



Participation of Patients'/Consumers' Representatives as Observer to the PhVWP

Background note

Following the Management Board's agreement at its March 2009 meeting for a pilot phase on the participation of patients'/consumers' representatives in Pharmacovigilance (PhVWP) meetings, an analysis of the pilot phase has been undertaken. Taking into account experience obtained a proposal is made to the Board for participation of patients'/consumers' representatives as observer to the PhVWP.

Matters for consideration

The pilot phase took place from April to June 2009, allowing for 2 patients'/consumers' representatives to participate to 3 consecutive meetings of the PhVWP. The outcome of the pilot was very positive, indicating general support to the concept by all involved parties. A number of recommendations have been made with particular emphasis on the ideal profile of patients'/consumers' representatives participating at the PhVWP, as well as some practical aspects of the participation.

Taking into account the outcome of the pilot phase it is proposed:

- For one patients'/consumers' representative with proven background experience on medicines regulation to participate at the PhVWP as an observer and for a second representative to be an alternate.
- To select these persons, taking into account well defined selection criteria, on the basis of a call for expression of interest, whereby the decision will be made by the EMEA Executive Director on the basis of a shortlist of candidates drafted by the EMEA.
- For patients'/consumers' from scientific disease areas to be consulted when matters arise.



**REPORT FROM EXPERIENCE ACQUIRED FROM PILOT PHASE PARTICIPATION
OF PATIENTS/CONSUMERS REPRESENTATIVES IN PhVWP AND PROPOSAL FOR
PARTICIPATION OF PATIENTS'/CONSUMERS' REPRESENTATIVES AS
OBSERVER TO THE PhVWP**

1. INTRODUCTION

During its 5th March 2009 meeting the EMEA Management Board endorsed a proposal for involvement and participation of patients'/consumers' representatives in the meetings of the CHMP Pharmacovigilance Working Party (PhVWP). The proposal foresaw for a preliminary pilot exercise where patients/consumers would participate as observers in 3 consecutive meetings of the PhVWP with the objective to gain experience. This experience would be analysed in order to make a more formal proposal for the participation of patients'/consumers' representatives in the PhVWP. This proposal will be part of the more general strategy to further progress with the involvement of patients/consumers at the level of the EMEA, which will imply a revision of the current framework of interaction.

The pilot phase was agreed by the CHMP in October 2008, by the ERMS Facilitation Group in November 2008, by HMA in January 2009, and finally endorsed by the EMEA Management Board in March 2009.

This proposal is built upon existing experience at the EMEA in involving patients and consumers in different activities (including safety related issues), but has also taken into account experience obtained in this area by Pharmacovigilance Expert Groups in some Member States (e.g. the "Commission Nationale de Pharmacovigilance" in France and the "Pharmacovigilance Expert Advisory Group" in the United Kingdom).

The pilot phase

The above described pilot phase was designed to run for 3 consecutive meetings of the PhVWP from April to June 2009, and two patients'/consumers' representatives were invited to participate to the entire meetings.

Patients'/consumers' representatives were selected based on a call for expression of interest among eligible organisations (organisations which fulfil the EMEA criteria for involvement - [EMEA/14610/04/Final](#)). Priority was given to those organisations which were members of the Patients and Consumers Working Party (PCWP). Following receipt of 5 valid candidates, the EMEA decided that a representative from International Alliance of Patients' Organizations (IAPO) and a representative from European AIDS Treatment Group (EATG) should participate in the pilot phase of this exercise.

Purpose of the pilot phase

The purpose of the pilot phase was to analyse various aspects in order to be in the position to formulate a clear proposal for involving patients and consumers in the meetings of the PhVWP. It was agreed that the patients/consumers who attended the PhVWP, together with the collaboration from members of the PhVWP and PCWP and of the EMEA secretariat, would draft a report analysing the outcome of the pilot exercise.

