31 January 2011
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Patient Health Protection

Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) with all eligible organisations - meeting of 30 November 2011

Role	Name
Chairpersons:	Isabelle Moulon (EMA-Head of Medical Information) and Lise Murphy (Eurordis)
Present:	PCWP members and eligible organisations: Alzheimer Europe (AE), 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 Institute of Women's Health (EIWH), European Liver Patients Association (ELPA), European Multiple Sclerosis Platform (EMSP), European Network of Fibromyalgia Associations (ENFA), European Myeloma Platform (EMP), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Public Health Alliance (EPHA), European Prostate Cancer Coalition (EUomo), Fabry International Network (FIN), Health Action International Europe (HAI), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Myeloma Euronet (ME), Rett Syndrome Europe (RSE), Thalassaemia International Federation (TIF) Representatives from the European Commission (via teleconference) Observers: Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMDh)
Apologies:	AGE Platform Europe (AGE), DEBRA International, European Genetic Alliances' Network (EGAN), European Heart Network (EHN), Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe), Insulin Dependent Diabetes Trust (IDDT), International Alliance of Patients' Organizations (IAPO), International Confederation of Childhood Cancer Parents Organisations (ICCCPO), International Diabetes Federation (IDF), European Parkinson's Disease Association (EPDA), Committee for Advanced Therapies (CAT), Committee for Orphan Medicinal Products (COMP), EMA

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Role	Name
	Management Board, Healthcare Professionals' Working Group (HCP WG), Pharmacovigilance Working Party (PhVWP), Committee for Medicinal Products for Human Use (CHMP), Paediatric Committee (PDCO), European Headache Alliance (EHA), Committee on Herbal Medicinal Products (HMPC)

Introduction

Isabelle Moulon and Lise Murphy (co-chairs) welcomed the participants to the meeting and thanked all those who had participated in the successful training session the day before.

Members were asked to declare any potential conflict of interest in relation to the topics on the Agenda - no issues were raised at this time.

Lise introduced the new EMA executive director, Guido Rasi, to the participants, followed by a tour-de-table whereby everyone introduced themselves and their organisations.

Guido Rasi explained that the patient/consumer contribution is of upmost importance when taking regulatory decisions which ultimately have an impact on many people's lives and the management of their disease. He emphasised this was also apparent within his personal experience as a physician.

He gave an example of how during his time working in the Italian Medicines Agency it became evident that in Italy many of the patient organisations were not initially in a position to contribute to the Agency's work, however following discussions, some organisations adapted and a working group consisting of patient and consumer organisations was created to work with the agency.

The executive director emphasised his intention to provide as much support as possible, within the mandate of the Agency, to aid the contribution of patients in the Agency's work and wished the organisations much growth and success for the future.

Following Guido Rasi's introduction some patient organisations expressed their satisfaction with the EMA's interaction with Patient/consumer organisations (PCOs) and as such they believe that it can be considered a model for other member states, however since the introduction of the Agency's new policy on conflicts of interest (COI) some have difficulties in nominating members to participate in certain activities; namely as Committee members. The PCOs clarified that although they fully understand the policy and do not want to be treated differently than other experts, they feel at a disadvantage and when applied to patients, it may hamper their contribution to certain regulatory activities.

The executive director stressed the need for the Agency to have robust methods in place to guarantee that the patients involved in the work of the Agency have no conflicts of interest, and that any interests are declared in a transparent manner. He finalised by saying that he would be very happy to meet further with the PCOs and that he would also like to fully participate in one of the future PCWP meetings at the Agency.

The EMA also highlighted the fact that during 2012, together with eligible PCOs, they will be looking at how to strengthen the process concerning the evaluation of PCOs, particularly in relation to the funding of the organisations.

1. General issues

1.1. Implementation of the roadmap to 2015; implications for patients/consumers

Emer Cooke, International Liaison officer at the EMA, gave an overview of the implementation of the Agency roadmap to 2015, especially regarding those topics having particular implications for patients and consumers (see presentation).

The roadmap was adopted and published in December 2010 (PCOs commented during the consultation phase). The drivers for progress and change have been categorised into three strategic areas; 1) addressing public-health needs, 2) facilitating access to medicines and 3) optimising the safe and rational use of medicines. It was made clear that the involvement of PCOs underpins the key work of the EMA.

