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Patient Health Protection

Annual Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) Joint Meeting

Meeting Minutes - 28 February 2012 - chaired by Isabelle Moulon

Role	Name
Present:	**Representatives from Healthcare Professionals' Organisations:** European AIDS Clinical Society (EACS), European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association of Hospital Pharmacists (EAHP), European Hematology Association (EHA), European Society of Medical Oncology (ESMO), European Society of Cardiology (ESC), European Union of General Practitioners (UEMO), Pharmaceutical Group of the European Union (PGEU), Standing Committee of European Doctors (CPME). **Representatives from Patients' and Consumers' Organisations:** European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Allergy and Airway Diseases Patients Associations (EFA), European Heart Network (EHN), European Federation of Neurological Associations (EFNA), European Multiple Sclerosis Platform (EMSP), European Older People's Platform (AGE), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Public Health Alliance (EPHA), Fabry International Network (FIN), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Rett Syndrome Europe (RSE), The European Consumers' Organisation (BEUC), The European Prostate Cancer Coalition (Europa Uomo). **Representatives and observers from the Agency's Scientific Committees:** Committee for Human Medicinal Products (CHMP),Committee for Orphan Medicinal Products (COMP) **Observers:** Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), EMA Management Board

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Welcome and introduction, interest disclosure and adoption of the agenda

Isabelle Moulon, Head of Medical Information Sector, chaired the meeting. She welcomed all participants and explained that, as agreed by the PCWP and the HCP WG, this was the first of two joint meetings planned for the year to further promote the interaction between both groups. She then invited participants for a *tour de table* to introduce themselves. EURORDIS referred to the PCWP mentorship and encouraged newcomers to use it.

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

The agenda was adopted with no additions.

1. Area of communication and information

1.1. Professionalisation of civil-society representatives in a European Union agency: a challenge to effective communication

A member of the Agency's staff gave a presentation on an academic research project that explored the tactics used by representatives of civil-society organisations to maintain their representativeness during long-term partnership with public bodies. The research showed evidence of professionalisation among the organisations interviewed (i.e. employed staff with professional backgrounds in public affairs, law, public relations) and outlined the techniques used by the organisations to overcome the risk of losing representativeness (see presentation).

Participants shared some of the practices in place in their organisations highlighting the specific issues faced by patient, consumer and healthcare professional organisations. Patient organisations recognised that the ideal situation would be to have a professional representative who would also be a patient although this was not always possible. Healthcare professional organisations mentioned the fact that their representatives are often healthcare professionals, but that it is difficult to find the most appropriate person in the organisation to represent the organisation on a specific matter.

This topic and the exchange of best practices among organisations will be further explored in future meetings.

1.2. Q&A on biosimilar medicines

Participants were informed about the ongoing update of the questions and answers (Q&A) document published by the Agency in 2008 on biosimilar medicines (see presentation). Biosimilars have gained a higher profile as more of them have been approved. Feedback received on the existing Q&A pointed out to the need to further explain the concept of similarity and include clarification on other related aspects such as interchangeability.

The Agency presented the draft updated Q&A.

Comments from the floor included a request to specify that biosimilars are not generics and to clarify that any change in prescription or any switch to a biosimilar medicine should always be done by a healthcare professional.

The chair invited organisations to submit their comments in writing within two weeks.

1.3. Public webpage on the summary of product characteristics

The Agency gave a presentation on a webpage dedicated to the summary of product characteristics (SmPC) (see presentation). The webpage was set up to facilitate implementation of the SmPC guideline among the regulatory network and contains SmPC related information and training presentations.

After one year of experience, it has been recommended to make it publicly available to share training material with pharmaceutical industry and other interested parties, and to increase awareness of the SmPC, in particular by Healthcare Professionals. For this purpose, a presentation entitled "SmPC: what is it and what does it contain?" has been drafted and circulated. Other presentations on the package leaflet and on older population and SmPC information may also be considered in the future.