The current report therefore identifies “pros and cons” of the planned interaction, and aims to cover the following aspects:

- Identify areas of common interest where cooperation with patients/consumers can be useful.
- Define the expected contribution from patients/consumers to those identified areas.
- Define the role of patients’/consumers’ representatives.
- Define the role of the PhVWP towards the patients’/consumers’ representatives.
- Define the expected outcome of the interaction.
- Address aspects related to confidentiality.
- Explore practical aspects of participation (i.e. number of representatives attending, frequency of participation, etc).
- Consider the different expertise of patients/consumers who will attend (patients as experts in specific therapeutic areas participating on a case-by-case vs. general patients’/consumers’ representatives who could attend more regularly).
- Explore resource and workload implications (for Patients’/Consumers’ Organisations, the PhVWP and the EMEA).

The first draft report was presented to the PCWP during its annual joint meeting with healthcare professionals on 9th June 2009 and to the PhVWP on 22-24 June 2009. Input was received from both parties as well as from the Chairs of the PCWP and the PhVWP.

The report is presented hereby together with a formal proposal for involvement and participation of patients’/consumers’ representatives in the meetings of the PhVWP.

2. ANALYSIS OF THE PILOT PHASE

Personal experience from participants

Patients’ representatives participating in the pilot phase declared that understanding the level of discussions was not a problem for them. However, this might be the case for people who are new to the EMEA and unfamiliar with the regulatory procedures. It is noted that the participants have been members of the PCWP for a long period, and that in addition they have been involved in many other regulatory activities at the level of the EMEA. They therefore recommend that for the time being, delegates/observers which would participate in the PhVWP would preferably have some previous experience in other EMEA activities (e.g. through participation in the PCWP). If this is not possible, training should be foreseen.

The participants also declared to feel very satisfied with the way their contribution was taken into account, and noted that very often their views were also encouraged by the PhVWP Chairperson.

Main difficulties encountered

- The nature of the pilot phase meant that participants were not aware of the historical background of some discussions. This could create some difficulties in the follow-up of some of the topics. The viewpoint of the participants to the pilot phase is that once appointed, observers would overcome this difficulty within a few months.
- The pre-mail documentation sent to them in advance of the meeting was in a way difficult to manage in the beginning; however participants learnt soon to select those topics which could be of more interest to them.
- The fact that the agenda changes significantly prior to the meeting made preparation a bit challenging. Participants were more used to this fact following the three-month period and did not foresee any special difficulty at a longer term.

Personal experience from the PhVWP

The PhVWP was satisfied with the good integration of the patients in the pilot phase, as it was not disruptive, nor did it delay the good functioning of the meetings. Integration in the meeting activities is expected to be even smoother once permanent observers participate regularly.

The PhVWP agrees that the technicality of many of the discussions held at the Working Party suggest the need to select patients/consumers with some background on medicines regulation. EMEA should consider providing training and individual support.

Identified areas of common interest (as per PhVWP agenda & discussions) and expected contributions from patients/consumers for each identified area in real practice

The representatives believe that given the fast increasing amount of safety information on pharmaceuticals, patient involvement in product safety related communication and on risk/benefit discussions is necessary. They have suggested the following areas as being of particular interest. Activities in these areas are expected to benefit if input from patients and consumers is incorporated:

- Communication issues related to safety of medicines. This is considered probably the most important area for patients and consumers at the PhVWP. Their regular participation to the meetings would guarantee timely input in this aspect, and it is felt that general patients/consumers involvement in safety communication would be optimised;
- Risk/benefit discussions when new safety information arises;
- Changes affecting SPC and Package Leaflet;
- CHMP consultations;
- Product withdrawals and suspensions;
- Community legislation on pharmaceuticals (participation in consultations & implementation).

The PhVWP has agreed with the above mentioned areas and activities as their outcome would be optimised by incorporating the patient/consumer views.

Role of patients/consumers

Participants to the pilot phase referred to the patient and user as the final arbiter of acceptable risk. They therefore expressed the need to include the patient view in discussions on medicines safety. The patient view is also important to put safety information into context (e.g. in chronic diseases where ongoing treatment is required). Pharmacovigilance discussions require the presence of patients/consumers (as well as healthcare professionals) in order to take both clinical practice and public health needs into account.

Patient observers to the PhVWP should also identify topics which may require or benefit from additional patient consultation and act as a link for other patients'/consumers' organisations (from specific disease areas). In this aspect, the existing EMEA network of patients/consumers experts is highlighted. Through this network, observers to the PhVWP could guarantee timely access to experts in the different areas whenever it is required, as usually the timings to allow such consultations is very tight.

