8 December 2015
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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

17 September 2015, 08:45hrs to 17:00hrs – meeting room: 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA), David Haerry (PCWP) and Gonzalo Calvo (HCPWP)
Present:	**PCWP members**: AGE Platform Europe (AGE); 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 Heart Network (EHN); 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' Organizations (IAPO); International Diabetes Federation European Region (IDF Europe); Patients Network for Medical Research and Health (EGAN) **HCPWP members**: European Academy of Neurology (EAN); European Aids Clinical Society (EACS); European Association for Clinical Pharmacology and Therapeutics (EACPT); European Association of Hospital Pharmacists (EAHP); European Association of Urology (EAU); European Federation of Internal Medicines (EFIM); European Society for Medical Oncology (ESMO); European Society of Endocrinology (ESE); 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 on Herbal Medicinal Products (HMPC); Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee (PRAC) **External speakers:** University of Groningen **Observers**: EMA Management Board; Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMDh); Spanish Agency for Medicines and

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Role	Name
	Health Products (AEMPS); European Forum for Primary Care (EFPC)

Introduction

Isabelle Moulon (co-chair) welcomed the participants to the meeting. They were asked to declare any potential conflicts of interest in terms of the topics on the agenda and then relevant fire evacuation procedures were highlighted.

The agenda was adopted with one additional point to be covered under A.O.B. – PCWP 10-year anniversary.

1. Benefit/Risk research

1.1. Follow up from PROTECT project; results from VISUALizE (benefit/risk) research study

A. Beyer (University of Groningen) summarised the outputs of the research project *Visualizing Uncertainty Among Laypersons and Experts* (VISUALizE), developed within the context of the Innovative Medicines Initiative (IMI), under the research programme "Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium" (PROTECT) (see presentation).

VISUALizE is a web-based, non-interventional, cross-sectional[1]study of graphical formats for presenting efficacy and safety data for medicinal products and the uncertainty surrounding this data.

The study also covers the impact of the graphical format on perception of risk and benefit and the comparison of two methods for the elicitation of preferences for treatment outcomes among patients (diagnosed with breast cancer, atrial fibrillation, and diabetes), healthcare professionals and the medical assessors who assess medicinal products.

PCWP and HCPWP members will be informed of the publication of the project's final report.

2. EMA initiatives and ongoing activities

2.1. Need for collaboration in pharmacovigilance to ensure effective health protection and promotion

J. Bouvy (EMA) presented the Pharmacovigilance and Risk Assessment Committees' draft strategy aimed at measuring the impact of pharmacovigilance processes and decisions (see presentation). The main goals are to determine whether regulatory actions have been successful and to identify barriers and enablers for effectiveness of processes and actions (e.g. what works and what does not) in order to improve/strengthen pharmacovigilance.

Current thinking behind the strategy includes some targeted surveys of patients and healthcare professionals particularly on key enablers such as engagement in pharmacovigilance and trust in the system. In this context, it is proposed to develop a survey to be conducted in 2016 with help from a virtual collaboration group identified amongst PCWP and HCPWP members.

[1] A cross-sectional study involves the analysis of data collected from a population, or a representative subset, at one specific point in time

Members welcomed their early involvement in the discussion of who would be targeted by the surveys and of what would be specifically surveyed.

I. Moulon (EMA) suggested to also reflect on future steps on the basis of the outcome of the workshop on risk minimisation measures organised on 16 September 2015, the outputs emerging from the SCOPE joint-action, and the work to be developed by the HCPWP topic group on risk minimisation measures and assessment of their effectiveness.

2.2. New pharmacovigilance systems and services

P. Arlett (EMA) gave an overview of the pharmacovigilance projects on information systems set out to support the implementation of the new EU Pharmacovigilance legislation, applicable since July 2012 (see presentation).

The legislation foresees various information systems to enhance Pharmacovigilance, particularly to support the collection, management and analysis of data, information and knowledge. These include the EU medicinal product database (Article 57) and EudraVigilance.