In terms of the roadmap implementation plan, priorities have been defined taking into consideration legislative changes and resource constraints. The plan will remain a 'living document' and is subject to regular monitoring and review.

Some of the key areas highlighted in the presentation were the geriatric strategy, public health threats, clinical trials in non-EU countries, access to non-prescription medicines, benefit/risk decision making and communication; increasing involvement of stakeholders to ensure views on the use of medicines in real life are taken into account in benefit/risk decision making, improving patient safety, pharmacovigilance and provision of information, availability of information on medicines and EMA's collaboration with the EU network.

Following the presentation the participants had several questions such as the issue of access to medicines and the fact that not all authorised medicines are available / reimbursed in each country – asking whether this could be addressed earlier in the assessment process.

- the EMA responded that although the availability and costing of authorised medicines is not within their remit, there are some related activities identified within the roadmap, e.g. the initiation of collaborative scientific advice with Health Technology Assessments (HTAs) as well as high level interaction with the HTA EU network (EUNeTA) to identify their needs. Additionally the aim is to make the EPAR content more usable for HTAs.

Another question related to whether EMA can help accelerate clinical trials and encourage industry to evaluate unmet medical needs.

- the EMA replied that it is not directly involved in clinical trials, however there is some ongoing work supporting research on pharmacogenomics (bio-markers to distinguish between good & bad responders). Other related activities refer to scientific advice where the trial plans are discussed; there is also the possibility for conditional marketing approval and compassionate use of medicines to aid the access for unmet medical needs.

A final question pertained to the inclusion of data for pregnant women.

- the Agency responded that there are currently activities and initiatives in this area, for example an ongoing survey within ENCEPP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) related to data from pregnant women. An additional example is the approval of the H1N1 vaccine where data on pregnant women was assessed, considered and provided.

2. New pharmaceutical legislation

2.1. Implementation of the anti-falsification legislation

David Cockburn from the Manufacturing and Quality Compliance section at the EMA, gave a presentation on the implementation of the new anti-falsification legislation (see presentation).

According to EU legislation a falsified medicine is one with a false representation of: identity (e.g. name or composition), source (e.g. country of origin, marketing authorisation holder) and/or history (e.g. distribution records). This does not include unintentional quality defects.

The new legislation will enter into force on 2 January 2013, however provisions for the import of active substances will take effect 1 July 2013, the internet common logo should be in place one year after the relevant delegated act and the requested safety features 3 years after the relevant delegated act. The four main areas of change will be the safety features, Good Distribution Practices, active substances (and excipients) and internet sales.

With regards to safety features, although they are subject to further legal definition, it is likely they will be applicable to most prescription medicines (the EC will adopt detailed rules for safety features). For the distribution of medicines, "Good Distribution Practice" provisions will be strengthened with increased obligations for wholesale distributors and new obligations for brokers who will have to be registered at national level. Manufacturers, importers and distributors of active substances will have to register. There will be a public Union database for wholesale distribution authorisations and active substance manufacturers, importers and Distributors.

Concerning internet sales, internet pharmacies will have to notify member states of the products they offer and they also will have to display the new "authenticity" EU logo with a link to authority's website. Member States (MS) will list all authorised internet pharmacies and public awareness campaigns will be initiated. The EMA will also establish a website with links to the MS. Member States are obliged to introduce penalties and sanctions in connection with falsified medicines, including the operation of an unlawful internet pharmacy, which are disuasive.

Following the presentation there were some points raised by the participants, for example it was highlighted the risk that the new legislation may hinder the availability of some medicines imported via parallel importation

– the Agency explained that the new legislation does not intend to disrupt the parallel distribution business but that they need to comply with the new safety features.

It was asked whether the legislation would also apply to generic medicines.

- the EMA responded that the legislation applies to all medicinal products for human use.

An additional question asked who would verify the logos.

- The EMA explained that the logo will be technically sophisticated enough in order to avoid being easily replicated.

Finally it was requested whether the EMA will also be looking at medical devices, to which they responded that in this case medical devices are not in the remit of the Agency's work.

2.2. General update on implementation of pharmacovigilance legislation

Peter Arlett, head of pharmacovigilance and risk management sector, gave an overview of the implementation of the new pharmacovigilance legislation to date (see presentation).

