EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) joint meeting

Meeting minutes – 27-28 February 2013 - chaired by Isabelle Moulon

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 Association of Urology (EAU) (via teleconference), European Federation of Internal Medicine (EFIM), European League Against Rheumatism (EULAR), European Society for Medical Oncology (ESMO), European Society of Cardiology (ESC), European Society of Radiology (ESR), 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 Patients' and Consumers' Organisations: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), The European Consumers' Organisation (BEUC), European Federation of Allergy and Airway 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), International Diabetes Federation Europe (IDF-Europe), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Pain Alliance Europe (PAE), The European Prostate Cancer Coalition (Europa Uomo).

Representatives and observers from the Agency's Scientific Committees: Committee for Human Medicinal Products (CHMP), Committee for Herbal Medicinal Products (HMPC), Pharmacovigilance Risk Assessment Committee (PRAC).

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

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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 introduced the agenda.

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

The agenda was adopted with no additions.

The chair announced that the new members of the Agency's Management Board representing civil-society have been nominated: Nikolaos Dedes from the European AIDS Treatment Group and Dr W.H.J.M. Wientjens from the International Diabetes Federation Europe, will represent patients' organisations; Dr Wolf-Dieter Ludwig from the Standing Committee of European Doctors and Dr Christophe Hugnet from the Federation of Veterinarians of Europe will represent healthcare professionals.

1. Legislation on falsified medicines

1.1. Update on the implementation of the new legislation

Stefan Führing (European Commission, DG SANCO) provided an update on the implementation of the falsified medicines Directive adopted in 2011 and in force since January 2013.

The new legislation aims to prevent falsified medicines entering the legal supply chain and reaching patients. It introduces harmonised safety and strengthened control measures across Europe by applying new measures, including:

- obligatory features on the outer packaging of medicines to demonstrate that they are authentic;
- strengthened requirements for the inspection of the manufacturers of pharmaceutical ingredients;
- the obligation for manufacturers and distributors to report any suspicion of falsified medicines;
- an obligatory logo that must be placed on the websites of legally operating online pharmacies, with a link to official national registers.

The new legislation is not aimed at harmonising the very different rules for the operation of online pharmacies in member states but rather foresees the creation of an obligatory logo or 'trust mark' intended to increase reliability of the legality of online pharmacies. The Commission completed a public consultation on how the common logo will look like in February 2013. Once the logo has been defined awareness will have to be raised by the Commission, in cooperation with the Agency and member states. Input from PCWP and HCPWG will be sought at this time, but initial views were already collected at the meeting.

Several considerations were made by different participants, the main point being that the awareness campaign needs not only to focus on the logo and what it means, but also to clarify what is expected from consumers/ citizens (e.g. help detecting illegal sites and what to do in case an illegal site is identified). It is also important to explain how legally operating sites using the 'trust mark' are supervised and kept trust worthy.

One participant expressed concern over the possibility that inspections of importers of active substances, as introduced by the new legislation, may lead to shortages in the supply of medicines. It was clarified that several measures had been foreseen to avoid shortages, including cooperation with third countries and strengthening collaboration among inspectors.

This topic, and in particular aspects related to the awareness campaign, will be further discussed at later meetings of both groups.

2. Area of communication and information

2.1. Communication on safety referrals

Rebecca Harding (EMA) gave a presentation on how the Agency communicates on the outcome of safety-related referrals (see presentation), showing concrete examples of communications issued following the first months of operation of the Agency's Pharmacivigilance Risk Assessment Committee (PRAC).

Safety-related referrals are assessed by the PRAC and then either by the Committee for Medicinal Products for Human Use (CHMP) or, for nationally authorised medicines, by the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh). Throughout the referral procedure the Agency communicates at three different stages:

- Start of the safety referral by PRAC – an 'EMA announcement of start of referral' is published;
- PRAC recommendation – a 'Summary of PRAC recommendation' is published;
- CHMP/ CMD(h) – an 'EMA public health communication' is issued, including specific recommendations for patients and healthcare professionals.

The communication on the PRAC recommendation is intended to summarise the main points made by the PRAC on its assessment of the safety issue. It also explains the next steps in the review, namely that the PRAC recommendation will then be considered by the CHMP or CMD(h) in their final deliberations and recommendations for patients and healthcare professionals.

Some participants underlined the importance of receiving safety communications in a timely manner and adapted to their national situation as much as possible. The Agency mentioned that communications are coordinated within the EU regulatory network to ensure core messages allow for further adaptation to national aspects, as necessary.

Nathalie Bere (EMA) explained the different possibilities to involve PCWP and HCPWG members in the review of these communications and their timelines (see presentation).

It was agreed that patients', consumers' and healthcare professionals' organisations will be involved in all three steps, as relevant.

