EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 August 2011
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Patient Health Protection

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

Meeting Minutes - 16 June 2011 - chaired by Isabelle Moulon

Role	Name
Present:	**Representatives from Healthcare Professionals' Organisations:** European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association for the Study of Diabetes (EASD), European Association of Hospital Pharmacists (EAHP), European Federation of Nurses Associations (EFN), European Union Geriatric Medicine Society (EUGMS), European Union of General Practitioners (UEMO), Groupement Pharmaceutique de la Communauté Européenne (GPEU), Standing Committee of European Doctors (CPME), The European Specialist Nurses Organisations (ESNO) **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 Institute of Women's health (EIWH), European Network of Fibromyalgia Associations (ENFA), 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), Global Alliance for Mental Illness Advocacy Networks (GAMIAN), Health Action International (HAI), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), The European Consumers' Organisation (BEUC), Thalassaemia International Federation (TIF), The European Prostate Cancer Coalition (Europa Uomo) **Representatives and observers from the Agency's Scientific Committees:** Committee for Orphan Medicinal Products (COMP), Committee for Advanced Therapies (CAT), Paediatric Committee (PDCO)

	Observers: Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), EMA Management Board

Welcome and introduction, adoption of the agenda

Isabelle Moulon, Head of Medical Information Sector, chaired the meeting. She welcomed and invited new participants to introduce themselves. EURORDIS proposed to add the topic "PCWP mentorship" under A.O.B. in the agenda. No conflicts of interests were disclosed in relation to the agenda items.

1. Area of pharmacoepidemiology

1.1. ENCePP: Where we are and where we are going

The Agency gave a presentation on the European network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) initiative, outlining its objectives, recent developments and guiding principles. The ENCePP network, which is led by the Agency, now includes 89 centres and 13 networks in 17 EU countries and aims at increasing independence, standards and transparency of clinical studies across EU member states. The audience expressed a high level of interest on this project and welcomed its promotion across Europe. Some participants flagged the current financial difficulties in conducting clinical trials in particular circumstances (e.g. in pregnant women and in the field of pharmacogenetics) and the Agency confirmed that the ENCePP mandate does not cover the commissioning and financing of clinical studies.

2. Area of information on medicines

2.1. eHealth – Users' involvement in EU initiatives

A representative from CPME presented an overview on the current EU eHealth initiatives and how users (patients, healthcare professionals, etc) are involved in the development of these tools. Participants highlighted that the potential of eHealth is enormous but expressed frustration regarding the current usability of these tools. They also highlighted the need for a clear strategy in this field and for an increased involvement of potential users, in particular older people, in early phase of development. Personal data protection and human rights issues were highlighted as important challenges in the development of eHealth.

2.2. Survey on EPAR summaries

The EPAR summaries were first published in 2006 and after five years of experience and feedback the EMA decided to review their format and content. In this context, Theo Raynor, Professor of Pharmacy Practice at the University of Leeds, presented the results of a study which applied the process of user testing to EPAR summaries. The study tested the current Bondronat EPAR summary with members of the public and then tested a revised version of the document, taking into account the results from the first round of testing. The results presented suggested room for improvement in the current content and format. EMA informed that the current format of the EPAR summary is being looked at and that the results of this study were noted.

Some participants raised questions about how to reach people with EPAR summaries. In this study, the pool of participants were members of the public, with a range of levels of education, who are the stated audience for EPAR summaries. The audience suggested that individuals with different culture and education would benefit differently from different formats of EPAR summary and underlined the importance to make the EPAR summaries understandable by and accessible to a wider range of people. Participants also debated the importance to maintain consistency among the original version of EPAR summaries and translations to other EU languages.

2.3. Website developments and 2011 web survey results

The Agency presented the results of the survey conducted during March 2011 on the EMA website. 528 replies have been received and analysed. A list of recommendations has been produced highlighting the need for: an increased range of search and browse functionalities, an email alert service, more granularity of information on some pages and an improved search engine. Recent upgrades of the website were also presented, which include: the possibility to download Excel files of EPARs, new disease area pages, new pages on the PharmacoVigilance legislation and a list of answers to the most frequent enquiries submitted to the Agency. One participant described the Agency’s website as an excellent source of information and invited members from the organisations to promote its use.

3. Area of clinical trials

3.1. EU Clinical Trials Register

The Agency provided participants with a presentation and a live demonstration of the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/). This portal was launched on 22nd 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 completed non-EEA studies which are part of agreed Paediatric Investigation Plan (PIP). Participants expressed much satisfaction about this information being published, and the way it can be accessed. Comments were made on the website. The Agency advised that font size when viewing the portal can be increased by clicking on the IE Browser tool bar menu >> view >> zoom feature. Some participants finally suggested to provide contact details of investigators and information on rejected clinical trials. PCOs were invited to be included in the database as contact points in the different therapeutic areas. PCWP secretariat will follow this up with the relevant PCOs.