During the pilot phase, the contribution of participants on Package Leaflet wording changes was much appreciated. Regular participants are also expected to take an active role in facilitating and coordinating the interaction between the PhVWP and the PCWP (e.g. PhVWP consultation on Package Leaflet wording).

Patient/consumer participating at the PhVWP will facilitate and prepare for the implementation of future legislation, whereby patients may become permanent members of the group.

Role of the PhVWP

The PhVWP should be able to identify those issues which may benefit from patient/consumer input and should formulate adequate questions in order to extract the patient/consumer view, therefore ensuring that the patient/consumer representatives play an active role in the discussions.

In some cases, it might be necessary to explain complex issues in non-technical language to guarantee full understanding of all issues.

During the pilot phase the role of the PhVWP Chairperson has been much highlighted, and participants have appreciated the Chairperson's pro-activity towards their involvement in the discussions, frequently asking for their views, and clarifying any issue whenever necessary. Reaction from the members equally facilitated patient involvement while not undermining the good functioning of the meeting.

With regard to the role of the PhVWP secretariat, and considering the experience during the pilot phase, the individual and flexible support offered to the participants, has been pointed out as critical in facilitating the exercise. Support should be tailored to the specific needs of the selected patient/consumer. Pre and post-meeting teleconferences where the agenda and other issues necessary for a good preparation were reviewed is proposed as an optimal way for their preparation.

Resource and workload implications (for patients/consumers, PhVWP and EMEA)

Feedback obtained from participants to the pilot phase indicates that attending a 3-day PhVWP meeting represents at least 7-8 workdays for the patient observer per month. This is felt necessary in order to guarantee an adequate contribution to the Working Party, and this fact should be clearly considered by any patients'/consumers' organisation when proposing a member to participate regularly in the meetings of the PhVWP. The long term sustainability without financial support has been questioned by the participants.

The EMEA secretariat provides specific technical and logistic support to patients/consumers who participate in EMEA activities, e.g. pre and post-meeting teleconferences, provision of scientific and regulatory background as necessary. A contact person from the EMEA secretariat should be appointed in order to provide specific support to patients/consumers before, during and after every meeting.

Aspects on confidentiality

Pilot phase participants were included in the mailing list of the PhVWP and received all relevant meeting documentation as any other member of the PhVWP. They were not allowed to disclose nor discuss any document or information with any third party, as they remained bound by confidentiality. In the framework of the specific confidentiality arrangements between the EMEA and the FDA, the EMEA informed the FDA of the participation of patients/consumers as observers in the PhVWP, prior to any related activity/exchange of information.

From the EMEA point of view, no issue related to confidentiality was identified during the pilot phase.

Confidentiality was neither perceived as a problem by the participants. However, some expressed disappointment at not being able to discuss some issues with other members within their organisations. They understood however the boundaries as agreed.

3. OUTCOME OF THE PILOT-PHASE

Outcome of interaction

The inclusion of patient observers and experts in the PhVWP will improve its outcome, is in line with current initiatives on transparency and would facilitate patients'/consumers' integration in case future legislation foresees for it.

The pilot phase has provided evidence of the potential benefit whereby regulatory recommendations and communications can be enriched with the patient/consumer view, and thus improve safety information which would lead to better and more appropriate use of medicines. Participants of the pilot phase consider that it is vital to include the patient perspective in discussions on risk/benefit of medicines and for them to contribute to safety communications. Their presence at the Working Party is expected to also improve transparency towards the general public as well as increasing public trust in the regulatory process.

The PhVWP welcomed participation from the patient's representatives and the contributions made so far, and therefore fully support future representation and increased cooperation.

Ideal profile(s) of patient/consumer participating

A medical background is not needed for patient/consumers observers to the Working Party. A broad view on medical and legislative questions related to the approval and use of medicines (regulatory know how at both national & European levels) is required. Patients/consumers acting as delegates/observers should be familiar with drug development, regulatory processes and the legal Community framework affecting pharmaceuticals. A broad understanding of pharmaceutical safety issues in specific disease areas and beyond is recommended.

Proven regulatory experience (e.g. through participation to the PCWP) as well as proven experience in patient advocacy at European level is considered to be key for a smooth integration of the patient observer(s) and experts at the Working Party.

