14 December 2011
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Patient Health Protection

# Minutes of the HCP WG meeting

28 October 2011 - chaired by Isabelle Moulon

| Role | Name |
|---|---|
| Chair/Vice -chair | Isabelle Moulon |
| Present: | **Representatives from Healthcare Professionals' Organisations:** European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association of Hospital Pharmacists (EAHP), European Academy of Paediatrics (EAP), European Association for the Study of Diabetes (EASD), European Association of Urology (EAU), European Federation of Internal Medicine (EFIM), European Federation of Neurological Societies (EFNS), European Society for Medical Oncology (ESMO), The European Specialists Nurses Organisations (ESNO), European Society of Radiology (ESR),The European League Against Rheumatism (EULAR), Pharmaceutical Group of The European Union (PGEU), United European Gastroenterology Federation (UEGF), European Union of General Practitioners (UEMO)<br>**Representatives and observers from the Agency's Scientific Committees and Working Parties:** Committee for Human Medicinal Products (CHMP), Committee on Herbal Medicinal Products (HMPC), Pharmacovigilance Working Party (PhVWP)<br>**Observers:** Patients and Consumers Working Party (PCWP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h))<br>**External experts:** The European Consumers' organisation (BEUC), The European Society of Contraception and Reproductive Health (ESCRH), Pharmaceutical Group of The European Union (PGEU), Medicines and Healthcare products Regulatory Agency (MHRA) |

## Welcome and introduction, adoption of the agenda

Isabelle Moulon, Head of Medical Information Sector, welcomed participants and introduced new representatives and observers to the audience.

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

The agenda was adopted with no additional comments.

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# 1. Area of involvement in the Agency's activities

## *1.1. Work Programme 2012*

The Agency gave a presentation on the involvement of healthcare professionals' organisations in the Agency's activities throughout 2011 and on the proposed HCP WG work plan for 2012 (see presentation 1.1). This will focus on the implementation of the framework for interaction between the Agency and healthcare professionals' organisations. Such implementation will include the formalisation of the current CHMP working group with healthcare professionals, which will become an EMA working party (HCP WP) with links to all human scientific committees. In addition, the implementation of the new legislation on pharmacovigilance and the strengthening of the Agency as a reference source of information on medicines will continue to be focal areas of work for 2012. Finally, the HCP WG will contribute to the identification of gaps and priorities in the overall interaction of the EMA and healthcare professionals' organisations. It will also continue to look into ways of raising awareness about the Agency's activities.

The chairperson explained that the schedule for 2012 includes now two joint meetings between the HCP WG and the PCWP, as opposed to the single annual joint meeting organised in previous years. Members agreed with this proposal.

Members were asked to provide their comments to the proposed work plan for 2012 and confirm its adoption by 11 November 2011. After this date, and should there be no significant changes, the work plan will be considered adopted by the HCP WG. It will then be presented to the CHMP and will be published in the EMA website.

# 2. Area of Pharmacovigilance

## *2.1. Web-based adverse drug reaction reporting*

As part of the implementation of the new pharmacovigilance legislation, the Agency provided an overview of what is foreseen in terms of developing standard web-based structured forms for reporting of suspected adverse reactions by healthcare professionals and patients (see presentation 2.1). A number of questions were put to the HCP WG in relation to the forms in order to identify aspects that could provide a better and easier reporting experience for healthcare professionals.

It was clarified that the implementation of web-based reporting will have to be done in the context of existing experiences in the different member states.

The Agency will send out the list of questions and collect members' input by 28 November 2011.

## *2.2. Effectiveness of risk minimisation activities in clinical practice: exploring two examples*

The HCP WG was considered as a potential forum to gather initial feedback on the effectiveness of risk minimisation activities. It was therefore proposed to analyze the recent experience with two cases where the Pharmacovigilance Working Party (PhVWP) has consulted the HCP WG.

The first case referred to the effectiveness of the communication practices in EU member states in relation to the dissemination of the recommendations of the CHMP on the use of gadolinium (Ga)-containing contrast agents for magnetic resonance (MR) and risk of Nephrogenic Systemic Fibrosis (NSF). This case was of particular interest because it dealt with a safety issue linked with a newly identified clinical entity – NSF. A member of the PhVWP provided an overview of the feedback received

during the consultation (see presentation 2.2.1). These revealed that, in this case, healthcare professionals would have preferred information from a central point (e.g. regulatory authorities), rather that from different parties (i.e. several marketing authorisation holders) emphasising the importance of coordinating messages between regulators, industry and learned societies. The consultation also pointed out the need to have clear information on the known uncertainties relating to a specific risk and on the evidence base for proposing a risk minimisation measure, such as new contraindications or warnings.

Further discussion with the WG concluded that it would be beneficial to communicate the safety issue beyond the community of radiologists, targeting also clinicians who would be detecting the symptoms of the disease following exposure to the contrast agent (e.g. dermatologists and general practitioners). In addition, the importance of the SmPC was underlined as the main tool to inform healthcare professionals about the conditions of use of a particular medicinal product and therefore additional progress should be made towards its usefulness and readability.

The speaker mentioned the consultation and the additional discussion with the HCP WG had provided very valuable input that would be reported back to the PhVWP in November 2011.

