation of the Regulation.

A. Marçal (EMA) then outlined the role of the EMA in the implementation of the new Regulation (see presentation), explaining that whilst authorisation and oversight of clinical trials remains the competence of Member States, the new legislation mandates the EMA to prepare the IT platforms to support sponsors and experts in the Member States in carrying out their roles in relation to the authorisation of trials, their supervision, safety reporting and compliance activities, as well as to enable public access to information on clinical trials. A. Marçal underlined that the implementation of the Regulation is dependent on the establishment of the EU portal and database, as foreseen by the legislation. The Regulation will be applicable 6 months after the publication by the European Commission that the EU portal and database are functional, but in any event no earlier than 28 May 2016. As part of the development work associated with these IT platforms, the EMA will liaise with the relevant stakeholders for specific feedback. A number of meetings will be organised between the EU CT Information System Expert Group and Stakeholders with the first one already scheduled for 25 June 2014. Further involvement will be considered as progress is made.

Further to questions received it was clarified that as foreseen by Clinical Trial Regulation the Eudravigilance database will be used for safety reporting. With regards to the existing EudraCT the EMA will consider various options on how to deal with the legacy data from this database. Once the EU database as established by the new Regulation is fully functional, there will be a 3-year transition period to handle legacy data and enforcement is up to Member States.

At present, the data on the results of clinical trials are entered into the EudraCT database by the sponsors themselves on a voluntary basis and a summary of the results is published in the EU Clinical Trials Register. With the release of the final version of EudraCT expected by the end of June, all functionalities will be in place to enable the posting of results by sponsors on a compulsory basis.

1.4. RMP summaries – a new communication tool

J. Garcia Burgos (EMA) presented the steps undertaken by the Agency in order to make public risk management plan (RMP) summaries (see presentation).

Information on a medicine's RMP is currently included in the respective assessment report (as tabulated information) and the summary of the medicine (known as the 'EPAR summary' which is written in public-friendly language) has been adapted to include key information on the RMP. In addition, a standalone RMP summary has now been developed targeting readers who wish to know more about how the risks of a medicine are being managed.

The Agency started publishing RMP summaries in March 2014 and is piloting it for medicines authorised centrally for 1 year. Information gathered during the 1-year pilot phase will be discussed with stakeholders (patients, healthcare professionals, EU regulators and industry) to assess the usefulness of RMP summaries as a communication tool. The feasibility and impact of these summaries as a standalone document will be analysed as well as whether patients and healthcare professionals should revise them during reparation and prior to publication.

Some participants stated that the RMP summary is a useful document and having it anchored to the EPAR summary seemed logical. There was a suggestion to also create a link between the list of medicines under additional monitoring and their respective RMP summaries. The EMA clarified that there is already a link to the product information where the landing page is the medicine's EPAR page; nevertheless, integration and linkage of existing documents could still be improved in the context of the new European medicines web-portal. Another participant pointed to the importance of keeping the balance between risks and benefits and that these are clearly communicated.

PCPW/HCPWP members will be contacted at a later stage to participate in a short survey to assess experience gained during the 1-year pilot phase.

2. Organisational matters

Agency on the move

A. Brandt (EMA) presented the new EMA premises at 30 Churchill Place, Canary Wharf.

The next PCWP/HCPWP meeting will take place in the new building and a delegate's information package will be sent together with the invitation to the meeting.

Update on EMA's policy on handling of conflicts of interests (CoIs)

This agenda item was not addressed due to time constraints.

3. Sharing national experiences of involving patients and healthcare professionals in regulatory decisions

D. Nguyen-Bonnet (ANSM, France), S. Kruger-Peters (CBG-MEB, the Netherlands), J. Jolly (MHRA, UK), J. Ahlqvist-Rastad (MPA, Sweden) shared their experiences of involving patients and healthcare professionals in regulatory decisions from their Agencies' perspective (see presentations).

A lively discussion followed where by participants noted that whilst there is a variety of approaches and different levels of maturity in involving patients and healthcare professionals in the activities of the national medicines agencies across the EU, the increasing efforts to implement such involvement were clearly emerging. The exchange of information within the EU Regulatory network, as well as with representative patient and healthcare professional organisations, was highlighted as important and welcomed to further learn from each other's experience.

Following a request by PCWP members, EMA will propose a short survey to the Communication Professionals Working Group (National Competent Authorities) on this topic.

4. A.O.B

Common position between patients', consumers, and healthcare professionals' organisations on supply shortages of medicines

F. Houyez (EURORDIS) updated participants on progress made with endorsement of the document by different organisations and on the planned steps to increase awareness about this issue with Commission officials.

Workshop on benefit-risk communication 17 September 2014

I. Silva updated participants on the preparatory work for the planned PCWP/HCPWP workshop on benefit-risk communication, briefly outlining the topics and format of the workshop.

The chairpersons thanked all participants for their active contribution to the discussions and closed the meeting.

Close of meeting

Next PCWP/HCPWP meeting: 16 September 2014; followed by the PCWP/HCPWP workshop on benefit-risk communication on 17 September 2014