2.2. Risk communication on medicines

As an introduction to a broader discussion on how to communicate risk of medicines in a more transparent regulatory environment, three speakers were invited to present on recent and on-going research and other initiatives in this field.

Frederic Bouder (Maastricht University) elaborated on the question of communicating risk in a more transparent environment, supported by the scientific work of several researchers in the field of risk communication. He particularly focused on the need to think more strategically about the impact of

new transparency initiatives and to promote science-based risk communication on medicinal products (see presentation).

David Haerry (EATG) reported on the main findings of the 'Ditchley Group', a multidisciplinary group gathering different stakeholders to discuss transparency and risk communication by regulators. According to this group, the only way forward is towards more transparency, but it is important to differentiate between transparency and communication (see presentation).

Priya Bahri (EMA) presented the global lessons learnt on risk communication published in the *Drug Safety* edition dedicated to this topic (see presentation). She underlined the importance of bringing communication science into pharmacovigilance (i.e. integration of risk assessment with risk communication) and the need for regulators, patients and healthcare professionals to analyse together their specific contexts, concerns and information needs.

All three speakers pointed to the need to improve the way regulators communicate on risk to build trust in the regulatory system.

The main points raised during the discussion are summarised below:

- More transparency is generally welcome but there is a need to assess the impact of bringing into the public domain certain information. Information needs to be conveyed in an adequate manner to users of medicines (patients and healthcare professionals) - more transparency does not necessarily mean better communication;
- Appropriate tools need to be developed to support healthcare professionals when conveying messages to patients; communicating in a clinical setting is different than communicating to the general public and some communication tools developed by regulators may not be sufficient to respond to the level of detail and practical information that would be needed at point of care;
- Involvement of healthcare professionals and patients in the preparation of safety-related communications should be encouraged; pre-notice of important communications to the representative organisations can also support their preparedness and facilitate their role as multipliers of the messages to be communicated;
- There is a need for multi-layer information to ensure that different cognitive levels and cultural backgrounds are appropriately addressed;
- European and national regulators need to provide one collaborative single view in relation to what is communicated; different views among regulators promote mistrust;
- Appropriate interaction with the media requires special attention supporting that messages communicated by regulators are handled within their scientific context;
- Impact assessment analysis is necessary to measure change of behaviour in people; research is being performed on how behavioural change could be used to measure effectiveness of proposed risk minimisation activities;
- Feedback from patients, consumers and healthcare professionals' organisations on the type of questions received following EMA safety communications could help shaping future communications.

The Agency will explore the organisation of a workshop on risk communication with all stakeholders in 2014. The chair remarked that it should cover risk communication on medicines used by healthy people (e.g. vaccines, oral contraceptives).

2.3. Dissemination of new information on medicines – the example of Insulin degludec

Ivana Silva (EMA) reported on the input received from patients and healthcare professionals' organisations following the Agency's communication on the CHMP positive opinion on Insulin degludec in October 2012.

Insulin degludec is a new basal analogue insulin for the treatment of diabetes mellitus in adults which will be available in a pre-filled pen in two formulations – 100 units/ml and 200 units/ml. This is the first insulin approved in Europe at a higher strength than the European Union (EU)-wide standard of 100 units/ml, for many years the only strength of insulin available across the EU. The introduction of a new insulin strength is a significant change in the therapeutic environment and risk-minimisation activities to reduce the risk of medication errors between the 100-unit/ml and 200-unit/ml strengths have been agreed including an educational programme to support healthcare professionals and patients using this new strength.

In addition to the agreed risk-minimisation activities it was also recommended that the Agency would use its network of EU organisations representing patients and healthcare professionals to encourage national diabetes patient associations and learned societies to prepare their members for the market introduction of the new strength.

All organisations contacted by the Agency for this purpose disseminated the information among their networks using their internal and external communication channels.

PCWP/HCPWG members were also informed that the European Commission decision granting a marketing authorisation for this medicinal product was issued in 21 January 2013 and that the roll out of the higher-strength insulin should be expected in the coming months. The Agency suggested this would be a good time to reinforce awareness among their national members on the new strength.

2.4. EMA Online Roadmap

Sarah Weatherley (EMA) presented the EMA online roadmap 2012-2017. The roadmap sets out the Agency's vision for its online presence as one that is customer-focused, user-friendly and supports its legal obligations on communications and transparency. Three main channels are identified in this strategic document:

- Upgraded corporate website –aimed at fee-payers and high influence, high power stakeholders, the Agency's core communication channel focuses on providing content for these groups and raising awareness about the work of the Agency, its regulatory processes and public health decisions;
- New EU medicines web portal – will be created in response to a legal requirement established by the Pharmacovigilance legislation and will target EU citizens, patients, healthcare professionals and those members of the public looking for data on medicines;
- New intranet/extranet – a password-protected website intended to meet the needs of Agency staff and the EU regulatory network (delegates, experts and staff).