3.2. Draft Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorization applications to the EU Regulatory Authorities

The Agency presented an overview of the draft reflection paper which was released for public consultation during 2010. This document is intended to provide information on the practical application of ethical standards for clinical trials conducted in third countries and which are submitted in Marketing Authorisation Applications (MAAs) to the EMA or to National Competent Authorities. It also highlights the practical steps to be undertaken during the provision of guidance and advice in the drug development phase and during the evaluation of Marketing Authorisation Application. The aim is to strengthen the overall process to assure, at the time of MAA assessment, that clinical trials conducted in third countries and submitted in Marketing authorisation Applications to the EMA or to the National Competent Authorities have been conducted in accordance with the principles of Good Clinical Practice and equivalent ethical standards as those applied/requested in the EU. Extensive comments were received during the consultation phase; many proposed that the paper focus more on the practical aspects, e.g.: the scope of the document extended to include clinical trials submitted in MAAs to

National Competent Authorities through decentralised, mutual recognition, or National procedures with the overall document length being streamlined and shortened.

The new draft will be circulated to the relevant Committees and Working Parties for comments by beginning of July 2011. Thereafter it will be submitted for adoption at the CHMP in September 2011 and at the EMA Management Board and the Head of Medicines Agencies in October 2011.

Please find the link to the Report of the International Workshop organized as part of the consultation phase on 6-7 September 2010:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106446.pdf.

3.3. Reflection paper on the Use of Interactive Response Technologies (Interactive Voice/Web Response Systems) in Clinical Trials

The MHRA gave a presentation on Interactive Voice Response System (IVRS) – telephone dial-in, and the Interactive Web Response System (IWRS) – similar to IVRS but used via the web. Both have been in existence for over 15 years and are used for several purposes such as patient enrolment and randomisation in Clinical Trials. These systems were developed initially to optimise drug availability at sites. However, this has expanded into other areas such as dose titration, unblinding and expiry date updating. This of course may, if not handled appropriately, pose an increased risk to the patient and so IVRS/IWRS is of increasing interest to National Competent Authorities. The audience was advised that a draft reflection paper prepared by the GCP Inspectors Working Group on this issue would be circulated shortly for comments. The paper seeks to provide guidance on the use of these systems and methods by which the National Competent Authorities could gain knowledge of the use of these systems. Further to the collection of comments by this group, it is anticipated that the draft paper will be published on the EMA website for public consultation in Q4 2011.

4. Area of geriatric medicines

4.1. Active and Healthy Ageing Innovation Partnership

EUGMS presented the Active and Healthy ageing innovation Partnership (AHAIP), a project that aims to increase the quality of life of older persons, diminishing the pressure on healthcare resources and stimulating innovation and employment. The presentation covered many aspects related to the increasing aging population and the current low capability of this society to meet the social and healthcare needs of older people.

4.2. EMA Geriatric Medicines Strategy

As a complement the EMA presented their Geriatric Medicines Strategy outlining the objectives, vision and key points behind this initiative. The strategy’s main target is to ensure that the development and evaluation of new medicines take into account specific safety and efficacy aspects related to the elderly population. It was pointed out that there is a need for an increased involvement of older people in clinical trials and, moreover, their enrolment criteria should take into consideration various factors such as the use of multiple medications and the real-life conditions for these patients. The audience expressed a high level of interest on this topic and participants were requested to promote the EMA Geriatric Medicines Strategy across their organisations.

5. Area of pharmacovigilance

5.1. The effectiveness of Risk Minimisation Measures in clinical practice

The Agency gave a presentation on risk management systems and the role of regulators in assessing effectiveness of risk minimisation activities. In particular regulators should ensure that: risk minimisation activities are clear, product information is targeted, comprehensible and reaches those who need it. Finally it also should be ensured that educational material is not promotional. In the context of risk minimisation activities, the Agency presented a list of questions to healthcare professionals and PCOs on the implementation of the Isotretinoin Pregnancy Prevention Program (PPP) in the EU Member States. Participants commented that differences observed among Member States could be explained by national difference in the current prescribing pattern, availability of generic products on each market and cultural diversity. These differences should be taken into account when analysing the results of the questionnaire. Feedback from HCP organisations will be collected by the end of July 2011 and discussed at the September meeting of the 2011 PhVWP and will serve as test exercise for the involvement of healthcare professionals and PCOs in the evaluation of risk minimisation activities.

6. A.O.B.

The chairperson thanked the participants for their contribution and participation and closed the meeting.