



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Patient Health Protection

## Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCP WP) joint meeting

Meeting minutes – 5 June 2013 - chaired by Isabelle Moulon

### Present

**Representatives from Healthcare Professionals' Organisations:**

**Representatives from Patients' and Consumers' Organisations:**

**Representatives and observers from the Agency's Scientific Committees:**

**Observers:**

## Welcome and introduction

Isabelle Moulon, Head of Medical Information sector, chaired the meeting. She welcomed all participants, including observers from the MHRA, 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 gave a brief overview of the Agency's planned re-organisation, for which details have recently been published ([re-organisation](#)). The changes reflect a renewed focus on three key elements:

- how to better support the scientific work of the EMA committees;
- how to better share the data the Agency holds;
- how to better meet the needs of its stakeholders and partners.

The changes are the result of a review initiative announced at the end of 2012 and are aimed to meet the needs associated with the increased complexity and diversity of the Agency's activities and to ensure the EMA is ready to handle future challenges. These changes are expected to improve the efficiency of operations, through a better use of existing resources.

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The changes also aim to improve the way the Agency engages with and supports its stakeholders and partners which includes consolidation of interactions with patients and healthcare professionals.

The new organisational structure will take effect from the beginning of August 2013 but the full implementation is expected to take place over a period of 18 months. Further information will be published shortly.

## **1. Eligibility criteria**

### ***1.1. Evaluation of financial information from patients/consumers and healthcare professionals organisations***

Juan Garcia (EMA) provided an overview of the draft document "evaluation of financial information from patient/consumer and healthcare professional organisations for assessment of EMA 'eligibility' and subsequent involvement in product-related evaluations", which has already been presented and discussed at previous meetings.

The Agency has a set of criteria used for assessing eligibility of patient/consumer and healthcare professional organisations; one such criterion is related to transparency, including organisations' funding sources. The criteria do not however include information on the manner in which the EMA uses this funding information. The purpose of this document is therefore to explain how financial information obtained from organisations is used to decide whether that organisation can be considered "eligible". It also outlines the framework to identify and handle potential conflicts of interest when an organisation may be involved in product-related evaluations or discussions.

It is important to note that this policy applies to patient/consumer and healthcare professional organisations as a whole, not to the involvement of individual experts in EMA activities.

It is proposed to introduce the concept of diversity of funding as a way to ensure independency.

Following the presentation there were several comments and questions from the participants.

It was asked whether a distinction will be made between core and project funding, to which the EMA responded that all funding is included together as a whole.

It was mentioned that for organisations whose percentage of funding from companies is small (in terms of all income), it might be difficult to apply the concept of diversity of funding.

The EMA acknowledged the comment and proposed to look again at this particular aspect, include potential amendments. An updated document will be circulated for written comments shortly.

## **2. Area of supply shortages**

### ***2.1. EMA initiatives on medicine shortages related to manufacturing/quality problems***

The chair explained that this session on supply shortages was aimed to have a preliminary discussion in advance of a proposed workshop on supply shortages that will be held at the EMA in October. It will also explore if a common position can be found in certain aspects related to shortages.

The session began with a presentation by Andrea Taft and Brendan Cuddy (EMA) on the work which has been done by EMA/CHMP and HMAs on how to improve the management of shortages of medicinal products due to manufacturing and quality problems (see presentation).

There can be several reasons why the supply of a particular medicine may be disrupted, e.g. manufacturing failure, closure of a manufacturing site, quality defect (product, packaging), raw material unavailability, GMP non-compliance at a manufacturing site, contamination, unexpected increase in demand, drug recall, discontinuation, etc. Unfortunately the occurrence of shortages of medicines seems to have increased over the last few years and can have a huge impact on those who need the medicines.

The EMA, together with member states has developed a strategy aimed to help the EU medicines regulatory network deal with supply shortages more efficiently (on EMA website: [Shortages](#)). A reflection paper and associated implementation plan has been developed in collaboration with the European Commission and other EU regulatory authorities. It provides both a short and medium-term plan to prevent, mitigate and manage shortages of important medicines, based on lessons learnt from previous crises. It also includes a number of activities to encourage more active risk management by the pharmaceutical industry, reducing the vulnerability of supply chains, such as risk minimisation measures to alleviate the impact on patients, and to ensure effective communication with all concerned, including patients and healthcare professionals.

## **2.2. Communication aspects on shortages and recalls of medicines**

Inga Abed (EMA) gave a presentation on a proposal to improve EMA communications on shortages of medicines (see presentation) which is part of the high-profile initiative to improve management of medicine shortages.

Until now, the Agency has communicated on shortages using existing high-profile communication tools such as press releases (PR) and question & answer (Q&A) documents. These communication tools are not optimal as the information can often be condensed and does not warrant the detail and the visibility of a PR or Q&A. In the past, the decision to communicate has been made on a case by case basis and communication has not always been consistent. In addition, follow-up communication on the resolution of shortages has not always been issued.

It is therefore proposed to communicate on shortages via a public catalogue using agreed criteria. Information will be included in cases where the shortage affects centrally authorised medicines or nationally authorised medicines within a referral procedure, where the shortage affects more than one EU Member State and where an assessment has been made by one of the EMA committees. The catalogue will be hosted on a dedicated webpage with links to and from the EPAR pages of affected medicines. The information in the catalogue will be updated when necessary and will always reflect the present status of the shortage.