The Agency is currently working on 'User personas' to assess potential user needs for an EU medicines web portal. PCWP/HCPWG members will be invited to validate these user personas, as appropriate.

Regular updates will be provided as further progress is made in the implementation of the online roadmap and more input will be collected from PCWP/HCPWG members as relevant.

3. Area of pharmacovigilance

3.1. EMA workshop on medication errors

Thomas Goedecke (EMA) introduced the objectives and topics to be covered by the EMA workshop on medication errors (see presentation). This event is organised in order to bring together various stakeholder groups, including regulators, national patient safety agencies, patient and healthcare professional representatives, academia and the pharmaceutical industry. The primary objective is to raise awareness among the stakeholders involved in the reporting, evaluation and prevention of medication errors of the new legal provisions at EU level with the aim to facilitate their implementation.

Topics covered include the assessment of the potential for medication errors during drug development and in the post-authorisation phase by industry and regulators, experience with medication error reporting at the level of regulatory agencies and national patient safety authorities and the regulatory tools for managing the risk of medication errors and the implementation of preventive measures by different stakeholders. A panel of experts representing the various stakeholders will discuss and summarise the key findings and recommendations of the workshop.

The EMA will publish the workshop report on its website end of April 2013.

Post-meeting note: all presentations have been published in the EMA website. The meeting was broadcasted and videos of all presentations are also available.

3.2. Additional monitoring of medicinal products

Alexios Skarlatos (EMA) gave an update on the implementation of the Pharmacovigilance legislation requirements to introduce a black symbol and accompanying explanatory statements in the product information of medicines under additional monitoring (see presentation). He informed that a revised QRD template and an implementation plan, outlining the regulatory process and timeline the companies need to follow to comply with these new requirements, would be published in the EMA website in March 2013.

The European Commission issued a Commission Decision selecting a black inverted triangle as the black symbol (and the standardised sentence explaining that the medicine is under additional monitoring) which will be included in the summary of product characteristics and package leaflet of all medicines subject to additional monitoring from September 2013.

The Agency will publish the first list of medicines that will need to carry this symbol in April 2013. It will include:

- medicines authorised after 1 January 2011 that contain a new active substance;
- biological medicines for which there is limited post-marketing experience;
- medicines with a conditional approval or approved under exceptional circumstances;
- medicines for which the marketing-authorisation holder is required to carry out a post-authorisation safety study (PASS).

Other medicines can also be placed under additional monitoring, based on a decision by the PRAC.

Daniel Glanville (EMA) presented a proposal for a communication strategy on additional monitoring intended to ensure EU citizens receive a clear, consistent and coordinated message about what the black symbol means (see presentation). Participants had some questions and suggestions on issues such as the gap between the inclusion of a medicine in the list and the appearance of the black symbol

in the printed package leaflet, and translation of communication materials. The idea of developing a video to support communication was welcomed and some suggestions were made in this regard.

One participant highlighted the need for specific information to be provided to healthcare professionals in the UK, where a similar system for intensive monitoring is already in place at national level. It was clarified that the EMA is co-ordinating messages closely with national competent authorities, who are developing supplementary information for national audiences on country-specific aspects.

The overall strategy and the key messages (in the form of a draft Q&A) will be circulated for input from PCWP/HCPWG members. Members are asked to act as information multipliers by publishing and disseminating communication materials sent to them, following publication of the list by the EMA.

4. Area of involvement in EMA activities

4.1. EMA policy on conflicts of interest – update

Juan Garcia (EMA) provided feedback from a teleconference on handling of conflicts of interest for patients' and consumers' organisations organised in early February 2013 (see presentation). Some patient organisations' reported on the negative impact the policy would have on their participation as members in EMA committees; other areas discussed related to the funding of organisations and the definition of consultancy.

The EMA will organise a workshop on conflicts of interest with all stakeholders later in 2013, which will serve as a basis to consider a policy revision to be presented to the Management Board.

4.2. Involvement of children and young people in the work of the paediatric committee

Elin Haf Davies (EMA) gave an overview of the EMA initiative to involve children and young people in the work of the EMA paediatric committee (PDCO), outlining the benefits and challenges of doing so (see presentation). The objective is to develop a framework of interaction for the involvement of children and young people in the work of the PDCO, particularly: i) when and to what extent and ii) how their views can be sought, and iii) the manner in which their views can be applied.

Prior to the engagement and involvement of children and young people it is important to determine the scope of involvement, and to define the expectations from such a dialogue.

The views of children and young people will be sought to determine how they feel about taking various types of medicines, and about taking part in clinical trials of drugs. A draft questionnaire prepared for this purpose was sent to PCWP/HCPWG members for comments.

