14 November 2012
EMA/685483/2012
Patient Health Protection

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) Joint Meeting

Minutes – 24-25 September 2012 - 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), European Federation of Internal Medicine (EFIM), European Federation of Nurses Associations (EFN), European Haematology Association (EHA), 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 Institute of Women's Health (EIWH), 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), Health Action International (HAI), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation Europe (IDF-Europe), International Patient Organisation for Primary Immunodeficiencies (IPOPI).

Representatives and observers from the Agency's Scientific Committees: Committee for Human Medicinal Products (CHMP), Committee for Orphan Medicinal Products (COMP), Committee for Herbal Medicinal Products (HMPC).

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

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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 topics for the two-day meeting.

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

The agenda was adopted with no additions.

1. Area of pharmacovigilance

1.1. Update on the implementation of the new legislation

Franck Diafouka (European Medicines Agency, EMA) presented the main achievements in the past 18 months, covering the Agency's preparatory activities on the implementation of the Pharmacovigilance legislation and the first months following its entry into force (see presentation).

The Sixth Stakeholders Forum, scheduled for 8 November, will serve as an opportunity to gather input on the first experiences following the implementation of the legislation, giving particular attention to the functioning of the PRAC, the publication of lists (such as the EURD list[1]), safety communications and notification of referrals, and the use of the black symbol.

The Agency will continue the implementation according to priorities: firstly, public health activities; secondly, transparency and communication activities; thirdly, simplification activities.

Following some questions from the floor, the Agency clarified that adverse drug reaction (ADRs) reports continue to be received via the national competent authorities, including those directly reported by patients (for more details see point 1.5). The Agency also clarified that in relation to the timings for publication of safety announcements (e.g. question-and-answer documents [Q&As] and press releases) work is underway to adapt current communication practices. As for assessment reports of periodic safety update reports (PSURs) these will be published in the future although a date for starting such publication has yet to be defined.

1.2. Call for patient and healthcare professional representatives to PRAC and CAT

Florian Schmidt (European Commission) gave a presentation on the European Commission's call for patient and healthcare professionals' representatives for the Pharmacovigilance Risk Assessment Committee (PRAC) and the Committee for Advanced Therapies (CAT) (see presentation). He explained a first call had been launched in September 2011 but due to the low number of applications received the European Parliament had asked the Commission to re-launch the call, which was published in July 2012. Whilst the limitations to identify a higher number of candidates are acknowledged, the Commission recognises the need to have a larger choice of applicants and therefore encouraged members of PCWP and HCPWG to further disseminate the call among their national networks.

One participant asked on what basis the previous candidates had been rejected. The Commission clarified that no applicant had been rejected. The intention of the re-launched call was to increase the number of applicants and that previous applicants were welcome to apply again.

[1] List of European Union (EU) reference dates and frequency of submission of periodic safety update reports (PSURs)

Another participant commented that there were differences on how a civil society representative could accommodate the workload involved in such activity compared to representatives from national competent authorities and that monetary aspects needed to be reflected upon. The Commission stated that they were confined by a legal requirement and that the funding aspect, although recognised as an important limitation, could not be resolved in a short term and would have to be discussed in the broader context of EMA scientific committees. A participant remarked that when a new legislation is drafted, the cost of involving civil society should be taken into account in its impact assessment.

Additional clarifications were asked regarding the role of the members of the committees and if there was any legal provision preventing civil society representatives from undertaking specific activities. The Commission clarified that all committee members have full voting rights and access to information, however a detailed scientific assessment of a specific product may require specific expertise and direct access to an assessment team of a national competent authority. Based on the assessment team findings, the whole Committee then has the opportunity to express an opinion and vote on the action to take.

One participant asked if the Commission was looking for specific fields of medical expertise for each of the Committees. The Commission replied that this was not specifically requested.

The chair invited organisations to indicate whether they intended to submit an application and three organisations said they would do so. The chair encouraged participants to further disseminate the Commission call among their networks and to consider submitting an application by 1st October 2012.

1.3. Additional monitoring – proposals on the black symbol for SmPC/PL – PCWP/HCPWG position

Alexios Skarlatos (EMA) provided an update (see presentation) on the work which has been carried out to identify the black symbol that shall be included in the summary of product characteristics and the package leaflet of medicinal products subject to additional monitoring. The black symbol will be followed by an appropriate standardised explanatory sentence.

The Quality Review of Documents (QRD) group has worked on draft proposals which will assist the PRAC when drafting the recommendation on the black symbol for the European Commission. The QRD group proposed an inverted black triangle (▼), as preferred choice. QRD presented two options among the various which were considered. The Agency would like to have feedback from patients, consumers and healthcare professionals' regarding the black symbol prior to finalising the PRAC recommendation.