The second case referred to the Isotretinoin pregnancy prevention programme (PPP) in the EU member states. The aim was to get an insight into any difficulties around the implementation of the PPP in clinical practice. The PPP, in consideration of the population exposed, is achieving overall a successful result however data showed that some of the women still had not used any appropriate method of contraception and that there was a small number of exposures to isotretinoin during pregnancy. Data do not allow concluding on the individual factors that may have played a role in these cases. A representative of the Medicines and Healthcare products Regulatory Agency (UK) presented the outcome of the consultation focusing on the proposals for improvement suggested by the responders (see presentation 2.2.2.a). The consultation provided extremely valuable feedback, including some suggestions which now need to be elaborated in more detail before they can be taken further. The results of the consultation will be reported back to the PhVWP in November 2011.

A representative of the Italian consumers' organisation (AltroConsumo) also gave a presentation outlining their experience involving patients in reporting adverse drug events (see presentation 2.2.2. b). An online questionnaire which was tailored to isotretinoin can be found in the following link: http://www.altroconsumo.it/salute/farmaci/inchieste/ho-usato-isotretinoina-per-l-acne-e-questa-e-stata-la-mia-esperienza. Since its launch in April 2009 until October 2011, 335 questionnaires were submitted and the analysis of results performed by AltroConsumo reinforces the usefulness of patient reports.

The chair remarked that evaluation of the effectiveness of risk minimisation measures is part of the new pharmacovigilance legislation. It will be a challenge to identify what will be the outcome measures and where to set a threshold to consider a risk minimisation measure effective (or not).

Building on the examples of gadolinium and isotretinoin it was agreed to continue consulting the HCP WG in similar issues on a case by case basis. It is proposed to discuss later in June 2012 the experience in both fora (PhVWP – HCPWP) to draw some conclusion and identify key factors for a fruitful and useful interaction.

HCP WG members and PhVWP representatives in the meeting agreed with this proposal.

### *2.3. Access to EudraVigilance Data*

The Agency provided an update on the progress so far in the implementation of the EudraVigilance Access Policy which aims to give, in the first phase of the implementation, access to adverse drug reactions data for the healthcare professionals and the general public (see presentation 2.3).

Work is underway to enable the publication of aggregated data for centrally authorised medicines. The public interface allowing access to this data is expected to go live in January 2012. Furthermore, it is foreseen that by the end of 2012, aggregated data for medicinal products non-centrally authorised will be published.

The EudraVigilance Users Group (composed by representatives of the HCP WG and the PCWP) has been involved in the consultations leading to the format and the content presented in the reports which will be made available. Further consultation will now take place during the preparation of guidance to help users interpret and put into context the information on adverse reactions. Members of the HCP WG stressed the importance of such guidance.

There was a suggestion on whether it would be acceptable that HCPs' organisations include a link to EudraVigilance once it is available. The EMA clarified that this is encouraged.

The Agency will give a live presentation at the PCWP/HCP WG joint meeting on 28 February 2012.

## 3. Area of information on medicines

### *3.1. New falsified medicines legislation*

The Agency presented the new falsified medicines legislation which is intended to protect the legitimate supply chain of medicines and will enter into force in January 2013 (see presentation 3.1). The main areas of change in the current legislation were summarised, focusing on the following new measures:

- An obligatory authenticity feature on the outer packaging of the medicines (safety feature);
- A common, EU-wide logo to identify legal online pharmacies;
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients; and
- Strengthened record-keeping requirements for wholesale distributors.

The impact of the new legislation on national competent authorities, the European Commission, the EMA, healthcare professionals and patients was also outlined.

Clarification was provided in relation to the safety feature. The new legislation foresees the inclusion of a unique identifier on the outer packaging which allows verification of the authenticity of the medicinal product and provides the legal basis for establishing details for these safety features and the level of their control in the distribution chain. This obligation applies to all prescription medicines – with the possibility of exceptions if a risk assessment has shown that these products are not at risk. It normally excludes over the counter (OTC) medicines, as these products are usually not the target of falsifiers. However, based on a risk evaluation, OTC medicines can be included in exceptional cases. It was explained that the European Commission was preparing a consultation (expected in December 2011) on the delegated act that will deal with the technical aspects related with the implementation of the safety features, based on the risk of falsification.

Some members expressed concern about the use of an EU logo to ensure the authenticity of internet pharmacies. The Agency mentioned this is not an isolated measure and had to be seen in the context of the awareness campaigns foreseen in the legislation.

Finally, the issue of magistral preparations was raised and how the active substances used for their preparation would fall under the legislation. It was pointed out that, under the new legislation, companies marketing active substances would need to have an authorisation for distribution and would be subject to inspections.

Further progress on the implementation of this legislation will be communicated to the HCP WG in 2012.

### *3.2. Update on the EMA website*

Members of the HCP WG were informed of the recent developments of the EMA website. These include new search functionalities for human medicines, information for the lay reader on the Agency's frequently asked questions, and more multimedia features. The Agency is also working to increase the Agency's presence in social media (Twitter, Facebook, LinkedIn, blogs, online platforms, etc.) and is developing a social media strategy.

Members of the HCP WG were asked to provide a contact person with whom the Agency could liaise in case the organisation has or is developing a social media strategy.

Furthermore, the EMA web team is working on the implementation of the new pharmacovigilance legislation.

## A.O.B.

No other business was proposed for discussion.

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

Close of meeting

Next meeting: 28 February 2012