In 2003 the European Commission decided to undertake an assessment of the Community system of pharmacovigilance in order to strengthen and rationalise European pharmacovigilance to better protect public health. The new legislation (Regulation (EC) 1235/2010 & Directive 2010/84/EC) was published at the end of December 2010, and will apply from July 2012, with some transitional provisions. This new legislation represents the largest change to the legal framework for human medicines since 1995 and has the key aim of reducing the burden of adverse drug reactions (ADRs) to optimise the use of medicines and save lives. Some of the main objectives are to provide clear roles and responsibilities within a robust and rapid EU decision-making which is science based, integrating proportionate benefit/risk assessments, to further involve patients and healthcare professionals and finally to increase transparency and provide better information on medicines.

Peter explained that EMA resource constraints is one of the biggest challenges for the implementation of the new legislation; the new fee regulation revision is critical for success. So far the implementation planning and execution has been extensive, including 6 project teams involving EMA and member states as well as several stakeholder meetings including EMA, Member States, European Commission, Industry, Patient and Healthcare Professional representatives (3 meetings held in 2011 - presentation and videos on EMA website), proposed dates for 2012 are: 27 February; 25 May; 1 October.

One of the main provisions is the creation of the new pharmacovigilance and risk assessment committee (PRAC), to commence operation in July 2012. Membership will include MS experts, Commission appointed experts, a patient representative (& alternate) and a healthcare professional representative (& alternate). A key theme throughout the legislation is an increase in transparency, including online information for the public (assessments, recommendations, opinions, approvals and decisions) to ensure full clarity on the regulatory procedures and outcomes. The Agency will be launching an EU medicines web portal (in 23 official EU languages) designed for the public, with links to national web portals, to highlight information and safety issues, promote patient reporting and also to potentially announce public hearings. Full details on how and when public hearings will be held have not yet been finalised. Eudravigilance data (safety reports) will also be made public from 2012 (although for Centrally Authorised Products only in 2012).

A concept paper on implementing measures has been published by the European Commission – *link.* The new legislation will be implemented following a phased approach and priorities will be discussed during the next Management Board meeting.

After the presentation the meeting participants posed several questions; such as why only one patient representative (plus alternate) will be nominated as member in the PRAC.

– the EMA explained that the composition of the PRAC has been decided by Council and Parliament, and mentioned that in practice it could be that the alternate also has a key role to play. Additionally the PRAC can, at any time, consult with additional individual patients or patient/consumer organisations regarding specific products during the evaluation or communication phase.

An additional query pertained to risk management plans (RMP) and how those for already authorised products would be addressed.

– The Agency explained that, once in place, the new legislation will ensure all new products will have a RMP, as well as key 'older' products. However, it was acknowledged that it will be difficult to achieve complete harmonisation of risk minimisation throughout the EU, especially for 'older' products.

There followed a discussion on direct patient reporting of ADRs and the EMA explained that they would make available a web-based reporting form (or structure) as a basis for use by the Member States. PCOs highlighted that it is vital that there are other methods for patients to report apart from this online form. The EMA agreed and explained it would be up to each MS to put in place additional reporting methods. One participant asked about which reports would be included/excluded from Eudravigilance? - The EMA highlighted that once the legislation is fully implemented all reports will be included (not only serious ones).

Another query was in relation to whether the legislation covers nutritional supplements.

– the EMA explained that the Agency does not deal with these, unless they are medicinal products. Thus they are not covered within the new legislation.

2.2.1. Additional monitoring of medicines & direct patient reporting – impact on the package leaflet

Ana Sempere, from the Medical Information Sector at the EMA, gave a presentation on the provisions in the new pharmacovigilance legislation which has an impact on the package leaflet (PL).

The new legislation defines that certain medicinal products will be included on a list and subject to 'additional monitoring'. With regards to these products, it is proposed to include a black symbol and an explanatory sentence in the summary of the product characteristics (SmPC) and in the PL. Additionally a standardised sentence will also be included in the product information for all medicines, encouraging the reporting of suspected adverse reactions for these particular medicines.

The Working Group on the Quality Review of Documents (QRD), within the Agency, has worked on some draft proposals of the text to be implemented in the product information. Some Member States have also given information on currently used symbols and made proposals for the new symbol and its location in the PL. The final proposals will be sent to the Pharmacovigilance Risk Assessment Committee (PRAC) after additional internal and external consultation. The black symbol will be chosen by the Commission following a recommendation of the PRAC after the new committee is established in July 2012.

