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Minutes of the joint meeting of the EMA Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) and the EMA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)

05 March 2010

Role	Name
Co-chairpersons:	Isabelle Moulon (Head of Medical Information/PCWP) and Noël Wathion (Head of Patient Health Protection Unit/HCP WG)
Present:	**Representatives of Patients' and Consumers' Organisations:** European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), The European Consumers Organisation (BEUC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), 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), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Patients with Primary Immunodeficiencies (IPOPI) and Health Action International (HAI). **Representatives of Healthcare Professionals' Organisations:** Standing Committee of European Doctors (CPME), European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association for the Study of Diabetes (EASD), European Federation of Nurses Associations (EFN), European Haematology Association (EHA), European Society of Cardiology (ESC), European Society of Endocrinology (ESE), Pharmaceutical Group of The European Union (PGEU), United European Gastroenterology Federation (UEGF) and European Union of General Practitioners (UEMO). **Representatives of Agency's Scientific Committees**: Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Committee on Herbal Medicinal Products (HMPC); Paediatric Committee

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Role	Name
	(PDCO), Committee for Advanced Therapies (CAT). Observers from: Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)) and Management Board (MB). **Observers from accession countries:** Croatia, Turkey, Montenegro and Serbia.

INTRODUCTION

Noël Wathion welcomed everyone to the meeting and introduced two new participants; European Haematology Association - EHA and European Federation of Allergy and Airways Diseases Patients' Associations - EFA.

The agenda was adopted with no changes or additions.

1. Area of involvement of stakeholders in the EMA activities

1.1. Road Map to 2015

Noël Wathion informed that this presentation was a follow up to presentations given during 2009 and was being presented with the aim of gathering some additional views from the different organisations.

The discussion commenced with the Agency general objectives and priorities for the next five years; the first priority remaining the success of its core business, with a focus on increasing the quality of the outcome of the agency work whilst at the same time strengthening efficiency. In addition to the core activities other objectives have been summarised into three strategic areas; addressing public health needs, facilitating access to medicines and optimising the safe use of medicines.

Overall the general feedback from the group was that the document was well written, concise and that the division into the three separate strategic areas is helpful. It was however mentioned that the document itself does not specifically outline how to implement its main objectives. Participants noted that, in their view, the Road Map should describe in more detail the collaboration with health technology assessment bodies (pre and post-licensing) and that benefit/risk methodology should be more communicable.

The EMA replied that the agency has learnt from the previous five-year strategy, and the Road Map to 2015 is a strategic document, which does not include all details, but rather highlights the direction in which the agency wishes to go. It sets out the vision and will be supplemented by a document detailing its implementation as well as yearly work plans. Details of the specific steps to be taken will be outlined in a separate document; "From Vision to Reality" which will be drafted following the outcome of the public consultation on the Road Map to 2015.

The EMA acknowledged the necessity to put in place international strategies to harmonise the work with other regulatory agencies and the need for a specific regulatory framework. It was confirmed that this interaction is already occurring and progressing fast, especially in relation to product safety issues. The discussion continued with the request for comments on each of the three strategic areas.

Main comments on the strategic area "Addressing public health needs" concerned the issue of unmet medical needs (e.g. rare diseases and paediatrics) within different disease areas.

Participants also noted that the general population should have increased access to adequate information, especially on concomitant use of medicines and access to documents which are not currently available, such as assessment of the benefit/risk balance.

In response to these observations, the EMA secretariat confirmed that the agency always aims to improve its role as a provider of information on medicines and the Road Map hopes to address such measures. Concerning the active role of the Agency in stimulating research and development, the chair explained that there is already a project in place - the "Innovative Medicines Initiative" which is ongoing, but in addition they will look at other ways within the implementation plan.

Participants asked how the Agency can be involved in initiatives from Patients Organisations aimed at combating inequalities in local legislation and improving awareness of unequal availability of medicines across Europe. The chair responded that the role of the national competent authorities (NCAs) and the EMA should complement each other and that there should be a close collaboration with the Heads of Medicines Agencies (HMA), as EU member states are best placed to deal with individual needs at the local level. The agency works within a network and needs to have a pivotal role in ensuring the availability of harmonised information. In general, the inclusion of the strategic area "Optimising safe use of medicines" into the Road Map was welcomed, and the importance of including patient experience when conducting pharmacovigilance studies was highlighted by the participants.

The EMA secretariat confirmed that the Agency would welcome any suggestions on how patient experience can be included in pharmacovigilance studies, and added that more specific actions, also in relation to risk minimisation measures, will be detailed within the "Vision to Reality" document.

The draft Road Map is currently available on the EMA website for written comments until 30 April 2010 and the use of the attached template is encouraged in order to facilitate the work of the secretariat.

2. New PCWP composition

Isabelle Moulon announced that following the launch of a call for interest at the end of 2009 to increase the membership of the PCWP, the new composition now includes five new members and is as follows:

European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Federation of Neurological Associations (EFNA), European Heart Network (EHN), 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), Health Action International Europe (HAI), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), The European Consumers' Organisation (BEUC).