Practical aspects of participation

Based on the experience from the pilot phase participants, it is recommended that one patient/consumer representative with proven background experience on medicines regulation joins the PhVWP as an observer; a second representative with similar profile and background should stand as alternate. Both delegate and alternate will receive full documentation and the alternate will attend when the delegate is not able to do so. Both should ensure that they communicate and coordinate between themselves. The alternate would need to participate at some meetings for training purposes, and should be offered the possibility to attend the WP meetings at least 2-3 times per year (even if the member is attending as well).

Patients/consumers from specific disease areas could be consulted as experts when matters arise. Experts already in the EMEA network of patients/consumers experts should be given preference. Observer/alternate is expected to take an active role in the liaison and interaction with the expert. This consultation could be done by written procedure or alternatively the patient/consumer could be invited to attend the specific discussion of the PhVWP.

4. PROPOSAL FOR INVOLVEMENT AND PARTICIPATION OF PATIENTS' /CONSUMERS' REPRESENTATIVES IN THE MEETINGS OF THE CHMP PHARMACOVIGILANCE WORKING PARTY

Legal basis

The involvement of patients and consumers in EMEA activities has been introduced in Community legislation in 2000, in particular through the entry into force of Regulation (EC) N° 141/2000 on orphan medicinal products. As a consequence of such legislation, three representatives of patients' organisations have been members of the Committee on Orphan Medicinal Products (COMP). Their role has been the same as for the other members, for example acting as Rapporteur for Orphan Designation according to their expertise, when appointed by the Committee.

In addition, Article 4 (d) of Regulation (EC) N° 1901/2006 on medicinal products for paediatric use, states that the Paediatric Committee of the EMEA will include three members and three alternates in order to represent Patients' Associations. Their role will be the same as for the other members of the Committee.

Article 21 (d) of Regulation (EC) N° 1394/2007 on advanced therapy medicinal products, also foresees for two members and two alternates within the Committee on Advanced Therapy (CAT) in order to represent Patients' Associations.

The legislative provisions in Regulation (EC) N° 726/2004 widened the scope of involvement of patients in EMEA activities:

- Article 78 of Title IV of Regulation (EC) N° 726/2004 states the following:
 1. *"The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the health professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission".*
 2. *"The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article, shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products,*

in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees may, on an advisory basis, establish contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned."

Rationale for proposing participation of patients and consumers in the CHMP Pharmacovigilance Working Party

The proposal is in line with the revised EMEA strategy to further progress with the involvement and participation of patients and consumers in scientific activities of the EMEA Committees and their Working Parties.

Participation of patients and consumers in the meetings of the PhVWP has been highlighted as one of the first initiatives to be explored in this respect. The following reasons supported it:

- The initiative is compatible with provisions already in the mandate, objectives and rules of the procedure for the CHMP PhVWP ([EMEA/CHMP/PhVWP/88786/04](#)). Section VI.9 "Contacts with Interested Parties" states:
 - o *"Co-operation with interested parties, including the scientific community, will be notified to the CHMP and undertaken as considered appropriate, depending on the issue being raised. In particular, such contacts will be established, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and healthcare professional organisations"*.
 - o *"The PhVWP may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the CHMP and under specific conditions to be agreed by the CHMP"*.
- Outcome of the pilot phase confirms the interest and added value of involving patients and consumers in the PhVWP. In addition, all practical aspects which have been analysed are expected to facilitate smooth implementation of the proposal.
- Positive experience already exists on the regular involvement of patients and consumers in the activities of the PhVWP. In particular the PhVWP has sought in several occasions the view of the PCWP on a proposed wording to update the Package Leaflet of some medicines. This interaction is expected also to be improved by having a permanent patient/consumer attending the PhVWP.
- The European Commission's legislative proposals to strengthen and rationalise the EU system of pharmacovigilance foresee the establishment of a Committee within the EMEA to replace the existing PhVWP. Given that the composition of the Committee could comprise representatives of patients' associations as full members, implementation of the current proposal would facilitate a smoother integration of patients and consumers as full members of the Committee, once the future legislation is implemented.
- The experience analysed during the pilot phase on the involvement of patients and consumers in the work of Pharmacovigilance Expert Groups in some Member States (e.g. "Commission Nationale de Pharmacovigilance" in France and the "Pharmacovigilance Expert Advisory Group" in the United Kingdom are in line with the results of the pilot phase, and confirms the interest and added value of the participation of patients/consumers in the PhVWP (see Annex 1).
- The PCWP Work Plan for 2009/2010 includes an action to strengthen the interaction between the PCWP and the EMEA Scientific Committees/Working Parties.