Major deliverables from these projects are scheduled throughout 2016 and 2017 to support business activities of the revised pharmacovigilance legislation and to improve the relevant business functions to maximise the benefits for stakeholders. This will ultimately lead to greater access for patients and healthcare professionals to data and information held by regulators.

It was agreed to present more in detail the Article 57 database and the foreseen enhancements of EudraVigilance at an upcoming PCWP/HCPWP meeting.

Post-meeting developments: In October the EMA published a change management plan to provide stakeholders with comprehensive information to be ready for improvements to the EudraVigilance system. The plan details the technical changes as well as business process changes in relation to reporting, managing and analysing individual case safety reports (ICSRs) from medicines in clinical use and from clinical trials. For further reading please click here.

2.3. Clinical Trial regulation transparency update

As a follow up to previous updates and consultation in March and June 2015, F. Sweeney (EMA) presented progress made since then and informed about next steps towards publication in October 2015 of the final text of the Functional Specifications of the EU Portal and EU Database to be audited. Focus will then shift towards development of the EU portal and EU database.

Post-meeting developments: in October the EMA published the Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014". For further reading please click here.

Members will be kept updated of further developments.

2.4. Enhanced early dialogue to foster development and facilitate accelerated assessment (PRIME)

J. Llinares and Z. Hanaizi (EMA) provided an introduction to the EMA's initiative to enhance early dialogue with medicine developers to foster development and facilitate accelerated assessment to important new medicines.

Participants raised the points below as areas in need of additional clarification:

- Which criteria will be used for selection of candidate medicines;
- How will the scheme differ from an accelerated procedure;
- If and how HTA bodies will be involved;
- If it is foreseen that EMA may also advise companies to stop development;
- How will medicines in this scheme be authorised.

J. Llinares informed that a reflection paper was being prepared where most of the points would be addressed and which would be released for public consultation.

Members will be updated on developments as they progress, including possibilities for involvement.

Post-meeting developments: In October 2015, a draft reflection paper on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines (PRIME) was released for public consultation. For further reading please click here.

3. Committee / working party feedback

3.1. Feedback from scientific committees

H. Vella, from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), drew attention to recent discussions around the concept of European Reference Product, QR codes, and Periodic Safety Update Report Single Assessment (PSUSA) outcomes (see presentation).

H. Enzmann, from the Committee for Human Medicinal Products (CHMP) highlighted that, in the context of the pilot for patient involvement in CHMP, a third case of interaction would take place at their September meeting, allowing for additional experience to be gained.

M. Greco and K. Myhr, from the Pharmacovigilance Risk Assessment Committee (PRAC), pointed to the ongoing procedure on Human Papilloma Virus (HPV) vaccines. These vaccines have been used in around 72 million people worldwide and their use is expected to prevent many cases of cervical cancer and various other cancers and conditions caused by HPV. The review does not question that the benefits of HPV vaccines outweigh their risks but is aimed at further clarifying aspects of their safety profile.

M. Mavris (EMA) informed members that, within the scope of the Committee for Orphan Medicinal Products (COMP) activities, a relevant Worksop on 'Significant Benefit' will be organised on 7 December 2015 and a public call for expressions of interest was open until 31 October.

3.2. Overview of HMPC; tasks and responsibilities

S. Bager, from the Herbal Medicinal Products Committee (HMPC), gave a presentation addressing the activities of this committee with the aim of supporting a discussion on further involvement of patients in its work (see presentation).

A number of organisations pointed particularly to the relevance of increasing awareness of patients about interactions between herbal medicines and other therapies and expressed an interest to be further involved.

Potential involvement in the work of the HMPC will be followed up with the Committee for next steps.