In addition to the fifteen organisations above there are also five members who represent the EMA human scientific committees; Committee for Medicinal Products for Human Use (CHMP), Committee for Orphan Medicinal Products (COMP), Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO) and Committee for Advanced Therapies (CAT).

All members are nominated for a renewable term of three years which is effective from 5 March 2010. The group will continue to have observers coming from Management Board, Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)) and from the Healthcare Professionals' Working Group.

3. PhVWP update

The EMA secretariat gave an update on the progress of the proposal to have a patient or consumer as permanent observer (and alternate) for the PhVWP meetings. The proposal was presented to the Management Board in December 2009 and to the Heads of Medicines Agencies in January 2010 who agreed with the plan. Following a call for expression of interest, the EMA is finalising the procedure to select the observer and alternate. The EMA will inform all eligible organisations of the selected candidates in due time. The official participation will commence May 2010.

4. Scientific Advisory Groups (SAGs): participation of patients, consumers and healthcare professionals

The EMA presented the Scientific Advisory Groups which are groups of experts convened by the CHMP to provide advice during the evaluation of a specific product or treatment. Experts attend Scientific Advisory Group meetings to give their opinions on specific scientific questions. There are currently 7 Scientific Advisory Groups (Anti-infectives, Cardiovascular, Clinical neuroscience, Oncology, Central Nervous System, Diabetes and endocrinology, diagnostics and HIV/Viral diseases). Each Scientific Advisory Group meeting comprises core members as well as additional experts nominated for each meeting. An ad-hoc expert group meeting can also be convened where it concerns a therapeutic area for which there is no existing Scientific Advisory Group.

The CHMP reviewed the work carried out by the Scientific Advisory Groups during 2008/09 and the subsequent report proposed two actions which were agreed upon; 1) systematic involvement of patients and consumers at Scientific Advisory Group meetings and, 2) involvement of learned societies to help identify experts.

A Patient representative gave his personal experience of having participated at a SAG meeting recently; he felt that overall the patients' view made a difference to the discussion and the outcome.

Participants agreed with the added value coming from the participation of stakeholders in these meetings.

The chair informed that as of January 2010 patient representatives have systematically been contacted to attend the Scientific Advisory Group meetings and have attended three meetings so far.

One year from now a progress report will be made on the participation of the patients and consumers in Scientific Advisory Group meetings and this topic will also be re-discussed at the next PCWP meeting with all eligible organisations.

5. Involvement of patients and consumers in preparation and dissemination of European Medicines Agency communications – definition of criteria

This topic has been discussed at the PCWP since last year and follows an initial PCWP proposal led by Eurordis in which the need and added value of involving patients/consumers in "critical situations" was confirmed. In fact patients and consumers have already been involved in several safety communications (e.g. Viracept, Tysabri).

The EMA secretariat presented a practical proposal on how to involve eligible patients'/consumers' organisations in the agency's safety communications and as such the current framework on the interaction with PCOs will be revised to include this new procedure.

Involvement will include assisting with the preparation of communication material as well as the dissemination of the information after publication. Patients and consumers will be systematically invited to participate whenever the Agency prepares communications on emerging safety issues addressed to patients & consumers or when patients & consumers have been previously involved in the product's benefit/risk evaluation. Flexibility is needed as often the procedure has very short deadlines. These documents are highly confidential therefore all experts consulted must have signed the confidentiality undertaking in advance and all documents must be sent via EudraLink. Once published the final document will be sent to the contact person of the PCO for dissemination. Currently refusals and withdrawals of marketing authorisation application are not included within this procedure but can be disseminated to patients' and consumers' organisations once public.

Following PCWP agreement on these principles the procedure will be incorporated into the ongoing draft revision of the framework of interaction and will commence from April 2010.

Participants asked for the procedure to be established in detail; that the instructions given are very clear and the timelines clarified at each case.

The EMA will prepare a detailed document clarifying this procedure. Healthcare professionals also expressed interest and may be involved as a pilot phase.

6. Area of Advanced therapies

6.1. Unauthorised stem cell therapies

The Committee of Advanced Therapies (CAT) representative gave a presentation on the use of unauthorised stem cell therapies, and of the so-called "stem cell tourism" which have been discussed at the Committee of Advanced Therapies.

Stem cell research holds great promise for the development of new therapies for many serious diseases. The presentation addressed the problem of untested stem cell interventions being given directly to patients in clinics around the world where patients are put at risk with no proven benefit.

In response to these discussions the Committee of Advanced Therapies prepared a scientific article which is to be published in the near future.

The participants agreed this is an important issue for which action should be taken at national level.

6.2. Draft Public statement on access to medicinal products containing stem cells

The CAT has drafted a public statement to provide information for patients, consumers and the general public on the previous topic, warning of the risk derived from the use of untested medicinal products containing stem cells and recommending to only use these products within the regulatory framework. The document was presented by the EMA secretariat and feedback from the group was requested.

Overall it was felt to be a good initiative. Proposals for a better structure in order to adequately convey its message were given.

The EMA and CAT representative took note of the comments, which will be incorporated to the current draft. The statement will be published and circulated to both groups once finalised.