4.3. Urgent Union Procedure – stakeholders' submission form

Helena Matos (EMA) gave a general presentation on the urgent Union procedure.

An urgent Union procedure follows the provisions under Article 107i of Directive 2001/83/EC amended by Directive 2010/84/EU as regards pharmacovigilance. This type of procedure is triggered when a member state or the European Commission consider that urgent action on a medicine is necessary because of a safety issue. Situations that fall under this procedure include consideration for suspension or revocation of the marketing authorisation for a medicine, the prohibition of supply of a medicine or major changes to the marketing authorisation such as deletion of indications, reduction of the recommended dose or new contraindications. The procedure is also applicable in case of a safety issue with a class of medicines.

This procedure introduces for the first time the possibility for stakeholders who are not holders of a marketing authorisation (MAHs) to submit data which will be evaluated in the course of the PRAC assessment.

Two examples of on-going procedures were presented and additional information on how stakeholders which are non-MAHs could submit data through the available online submission form was provided.

4.4. EMA Scientific Advice

Jane Moseley (EMA) presented the work of the Agency in providing scientific advice to pharmaceutical companies and how patients are involved in this particular activity (see presentation).

Scientific advice is when the Agency gives advice to a company on the appropriate tests and studies in the development of a medicine. This is designed to facilitate the development and availability of high-quality, safe and effective medicines, for the benefit of patients. Companies can request scientific advice from the European Medicines Agency at any stage of development of a medicine, whether the medicine is eligible for the centralised authorisation procedure or not.

The Agency has routinely included patients' representatives in scientific advices for medicines intended to treat rare diseases and is currently rolling out further involvement to non-orphan areas. Patients are asked to contribute with their real-life perspective and add their views on the issues being discussed (e.g. feasibility or acceptability to patients of a proposed trial).

Maria Mavris (EURORDIS) shared the experience from a patients' organisation point of view in assisting the Agency in identifying and preparing patients' representatives to contribute to scientific advice (protocol assistance) for companies developing designated orphan medicines (see presentation).

Two organisations suggested involving also nurses and pharmacists in scientific advice whenever relevant and appropriate. The Agency will take this possibility into account for future scientific advice procedures.

The Agency, based on EURORDIS experience, will prepare guidance to patients (using current training material) including potentially a specific video.

5. Area of clinical trials

5.1. Release of data from clinical trials – feedback from EMA workshop

Francesco Pignatti (EMA) presented the objectives and main outcome of the EMA workshop organised in November 2012 to discuss the proactive release of data from clinical trials (see presentation).

The workshop gathered the views, interests and concerns of a range of institutions, groups and individuals with an interest in the issue, to help the Agency define how it should provide access to clinical-trial data in a manner that satisfies the needs of its stakeholders.

The Agency is developing a policy on the proactive publication of clinical-trial data, with the help of five advisory groups focusing on different areas identified during the workshop: protecting patient confidentiality; clinical-trial-data formats; rules of engagement; good analysis practice; and legal aspects.

There is a good representation of different stakeholders in each advisory group, including patients and healthcare professionals. The composition of all groups is publicly available on the EMA website. The groups are expected to conclude on their discussion and provide their advice by the end of April. In

June the Agency will publish a draft policy which will be opened for public consultation. It is foreseen that by January 2014 the Agency's policy will come into force.

The Agency will keep PCWP/HCPWG members updated on further progress.

5.2. EU-CTR and EudraCT

Ana Rodriguez Sanchez Beato (EMA) provided a general update on the EU clinical trials register and the EudraCT database (see presentation).

The register, which has been in operation since March 2011, contains trials that include at least one clinical site in the European Economic Area (EEA) and trials conducted outside the EEA when part of a paediatric investigation plan (PIP). The information contained in the register is also available through the WHO International Clinical Trial Registry Platform (ICTRP).

At the time of the presentation there were 19,891 clinical trials searchable in the Public Register, of which 2,614 involved subjects with less than 18 years of age.

PCWP/HCPWG members were also updated on the EudraCT V9 results simple form, published by the European Commission in January 2013, and which provides the list of fields that can be viewed when reviewing the results of clinical trials.

6. A.O.B.

6.1. Revised PCWP mandate and rules of procedure

Nathalie Bere (EMA) presented the proposed changes to the mandate and rules of procedure of the PCWP. The revised mandate was adopted.

6.2. Supply shortages

Several organisations raised their concerns regarding the increasing number of supply shortages in Europe and suggested this topic to be further discussed.

Responding to an invitation from the Chair, EATG, EURORDIS, PGEU and EAHP volunteered to prepare a document outlining the views from patients, consumers and healthcare professional organisations in relation to the handling of potential supply shortages. This will be integrated in on-going discussions on this topic by EMA/HMA/CHMP. A first draft should be prepared within one month and will be discussed at the next meeting.

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