Several considerations were made by different participants. The main point being that the black symbol does not necessarily have to have a meaning or to directly allude to an action as long as the accompanying text is clear enough and conveys the right message. Participants underlined the importance of communication and the need to launch an 'awareness campaign' to provide 'core' explanatory information on what the black symbol stands for and what additional monitoring implies.

The PCWP/ HCP WG agreed that the inverted black triangle (▼) was the preferred choice of both groups and should be located next to the invented name. The symbol should be large, prominent enough, and proportional to the invented name. A minimum size should be defined. A recommendation to include a link to the EMA/NCAs website was also consensual. The EMA/NCAs websites should provide further information on '*additional monitoring*' in lay language.

It was agreed that Ilaria Passarani (BEUC) would present the views of the PCWP/ HCP WG at the PRAC meeting, on 1-3 October 2012.

Once the black symbol and the explanatory sentence have been agreed and at the time of implementation, the EMA will coordinate and provide 'core' explanatory information, which can be used by patient, consumer and healthcare professional organisations to disseminate through their organisations/members.

1.4. Public hearings

François Houÿez (EURORDIS) shared his past experience with FDA public hearings, focusing on the suggestions and recommendations presented to the Agency's Management Board in March 2012 (see presentation).

Monika Benstetter (EMA) presented the current state of affairs on the Agency's reflection on public hearings. She emphasised the importance to involve the PCWP and HCP WG in the current thinking behind the organisation of public hearings (see presentation). Aspects related with when to hold public hearings, how to organise them, how to promote openness and transparency and what could be the modalities of participation have been reflected upon and are currently subject to discussions within the Agency. To support the discussions, the Agency is compiling a list of examples of existing medicinal products where a public hearing could have been organised. The criteria to hold public hearings will be part of specific rules of procedure and a consultation on these should take place in due course.

The current reflection will be discussed with the PRAC and the Agency's Management Board.

The chair invited organisations to provide comments on the presentation within 3 weeks.

1.5. Reporting of adverse drug reactions

Victoria Newbould (EMA) gave an update on the work undertaken by the Agency, in collaboration with the EU Member States, to develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients (see presentation). In the near future, a survey among national competent authorities may be carried out to obtain further experience of how patient reporting has been implemented and also how web-based forms have been utilised for both healthcare professionals and patients/consumers.

It was also informed that an analysis of reports in EudraVigilance between July 1st and end August 2012 shows that reports categorised as 'Non healthcare professional' have increased considerably compared to the same period in 2011 and compared to the 2 month period before the legislation came into force.

Phil Tregunno (MHRA) presented the UK's updated electronic Yellow Card reporting system and expected developments providing details on their experience with patient reporting from 2005 to date. It was noted that although patient reporting makes up only 8% of total cases received, more than 70% of those reports were received electronically, highlighting the benefits of the online system.

1.6. Understanding off-label use and the information needs of patients: a EURORDIS survey in rare diseases

Rob Camp (EURORDIS) presented the results of a pilot EURORDIS survey in rare diseases on understanding off-label use and the information needs of patients (see presentation).

The chair welcomed the initiative to present on this topic but explained that the Agency's remit to discuss off-label use was limited to the context of ADR reporting according to the current legislative framework and this should be the starting point of the discussion.

It was agreed to further discuss this topic at a later stage. Involvement of healthcare professional organisations in the discussions would be also welcome.

1.7. Good vigilance practice under consultation

Priya Bahri (EMA) introduced the Agency's work, in collaboration with national competent authorities, to develop good vigilance practices (GVP) (see presentation). GVP is guidance on pharmacovigilance which apply to marketing-authorisation holders, the Agency and medicines regulatory authorities in EU Member States. They cover medicines authorised centrally via the Agency as well as medicines authorised at national level. The guideline on GVP is divided into 16 modules, each of which covers one major process in pharmacovigilance. Several modules have already been finalised, some have just undergone public consultation and others are yet in the drafting process. The guidance is complemented with an annex covering a range of important definitions.

Juan Garcia (EMA) presented the GVP module on Safety Communication (see presentation). Safety communication refers to emerging new information on an authorised medicinal product which has an impact on its benefit-risk and is aimed to facilitate informed decisions on the rationale use of medicines and to support risk minimisation behaviour. Although the public consultation closed on 21 September 2012, comments were still welcome by PCWP/ HCP WG members until 5 October 2012. It was clarified that aspects related to collaboration with international bodies (such as FDA) in safety communication was also covered by the module.