Comments from participants included for example the need to clarify how the webpage and the presentation on SmPC will be available, and for which audience is intended (HCPs only or general public as well) as this would have an impact on the language used.

The chair invited organisations to provide comments in writing within one month on the draft SPC presentation.

1.4. Pandemic lessons learned: main recommendations on communication

The Agency provided an overview of its lessons learnt exercise 2010-2011[1] and underlined that communication has been identified as a key area for improvement, both during preparedness and during a pandemic (see presentation).

In particular, the lessons learnt report identified a need for a better future strategy on communication giving special attention to healthcare professionals. Critical issues where communication would need to be reinforced included difficulties during periods of uncertainty, use of adjuvants, recommendation for use in children and pregnancy, general vaccine uptake, and unexpected side effects. The report called for the Agency to harness the experience of its HCP WG to explore particular needs and concerns of healthcare professionals and to address those in designing future communications programmes. In addition, the way healthcare professionals and patients can get access to the information produced by the Agency would need to be addressed in the future.

Comments from the floor pointed out to the need to establish a network of trustable spokespersons at national level. Feedback received from some organisations was that the regular communication from the Agency enabled them to play their role in disseminating information among their (national) members. However this had triggered queries from members for which the organisations were occasionally unprepared to respond and for which EMA could not assist either.

In order to collect additional input from the PCWP and the HCP WG, it was agreed to circulate a questionnaire and based on the outcome of the written comments to organise, if necessary, a teleconference to further discuss improvements to the EMA future communication activities in this field.

[1] Pandemic report and lessons learned - Outcome of the European Medicines Agency's activities during the 2009 (H1N1) flu pandemic (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/04/WC500105820.pdf)

2. Area of clinical trials

2.1. EU clinical trials register (EU-CTR)

The Agency gave a presentation and a live demonstration of the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/) (see presentation). The register was launched in March 2011 and contains data from 1st May 2004 on European adult clinical trials of Phase II/III/IV and all the paediatric studies conducted in EEA. It also includes information on clinical trials conducted outside the EEA if they are part of an agreed Paediatric Investigation Plan (PIP). At present the registry does not include the results of the clinical trials but this information is expected to become available in 2013.

In order to raise further awareness and to promote use among patients and healthcare professionals the Agency would like to encourage PCWP and HCP WG members to include a link in their websites to the EU-CTR (*https://www.clinicaltrialsregister.eu/*). PCWP and HCP WG members agreed with this suggestion.

2.2. WHO international clinical trials registry platform (ICTRP)

The Agency informed participants that the EU-CTR had been recognised as a primary registry of WHO's International Clinical Trials Registry Platform.

EU-CTR's recognition means that its information will be available through the ICTRP web-based portal. It is also an endorsement of EU-CTR's importance for potential clinical-trial participants as well as sponsors, researchers, ethics committees and policymakers. In addition, this recognition will help authors include information on ongoing clinical trials in scientific publications as the International Committee of Medical Journal Editors (ICMJE) requires clinical trials to be registered prospectively in a public clinical trial register before accepting its inclusion in any publication.

3. Area of pharmacovigilance

3.1. Patients/Consumers participation in the PhVWP: experience gained

The PCWP observers to the Pharmacovigilance Working Party (PhVWP) gave a presentation outlining the experience gained so far. This will also be presented to the PhVWP.

Patient's participation has proven to bring an added value to the work of this working party and has been highly praised by the PhVWP chair and its members (see presentation). Whilst the PCWP observers provided a positive balance of their contribution to the working party, they underlined the workload involved and the personal commitment and investment needed to undertake such a role.

This experience was seen as very relevant for representatives of patients and healthcare professionals who will become members of the Pharmacovigilance Risk Assessment Committee (PRAC) as of this year. The PRAC will first meet on July 2012 with monthly meetings from September 2012. The group stressed the importance to provide adequate support to civil society representatives in the up-taking of their roles in the committee.