Ana highlighted some of the points that need to be considered in choosing the symbol and the text and explained that the Agency would like to receive feedback from PCOs on the draft proposals, by 20 December.

There were some comments following the presentation, for example it was mentioned that a black symbol has been previously used (e.g. in UK) and could thus cause confusion. It was also pointed out that the font size to be implemented in PL should not be too small. Some of the PCOs also supported the picture of a magnifying glass as a potential symbol.

2.3. Proposal for legislation on information to patients.

Patricia Brunko and Olga Solomon, from DG SANCO, at the European Commission, gave a presentation (via videoconference) on the European Commissions' amended proposals on the "information to patients" legislation (see presentation).

Patricia explained that the proposals amend Directive 2001/83/EC and Regulation (EC) No. 726/2004 and that the revised version was adopted by the Commission on 11 October 2011.

The amendments intend to address the fact that MS have adopted divergent national practices regarding the provision of information and there is unequal access to information on medicinal products. The overall aim is to provide a harmonised framework for the provision of non-promotional information to the general public on prescription only medicines. The proposals require that information must be clear, objective, reliable and up-to-date and national authorities will be responsible for the pre-control of the information and monitoring compliance. The revised proposals still have to be discussed by the council and European parliament.

Further details of the proposals are given in the presentation on this webpage.

Following the presentation, several members wished to raise some questions however as time was limited, it was proposed that PCOs would send their questions to the EMA who would then compile and forward them to the EC on their behalf.

3. Patient/consumer organisation activities

3.1. Results of survey project on representativeness in Agency stakeholder groups

Postponed to the next PCWP meeting in May 2012.

4. Involvement of patient/consumer organisations in EMA activities

4.1. Outcome of SAG pilot phase

Postponed until the joint meeting between PCWP and healthcare professionals on 28 February 2012.

4.2. Process for re-evaluation of PCO eligibility

Juan Garcia, from the medical information sector, presented the proposed revision of the process for the evaluation and re-evaluation of PCO eligibility, in accordance with the Agency's published eligibility criteria (see presentation).

Juan firstly explained the proposed amendments to some of the administrative processes involved which are aimed at streamlining the overall procedure. This was followed by a general discussion on issues surrounding the financial assessment of organisations; specifically funding which is given to some PCOs by pharmaceutical companies. After some initial discussions, it was decided that in order to adequately evaluate the way forward with regards to this subject, a working group consisting of PCOs and the EMA (including EMA legal services) should be organised.

Approximately 10 PCOs volunteered to be part of the working group and the Agency will propose a date for the group to meet early in 2012.

4.3. General update and PCWP Work plan for 2012

Nathalie Bere, from the Medical Information Sector, gave a general update and overview on the different activities involving patients and consumers to date, followed by a presentation on the draft PCWP Work plan for 2012 (See presentation).

Nathalie explained that, in addition to the ongoing 'established' PCWP activities within the Agency's work (e.g. review of documents for the public, committee consultations, participation in working groups), one of the key issues to be tackled during 2012 will be the revision of the framework on the interaction between the Agency and PCOs, which will address:

- The role of patients within the different scientific committees,
- their involvement in CHMP benefit/risk evaluations, and
- the development of a strategy for training and support

The revised framework will determine the involvement of patients and consumers in the work of the Agency in the coming years.

Additionally the new pharmacovigilance legislation will also have a significant impact and will strengthen the interaction; PCWP will not only be directly involved in its implementation, but will also be involved in the work of the new pharmacovigilance and assessment committee (PRAC).

Notwithstanding that the PCWP and the Agency will continue to monitor and report on the interaction with patients/consumers on a regular basis, it will also endeavour to ensure that involvement occurs in a transparent manner with appropriate organisations – as such the Agency will be updating the process for evaluation of 'eligible organisations'. One further aim is also to raise public awareness of activities where PCWP/PCOs are involved within the Agency and to increase awareness of EMA as a validated source of information on medicines for patients.

Following the presentation there were a few minor comments on the work plan (the inclusion of participation in EnprEMA and geriatrics initiatives) which were agreed.

Post-meeting note – the work plan was re-circulated to the group for any further comments by mid-December and then was considered as adopted, and will be published on the EMA website.

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

Close of meeting

Next meeting: Joint meeting between PCWP and healthcare professionals on 28 February 2012.