Isabelle Moulon (EMA) presented the preliminary work on the GVP module covering Public Participation (see presentation). Its objective is to describe and promote the role of the public as a fundamental actor in the pharmacovigilance process. The document is still under internal discussion and once finalised will be circulated for consultation. Participants welcome the initial work and mentioned it would be important to expand on how data protection is taken into account. The chair invited organisations to provide comments on the presentation within 3 weeks.

2. Area of communication and information

2.1. EMA current practice in disseminating information

Sarah Weatherley and Christopher Gadd (EMA) gave an overview of how the Agency disseminates the communication documents that it produces. They also presented the results of a survey on the use of EMA press releases and Q&As as well as the results of some research on syndication of EMA communication material by patient and consumer organisations (see presentation).

In general, the feedback received shows that patient, consumer and healthcare professional organisations are satisfied with the outputs produced by the Agency, but there remains room for improvement. The Agency encourages the organisations' to disseminate information and messages out to patients, consumers and healthcare professionals as much as possible and would like to work together with these organisations to ensure that the Agency and its work is referenced to its full potential.

In this context, the Agency will circulate the outcome of the research on syndication of EMA communication material to the organisations including a list of suggested information that they could link to from their websites (e.g. special topic pages, therapeutic area pages, European public assessment report [EPAR] searches). As the research focussed on patient and consumer organisations, a similar exercise may be done for healthcare professional organisations in the future.

It was also suggested to create links with the web editors of the different organisations as much as possible and to work on syndication initiatives to enable provision of content such as medicine information directly to the organisations' websites.

2.2. Communicating and disseminating information received from EMA: perspectives from healthcare professional and patient organisations

Jūratė Švarcaitė (PGEU), Michel Delvaux (UEG), Susanna Palkonen (EPF) and Christoph Thalheim (EMSP) presented on the current practice from their organisations in disseminating information produced by the Agency (see presentations).

Information sourced from the Agency represents a small but important proportion of the overall information organisations provide to their members and it is disseminated on a regular basis by most of the organisations. This dissemination is often complemented with information on what the Agency is and does.

Various organisations referred to the process of selection of information they undergo when tailoring communication to their members. They welcome any efforts to facilitate the identification of 'value-added information' from the Agency, based on the information needs of each organisation. The Agency acknowledged the important role of organisations in channelling EMA information towards national members and individuals and agreed to further explore ways of centralising the filtering of information relevant to its various stakeholder groups.

Whilst several organisations seem to be keen on using social media and plan to use it to communicate on specific topics (e.g. the 'black symbol'), others pointed out that the majority of their members still have a preference for more traditional channels of communication. This was particularly relevant for some healthcare professionals who continue to prefer scientific journals and email as means of communication.

A number of organisations suggested that audiovisual tools would enrich the communication experience and facilitate the understanding of complex messages. Short videos on specific topics were suggested. The Agency has already published some videos (e.g. video on the new pharmacovigilance legislation) and is currently working on another one which explains what a scientific advisory group meeting is and how patients are involved. Overall, participants welcome the sharing of experiences from different organisations as this encourages further learning among patient, consumer and healthcare professional organisations.

2.3. Proposal to update the EPAR summary template

Daniel Glanville (EMA) presented a set of proposed changes intended to improve the Agency's European Public Assessment Report (EPAR) summaries (see presentation). An EPAR summary explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use. The summaries are published in all official EU languages with the full EPAR at the time of a medicine's authorisation, and they are kept updated following authorisation. The current template was based on an extensive consultation process and has been used for six years.

The revised wording and proposed simplifications were discussed with participants. The proposals represent improvements rather than a departure from the existing template. They principally seek to reduce potential confusion between the EPAR summary and the package leaflet; to structure the information so that it is easier to follow; and to emphasise the elements of the summary which describe, in public-friendly language, the assessment process and rationale for decision-making. Some

suggestions were made by participants in this regard, and the chair invited organisations to provide further comments within 3 weeks, to be considered in the finalisation of the proposed revisions.

3. Other EU activities

3.1. The PROTECT project – benefit/risk integration and representation

Deborah Ashby (Imperial College London) gave an overview of the PROTECT project[2] with particular emphasis on the activities carried out in work package 5 to assess and test methodologies for the benefit-risk assessment of medicines and develop tools for the visualisation of benefits and risks of medicinal products (see presentation).

She mentioned that the PROTECT External Advisory Board had recommended that the optical representation of benefit/risk in WP5 should be tested with one or more patient/consumer and health care professional groups to get their feedback on the usability and interpretability of each representation. This could take the form of online surveys and focus groups.

To facilitate the expression of potential interest by members of PCWP and HCP WG to become involved in WP5, the chair suggested a contact point from PROTECT be identified. She further proposed to follow up on this topic at a future meeting.