3.3. Progress report from PCWP and HCPWP topics groups

Members were updated on progress made by each topic group as follows:

- Acknowledge and promote visibility of patient input in the Agency's activities, by I. Moulon (EMA). Objectives:
  - Explore how to raise awareness and visibility of patients/consumers work at the EMA.
  - Explore how to best acknowledge patient/consumer input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups.
  - Make recommendations.
- Training, by R. West (EURORDIS). Objectives:
  - Explore synergies with existing training initiatives.
  - Discuss and explore further training methods and tools for patients involved in EMA activities.
- Social Media, by D. Singer (EACPT). Objectives:
  - Map current practices in the digital world that are shaping clinical research and clinical care.
  - Prepare recommendations to EMA and to patients', consumers' and healthcare professional organisations:

    intended to raise awareness of how data and information related with real use of medicines is being collected and used for research and/or other purposes and call for actions as appropriate;

    on how to use their communication channels (internet and social media) more widely, to ensure easy, consistent and timely access to authoritative, reliable and understandable information on medicines;
  - Identify topics and speakers for a PCWP/HCPWP workshop on social media to be organised in 2016.
- EMA/CHMP/PRAC projects on information on medicines, by J. Peppard (EAHP) and L. Brassart (EMA). Objectives:
  - Setting the scene and summarising identified challenges.
  - Discuss the target audience(s) of the different information on medicines produced by EMA (e.g. healthcare professionals, those treating patients, bodies preparing therapeutic guidelines, or, journals/drug bulletins/other information providers).
  - Discuss healthcare professional organisations' role in the information chain, e.g. for communicating regulatory information or therapeutic guidelines/prescribing recommendations.
  - Identify ways to facilitate input from healthcare professionals into the preparation and update of regulatory information.
  - Prepare recommendations to EMA and to healthcare professional organisations on:

    how to use available resources to maintain high quality of product information throughout the lifecycle of the medicine whilst ensuring it reflects as much as possible clinical practice reality (with proposals for concrete pilots);

how to use or improve current EMA information outputs to support clinical practice;

how to bridge regulatory outputs with therapeutic guidelines/prescribing recommendations.

- Academia, learned society and healthcare professional organisations, by R. Giuliani (ESMO) and S. Bonini (EMA). Objectives:
  - Reflect on the need to review the EMA framework of interactions with HCPs.
  - Support the development of the EMA framework for collaboration with Academia.
  - Identify current practice with involvement in regulatory activities.
  - Discuss areas for improvement and foreseeable changes.
- Risk minimisation measures and assessment of their effectiveness, by I. Silva (EMA). Objectives:
  - Discuss current practices/experience (regulator and HCP perspectives) in the development and implementation of additional risk minimisation measures, using concrete examples of risk minimisation tools.
  - In the context of the PRAC project on product life cycle support, brainstorm on how to facilitate input from HCPs into the feasibility, information and evaluation of risk minimisation measures; explore aspects around product-specific issues, therapeutic class and overall therapeutic environment and prepare recommendations as appropriate.
  - Discuss how to better inform HCPs about ongoing activities and initiatives within the EU regulatory network related with post-authorisations Efficacy and Safety studies, registries, medication errors, RMP summaries and safety communications and prepare recommendations as appropriate.
- Involvement of young people / children, by N. Bere (EMA). Objectives:
  - Identify existing youth groups within eligible organisations; look to create, within the umbrella of the PCWP, a "young person's advisory network" with young participants.
  - Identify areas and methodologies for the involvement of young people in EMA/PDCO activities.
  - Explore how to raise awareness on the need for more participation in paediatric clinical trials.
  - Plan 20th anniversary activity at the EMA with young people on 7 October 2015.
- Measure impact of patient involvement, by N. Bere (EMA). Objectives:
  - Explore how to measure the benefit/value of patient input within EMA.
  - Explore the impact that involvement in EMA activities has on empowerment of PCOs.
  - Establish a system for regular cross-Agency collection of quantitative and qualitative data for monitoring and reporting purposes.

It was agreed to allocate sufficient time at the PCWP/HCPWP joint meeting of March 2016 to cross refer to the work under development by all groups, identify potential overlaps and align next steps.