It was agreed that a proposal on how to support the new members of the PRAC representing patient and healthcare professional organisations will be prepared by Lise Murphy (PCWP co-Chair) building up on existing initiatives and materials. This proposal will be discussed at the PCWP and HCPWG in near meeting.

3.2. Outcome of consultation on additional monitoring of medicines and ADR reporting – impact on product information

The Agency presented the feedback (see presentation) from the consultation with stakeholders on the draft proposals to develop a:

a) Standard text to be included in the SmPC and in the PL to encourage reporting of adverse reactions by patients and health professionals.

b) Black symbol and a standard sentence to be included in the SmPC and in the PL to identify medicinal products subject to additional monitoring;

The feedback received will be collated together with feedback received from Member States and further public consultation. An updated proposal will be provided to the Pharmacovigilance and Risk assessment committee (PRAC) for finalisation.

Members of the PCWP and HCPWG will be informed of the external consultation once this is published.

4. Area of involvement in EMA activities

4.1. Involvement in benefit/risk activities: scientific advisory groups (SAGs)

4.1.1. What are SAGs?

The Agency gave a presentation explaining what SAGs are and which covered aspects related with their mandate, rules of procedure, handling of conflicts of interests of SAG members and the experience gained so far (see presentation).

SAGs are convened at the request of the Committee for Human Medicinal Products (CHMP) to deliver answers, on a consultative basis, to specific questions. An average of 25 SAGs are organised annually, covering different therapeutic areas. SAG members are normally academic clinical experts. The inclusion of patients and healthcare professionals in SAG meetings guarantee that experience from real life and clinical practice is brought into the discussions, as most frequent questions to SAGs deal with the clinical interpretation of benefits and risks of the medicines under evaluation.

4.1.2. Participation of civil society

Participants were informed about the outcome of the 'pilot phase' exploring the participation of patients in SAG meetings carried out during October 2010-October 2011 (see presentation). The purpose was to evaluate the contribution from the patient to the SAG meeting and the impact on the overall process. Based on the results of the pilot phase - which were overall positive - the Agency concluded that patients will continue to be invited to SAG meetings.

The full report on the pilot phase is available in the EMA website:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/12/WC500119201.pdf

Patient organisations welcomed the fact that one of the measures proposed by the report was to provide extra training and support to facilitate patients' participation and performance in these meetings.

The Agency also presented the experience gained in involving the EMA network of EU healthcare professionals' organisations in identifying the best independent experts for SAG meetings (see presentation). Healthcare professionals are principally identified via the organisations members of the

HCP WG. Organisations are asked to take into account the specificity of the expertise required. The difficulty to find suitable, independent who may be available on the day of the meeting was highlighted; moreover most SAG meetings are scheduled with short notice. Organisations are encouraged to propose several experts who can be contacted for a same meeting.

The Agency will continue to work towards identifying the best possible independent expertise by providing in advance a more detailed profile of the expertise needed in each case.

4.2. Framework for interaction with healthcare professionals and criteria to be fulfilled by healthcare professional organisations

Participants were informed that, following the endorsement of the framework, a call for expression of interest for healthcare professional organisations to become involved in EMA activities was to be launched the following day. Organisations are encouraged to submit their applications at any time, preferably throughout March 2012.

The chair also mentioned that a call for expression of interest to become involved in a focus group to discuss how the Agency can provide more targeted information to patients, consumers and healthcare professionals would be soon launched among members of the PCWP and the HCP WG.

5. A.O.B.

Participants received feedback on an ad hoc meeting organised the previous day to discuss aspects related with funding sources and handling of conflict of interest of patient and consumer organisations. A more concrete proposal will be discussed at the PCWP in May and this will also be presented and discussed with the HCP WG in order to capture the experience from healthcare professional organisations.

In the context of the implementation of the new legislation on pharmacovigilance, participants were also informed that the Agency is currently preparing a module addressing public participation in regulatory activities as part of the guidelines on Good Pharmacovigilance Practices (GVP). A public consultation will follow later on in 2012.

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