4. Area of involvement in EMA activities

4.1. Handling of conflicts of interest of organisations

Juan Garcia (EMA) presented a draft proposal to improve the way to identify and handle in an adequate, proportionate and consistent manner any potential conflict of interest (CoI) that patients', consumers' and healthcare professionals' organisations may have when they are involved in EMA activities.

The current proposal distinguishes two processes: one to evaluate eligibility of patients', consumers' and healthcare professionals' organisations in relation to their funding; and another one to identify and handle any potential conflict of interest from patients', consumers' and healthcare professionals' organisations when they are involved in specific product-related evaluation and discussion.

The proposal would complement the existing criteria to be fulfilled by PCOS and HCPOs involved in EMA activities. It is different and must not be confused with the current policy on the handling of conflicts of interests of Scientific Committee members and experts.

It was underlined that the more an organisation would diversify its sources of funding, as encouraged by the current criteria, the more conflicts were likely to emerge. This was acknowledged as a challenge. Overall, the Agency wants to address as much as possible all these challenges and specificities posed to the different organisations while providing clarity on how it handles any potential conflict of interest.

Participants agreed that the proposal was an additional step forward in improving the handling of conflicts of interest of organisations. The Agency will circulate the draft proposal and the chair invited organisations to provide further comments within 3 weeks.

[2] PROTECT is a collaborative European project aiming to develop innovative methods in pharmacoepidemiology and pharmacovigilance. The EMA coordinates the project with a multi-national consortium of 29 public and private partners.

4.2. Pandemic communication strategy – outcome of the survey on communication practices during a pandemic influenza crisis and proposed lines for action

Ivana Silva (EMA) summarised the input received from 13 organisations on aspects related with communication practices during a pandemic influenza crisis, following an EMA survey carried out in April 2012 (see presentation).

Based on the outcome of the survey, the Agency has considered some lines for action for improving communication with patients, consumers and healthcare professionals' organisations in the context of the EMA pandemic communication strategy (see presentation). Among other actions, the Agency proposes to identify, within the network of PCOS and HCPOs, a core group with particular motivation and capacity (e.g. rapid response to urgent requests) to work closely with the Agency in preparedness activities and in the event of a pandemic.

Members of the PCWP and HCPWG welcome the proposed lines for action and were pleased to know that representatives of patient/consumers and of general practitioners were now members of the SAG vaccines. It was suggested that these representatives should also be part of the core group mentioned above and this was well accepted. The International Alliance of Patient organisations (IAPO), the European Association of Hospital Pharmacists (EAHP) and the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) expressed an interest to be part of the core group.

A particular question was raised by EURORDIS on the preparation of additional information for special groups of patients who need advice on whether or not to be vaccinated with live attenuated vaccines, e.g. immune-suppressed patients, or patients with Guillain Barré syndrome or many other conditions where doctors say such a vaccine may have some risks. EURORDIS asked whether effectiveness of vaccines in these special groups was being further addressed by the SAG vaccines. This matter will be brought forward to the SAG vaccines secretariat for further clarification.

An additional remark was made in relation to the importance of identifying EMA spokespersons in the event of a pandemic.

4.3. Update on the implementation of the Framework for interaction with healthcare professionals

Ivana Silva (EMA) gave an update on the progress so far in the evaluation of eligible organisations and the expected next steps to formalise the Healthcare Professionals Working Party (HCPWP) (see presentation). Following the first evaluations, 12 out of 15 applications have been granted eligibility with a first list of eligible healthcare professional organisations published in August in the Agency's website.

4.4. PCOS Annual report 2011

Nathalie Bere (EMA) presented the document highlighting the increase in the overall number of patients and consumers involved in EMA activities throughout 2011 (a total of 423, compared to 307 in 2010). The growth relates mainly to increased participation in SAG and ad-hoc expert group meetings, increased review of safety communications (Q&As) and package leaflets and increase in activities related to the implementation of new pharmacovigilance legislation (see presentation).

The report was adopted by the PCWP members. This will be published once approved by the Agency's management Board in October.

4.5. PCWP and HCPWP work programmes 2013

Nathalie Bere and Ivana Silva (EMA) presented the draft work programmes (see presentation).

There was significant interest on the medication errors workshop and the inclusion of this topic in the work programme was very welcome.

It was suggested to further consolidate the collaboration between PCOS and HCPOs throughout 2013. Organisations encouraged the Agency to take fewer topics in the joint meetings and use the platform to discuss topics more in depth.

The work programmes were adopted.

5. A.O.B.

Participants were reminded of the training scheduled for 29 November 2012, organised for all eligible patients and consumers' organisations. The training will be dedicated this year to Pharmacovigilance.

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