The intention is that the catalogue will replace PRs and Q&As in most cases and will provide consistent, relevant and up-to-date information.

There were a few questions raised by the patient groups, particularly in relation to having one central point of information and contact. However the Agency explained that it can only provide general, high-level information and that it is the responsibility of each member state to provide specific information which applies to the specific situation in each country.

The Agency also confirmed that the relevant PCOs and HCPOs would be involved in the communication aspects.

This proposal will be implemented once it has been approved by the CHMP.

### **2.3. Introduction to the EMA workshop on product shortages**

Brendan Cuddy gave an overview of the proposed workshop on product shortages which is expected to be held on 4 October at the EMA. He explained that industry, patients/consumers and healthcare professionals would be invited to participate and to share information on lessons learnt and future actions for improvement.

The agenda is not yet finalised so the participants were invited to propose specific questions or issues for inclusion, and also to indicate whether they would be interested to present their particular perspective.

The agenda and a call for expression of interest will be sent out in due course.

### **2.4. Patients and Healthcare Professionals views.**

Two patient representatives and two healthcare professionals presented their views on shortages (see presentations). The key messages were that it is vital that patient/consumer and healthcare professional organisations are involved right from the beginning, that there is better coordination between EMA, NCAs, industry and PCOs/HCPOs in terms of communication, an increase in transparency regarding remaining supply and the overall management process, stronger requirements for authorisation holders to ensure the reliable supply of products and finally sharing best practice of national authorities.

#### **2.4.1 Discussion of a common position**

It was agreed that a common position could be finalised at the joint PCOs/HCPOs meeting in September which would be brought to the workshop with the three main areas to concentrate on being: 1) prevention, 2) communication and 3) management.

A drafting group composed of Francois Houyez (EURORDIS); David Haerry (EATG); Sascha Marschang (EPHA); Jurate Svarcaite (PGEU); Roberto Frontini (EAHP); Jean-Marie Vlassembrouck (ESMO) and Carla Hollak (Academic Medical Centre) will prepare a draft common position.

The EMA offered to provide support to identify the activities that can be undertaken within the remit of the Agency's responsibilities.

## **3. Area of pharmacovigilance**

### **3.1. EMA workshop on medication errors : report and follow up actions**

Thomas Goedecke (EMA) provided feedback from the EMA workshop on medication errors which was held 28 Feb-1 March (see presentation). This event included various stakeholder groups, including regulators, national patient safety agencies, patient and healthcare professional representatives, academia and the pharmaceutical industry. The purpose of the workshop was to raise awareness and ease implementation of the new legal provisions at EU level.

A press release and 'special topic' on EMA website, including presentations and a broadcast of the workshop have been published. This includes a meeting report with proposed action plan for recommendations.

The Agency in collaboration with the European Commission and the EU regulatory network will develop an implementation plan for some key deliverables to be taken further through existing frameworks, e.g. a reflection paper for regulatory and scientific guidance on best practice for medication errors,

including coding in EudraVigilance. There is also a communication strategy envisaged to enhance exchange of information between national competent authorities, pharmacovigilance centres and patient safety organisations.

PCWP/HCPWP members will be kept informed of further progress.

## **4. Area of involvement in EMA activities**

### ***4.1. IMI-PROTECT project - involvement of healthcare professionals and patients in work package 6 - Benefit-risk assessment visualisation tools***

Andrea Beyer presented a proposed research study within WP 6 of IMI-PROTECT, specifically on benefit/risk assessment visualisation tools (see presentation). Andrea is looking to recruit patient representatives in the areas of atrial-fibrillation, diabetes and breast cancer to take part and would much appreciate the support of the PCWP.

Relevant organisations will be contacted for possible involvement if feasible.

The chair also highlighted that a workshop on patient involvement in benefit/risk is planned for later this year in September.

### ***4.2. Update on the implementation of the communication strategy on additional monitoring***

Daniel Glanville (EMA) gave an update on the implementation of the communication strategy on the additional monitoring of medicines (see presentation).

The new legislation gave the basis for the publication of a list of products under additional monitoring and the inclusion of a black symbol with an explanatory text in the product Information (both PL and SmPC) of these medicines.

The communication campaign is being co-ordinated by EMA in close collaboration with national medicines agencies and the European Commission, and with the involvement of patient and healthcare professional organisations. Support is being sought in terms of input on the strategy, testing of messages and dissemination of information.

Once the initial list of medicines was published on 25 April 2013, the EMA launched its public-friendly web page in all EU languages, with a press release. The materials were sent in advance to patient and healthcare professional organisations, including translations. Daniel provided feedback in terms of results/statistics regarding the dissemination of this information by Member States and by patient and healthcare professional organisations.

He explained that, by September 2013, the EMA intends to publish a short video on the black symbol, focusing on real-life situations, which will be available in All EU languages (the aim is to translate the audio).

The members were thanked for their help in preparing this information and any additional feedback is welcome.

## **5. EU Telematics governance structure**

### ***5.1. The new core EU telematics governance structure***

Luc Verhelst and Mireia Castillon (EMA) provided a summary of the new core EU telematics governance structure.

This new structure is a joint endeavour between the European Commission, the EMA and the National Competent Authorities (collectively, "The Network"), which aims to create an information technology framework to implement EU pharmaceutical policy and legislation to support and enable efficient working across the network.

EU Telematics aims to put in place and maintain common information technology services that are effective, add value and help to optimise support to this network.

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