3.4. PCWP and HCPWP work programmes for 2016

N. Bere and I. Silva (EMA) outlined the proposed activities to be covered by the work programmes.

As in previous years, the working parties will continue to serve as a platform to promote a better understanding of the Agency's activities and involvement in EU-wide initiatives. Both PCWP and HCPWP will continue to contribute to the Agency's discussions and initiatives to bring the real-life perspectives into the regulatory area, thus promoting a safer and more rational use of medicines.

In particular, the PCWP will work on the following main areas: measure the impact of patient involvement in EMA activities; acknowledge and promote visibility of patient input in the Agency's activities; training; social media; involvement of young people in EMA activities. The HCPWP will work on the areas covering information on medicines, risk minimisation measures, social media and EMA collaboration with academia, learned societies and healthcare professional organisations. This will be supported by topic groups set up for each of these areas and the members will be asked to reflect on and propose recommendations/ proposals for action.

Both work programmes were adopted by the working parties.

As a follow up action, the work programmes will be presented for adoption to all six Human Scientific Committees and published on the EMA website.

Post-meeting developments: the work programmes were approved and are published here: PCWP work programme for 2016; HCPWP work programme for 2016.

3.5. Reminder new eligibility criteria and new working party mandates

N. Bere and I. Silva (EMA) reminded participants that their organisations' compliance with eligibility criteria is a requirement for membership of the working parties.

In order to allow current eligible organisations to adjust and implement any necessary changes emerging from the revised criteria adopted in June 2014, a transitional period of 18 months was foreseen. As such, all eligible organisations will be expected to fully comply with the revised process by end of 2015.

Members are encouraged to refer to the guidance on the eligibility requirements to ensure compliance with the revised criteria.

Further information on mandates and elections of co-chairs of the working parties will be provided during the PCWP/HCPWP joint meeting of March 2016.

3.6. Results of survey to national competent authorities

Due to time limitations, it was agreed to take this agenda item at the upcoming PCWP meeting with all eligible organisations in November 2015.

4. Members voice: sharing practices

4.1. Improving multiple sclerosis management in Europe: better outcomes with better data

C. Thalheim (EMSP) presented the EUReMS project (see presentation) and shared with participants the thinking behind moving from a "proof on concept" of effective cross-border cooperation of national registries, data pooling and centralised data analysis towards a European network of multiple sclerosis registries. He then launched the idea of whether the concept of European Networks of disease specific registries could be further explored to support regulatory tasks and called for additional discussion amongst PCWP members.

I. Moulon (EMA) referred to the EMA initiative on Patient Registries, which main objective is to facilitate the use of existing patient registries and facilitating the establishment and utility of new registries if none are available or adequate, in order to collect and analyse high quality data informing regulatory decisions. She suggested that further discussion should take place in the context of that initiative.

4.2. European consortium study on the availability of anti-neoplastic medicines

A. Eniu (ESMO) presented the results from the ESMO Antineoplastic Medicines Survey (see presentation). Results show that there are disparities across Europe in access to cancer medicines, medicines shortages are affecting several "essential", old and inexpensive drugs and that inequalities exist in availability and patient costs, especially for newer, more expensive drugs, across Europe. He then explained how the ESMO Magnitude of Benefit Scale, applied on the availability data, can inform the process of prioritisation access to medicines, when resources are limited.

Replying to a question on whether these findings and the proposed scale had been discussed with HTA bodies, A. Eniu mentioned there were plans to further use them to inform the process of EUnetHTA (focusing on creating an effective and sustainable network for HTA across Europe).

5. A.O.B

5.1. PCWP – 10 year anniversary

M. Mavris (EMA) invited PCWP members to send any contributions of photos, ideas for interviews or to volunteer for to the preparatory work of the PCWP's 10th anniversary by 31 October 2015.

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

Close of meeting

Next meetings:

- 25 November 2015 Patient and consumer training session
- 26 November 2015 Plenary with all eligible patient and consumer organisations