Proposal for participation of patients'/consumers' representatives as observers to the PhVWP

Based on all previous considerations and result analyses from the pilot phase, the following is proposed:

- One patient/consumer representative with proven background experience on medicines regulation joins the PhVWP as an observer; a second representative with similar profile and background should stand as alternate.
- Patients/consumers from specific disease areas could be consulted as experts when matters arise. Experts already in the EMEA network of patients/consumers experts should be given preference for involvement.
- Patients/consumers to join the PhVWP as observer/alternate will be selected based on a call of expression of interest.
- The EMEA, pursuant to the selection criteria as identified below, will evaluate the candidates and will propose a shortlist of candidates in order of preference to become observers/alternates of the PhVWP.
- HMA and the EMEA MB will be informed of the proposed shortlist of candidates.
- Based on the shortlist of candidates, and as per the indicated order of preference, the EMEA Executive Director will nominate an observer and an alternate to join the PhVWP.
- Selected candidates will participate to the PhVWP according to the “rules for participation”, which are presented in Annex 3.

The selection criteria will be the following:

- The patient/consumer must be member of an organisation which fulfils the “*Criteria of Patients' and Consumers' Organisations for involvement in EMEA Activities*” as adopted by the Management Board in 2005 (see Annex 2).
- The candidate should have proven regulatory experience (e.g. through participation to the PCWP) as well as experience in patient advocacy at European level. Patients/consumers acting as delegates/observers should be familiar with drug development, regulatory processes and the legal Community framework affecting pharmaceuticals. A broad understanding of pharmaceutical safety issues in specific disease areas and beyond is recommended. A medical or any other scientific background is not specifically requested.
- The candidate should have a good understanding of the work implications of the tasks to be undertaken (as per the analysis in the current report) and should commit to participate regularly to the meetings of the PhVWP and to contribute as expected to the different activities for which he/she might be eligible.
- The capacity to potentially contribute to the work of the PhVWP will be taken into account.

ANNEX 1

EXISTING EXPERIENCE IN INVOLVING PATIENTS AND CONSUMERS AT NATIONAL LEVEL

The proposal for participation of patients/consumers in the PhVWP takes into account experience obtained with the involvement of patients and consumers in the work of Pharmacovigilance Expert Groups in some Member States. The examples of the “Commission Nationale de Pharmacovigilance” in France and the “Pharmacovigilance Expert Advisory Group” in the United Kingdom are hereby presented:

Experience in France (AFSSAPS)

In France a formalised model in which patients/consumers are part of a Pharmacovigilance Expert Group is in place. The “Commission Nationale de Pharmacovigilance” has 1 patient as member and 1 patient as alternate as part of its current composition. Both regularly attend the meetings of the “Commission Nationale de Pharmacovigilance” in its totality. They bring personal expertise to the group, but do not represent the views of any organisation. The organisations they belong to however fulfil the selection criteria laid down by the Ministry of Health.

Participation of patients/consumers is foreseen in the mandate of the group, which makes no difference in the rules which apply to all members equally. This model has been in operation for more than 4 years, and the analysis of the experience shows a very positive impact in terms of contribution.

Experience in the United Kingdom (MHRA)

The “Pharmacovigilance Expert Advisory Group” at the MHRA has two lay representatives as part of its current composition. They regularly attend the meetings of the Advisory Group in its totality, and provide the view of the patients and of the lay community. They do not represent any organisation, and have been selected and nominated based on their expertise.

Participation of these lay representatives is foreseen in the mandate of the group, which makes no difference in the rules which apply to all members equally. Lay representatives have been part of the “Pharmacovigilance Expert Advisory Group” for almost 2 years and, also in the UK, experience shows a very positive impact in terms of contribution.

ANNEX 2

Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMEA Activities

I. Introduction

This paper has been developed to define the criteria patients' and/or consumers' organisations should fulfil in order to be involved in EMEA activities, such as the COMP or the CHMP/EMEA working group with patients and consumers' organisations.