7. Visit of Commissioner John Dalli

7.1. Overview of the EMA's interaction with stakeholders

Isabelle Moulon gave a brief overview of the interaction of the European Medicines Agency with its stakeholders. Particular focus was put on the activities involving patients' and consumers' organisations, on the history of the PCWP and its main achievements to date; explaining how the interaction evolved over time to become organised into a proper working party. EMA activities involving the participation of healthcare professionals were also mentioned.

7.2. Address by John Dalli, EU Commissioner for Health and Consumer Policy

Noël Wathion introduced John Dalli, the EU Commissioner for Health and Consumers Policy who had expressed his interest to address the participants in the PCWP/HCP WG joint meeting. The Commissioner referred to the Agency's role in protecting public health by ensuring a rigorous control of medicinal products, and stated that patients and consumers should always come first and be at the centre of the Agency and the work of the EU institutions. To do this, there is the need to continue with a close cooperation and dialogue with stakeholders, in particular patients'/consumers' organisations. Commissioner Dalli acknowledged the value of the input from patients and consumers to the EMA and its scientific committees in different areas and activities and invited them to continue contributing to ensure delivery of the best service possible.

The Commissioner added that stakeholders' perspective is essential for the finalisation of the legal proposal on counterfeit medicines and pharmacovigilance, and for revisiting certain elements of the proposal on information to patients. In this respect, the Commissioner stressed the importance of providing high quality and understandable information to the public that responds to their needs. A special focus will be placed on clear difference between information and advertising. He thanked the participants for the valuable input that they have already provided to the European Commission during the preparation of these proposals.

The PCWP and HCP WG members agreed that it is important to consider the rights of patients and consumers, but also their duties and responsibilities. The "empowered patient" should be treated as anyone else and should not be discriminated against; there are currently health inequalities in access to care and in particular to newly marketed medicinal products. The Commissioner confirmed that one of the priorities is to eliminate discrimination and that the EU institutions work for an improvement in the publics' health behaviour by providing the right tools for making positive decisions towards a healthy lifestyle; prevention is identified as a cost-effective way of tackling health issues and a method to address inequalities.

The Commissioner confirmed once more that the EU institutions and the Commission in particular are very interested in continued dialogue with patients' consumers' and healthcare professionals' organisations, and thanked the EMA and all participants for all the work done so far in this aspect.

8. Area of Product Information

8.1. Benefit/risk of medicines: improving regulatory information towards better informed patients, consumers and healthcare professionals

The EMA secretariat gave a presentation on ongoing activities to improve the regulatory information provided to patients and healthcare professionals, in response to a EMEA/PCWP/HCP WG survey carried out in 2009. It emerged that there is a need to communicate benefits and risks together, to give a clear description of both qualitative and quantitative aspects, and to identify factors which may influence a benefit or a risk in an individual. Areas for improvement were identified for the summary of product characteristics, labelling and the package leaflet; for the public assessment report; and for product safety announcements.

The recent revision and implementation plan of the SmPC guideline were presented to illustrate how they will contribute to the optimisation of regulatory information, as well as the revised QRD annotated template which has now been released for public consultation. In addition, the EPAR (European Public Assessment Report) usability project, aimed at facilitating access and usability of EPAR information by all stakeholders, was briefly introduced. The meeting participants were asked to provide information on their experience with EPARs.

Many comments from the meeting participants pertained to the fact that very few people are even aware of the existence of the EPARs published on the EMA website, but that they are a valuable source to communicate products' benefits and risks. The participants mentioned that on the current website there are some difficulties navigating and locating the EPARs. It was suggested to explore ways to increase the visibility and awareness of these documents.

The EMA secretariat informed that the new website, which will become functional by 2Q2010, will facilitate the access and search of EPARs. Stakeholders will then be consulted to consider further improvements regarding the content and lay-out of EPARs.

8.2. The new Package Leaflet template

The EMA secretariat introduced the new QRD annotated template, with particular focus on the Package Leaflet (PL) section. The new QRD template has been recently released for public consultation until 3 May 2010.

The new PL has been revised following comments and discussions held at different fora, as well as the update of relevant European guidelines and the introduction of new legislation on advanced therapy medicinal products. Many of the suggestions collected during previous PCWP meetings have also been implemented within the new PL template. The EMA asked the patients, consumers and healthcare professionals for further input.

8.3. Overview on PROTECT IMI - Pharmacoepidemiological Research on Outcomes of Therapeutics – Innovative Medicines Initiative

The EMA secretariat gave an introduction on the project PROTECT-IMI (Pharmacoepidemiological Research on Outcomes of Therapeutics – Innovative Medicines Initiative), which is a public/private partnership with the goal of strengthening the monitoring of benefit-risk of medicines in Europe by developing innovative methods that will enhance the early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies).

The six main objectives of this project were illustrated, together with the potential impact of the project results. It was confirmed that there will be future updates and opportunities to collect input from patients' and healthcare professionals' organisations.

The chairpersons thanked the participants for their contribution and participation in the meeting.

Close of the meeting