These criteria do not apply to the procedure for external consultation on documents, since such external consultation is open to all external parties.

II. Definition of Patients'/Consumers' Organisations

Patients' organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies.

These could be:

- either general umbrella organisations (e.g. representing either European specific disease organisations and/or national umbrella organisations)
- or European disease specific organisations (i.e. representing national organisations or individual patients on acute and/or chronic diseases).

Consumers' Organisations are defined as not-for profit organisations which defend and promote the general interests of European consumers - citizens as purchasers or users of goods and services.

III. Criteria to be fulfilled

The organisations should be established at European Union (EU) level, and should fulfil the following criteria:

- Legitimacy: the organisation should have statutes registered in one of the Member States of the EU. If it is an international organisation not registered in a EU Member State, additional information needs to be provided demonstrating EU focus and activities.
- Mission/Objectives: the organisation should have its mission/objectives clearly defined and should agree to have it/them published on the EMEA website.
- Activities: the organisation should have, as part of its activities, a specific interest in medicinal products which should be documented (e.g. through a report published on the organisation website).
- Representativity: the organisation should be representative of patients or consumers throughout the EU. Organisations already registered at Community level, e.g. in the EU Health Forum, the Council of Europe, are considered to adequately represent patients or consumers for involvement in EMEA activities.
- Structure: the organisation should have governing bodies which are elected by their members, who shall be patients, their carers, or their elected representatives.

- Accountability and Consultation Modalities: statements and opinions of the organisation should reflect the views and opinions of its members and adequate consultation procedures with those members should be in place. In particular, the organisation should ensure that the appropriate flow of information is in place to allow dialogue both ways: from and towards its members.
- Transparency: as a general rule, the organisation should be as transparent as possible, e.g. by regularly publishing, on its website, a report on the activities undertaken. The organisation should also disclose its sources of funding both public and private by providing the name of the public and/or private bodies and their individual financial contribution in terms of percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. Any conflict of interest should be disclosed to the EMEA. In case of umbrella organisations the list of member associations should be publicly available. The reference to private bodies does not include private individuals unless this presents a potential conflict of interest as referred to above.

In addition, Patients' and Consumers' Organisations shall be committed to take active part in the interaction with the EMEA. To facilitate communication, a contact person shall be identified.

In case of lack of European associations for a specific disease or treatment areas, the involvement of national organisations may be considered even though preference will be given to European wide-associations. These associations will need to fulfil the same criteria apart from representativity which will be at national level.

In case of several associations existing in different Member States, a choice will be considered on a case-by case basis.

In order to further increase the transparency in this field, the EMEA will create a public registry of those patients' and/or consumers' organisations with whom it will interact, as a consequence of the fulfilment of the above criteria.

ANNEX 3

RULES OF PARTICIPATION OF PATIENTS' / CONSUMERS' REPRESENTATIVES IN THE PHARMACOVIGILANCE WORKING PARTY

- Patients/consumers will be nominated observer/alternate to the PhVWP for a period of 1 year, which may be renewed.
- Patients/consumers participating will be nominated following the procedure described in section of this document and according to defined criteria for selection.
- Patients/consumers acting as observer/alternate to the PhVWP will attend the whole PhVWP meetings, participate in the discussions, express their views, but cannot take part in the conclusion process.
- Patients/consumers are bound by confidentiality and by no means are allowed to disclose nor discuss any document or information with any third party. They will also have to adhere to the EMEA Code of Conduct.
- Patients/consumers will have to comply with the EMEA handling of conflicts of interests.
- Patients/consumers will be included in the current mailing list of the PhVWP and will receive all relevant meeting documentation as any other member of the PhVWP.
- In the framework of the specific Confidentiality Arrangements between the EMEA and the FDA, the EMEA will inform the FDA of the participation of patients/consumers as observer/alternate in the PhVWP, prior to any related activity/exchange of information.
- A contact person from the EMEA secretariat will be appointed in order to provide specific support to patients/consumers before, during and after every meeting.
- The alternate will attend when the delegate is not able to do so. Both should ensure that they communicate and coordinate between themselves. The alternate would need to participate at some meetings for training purposes, and should be offered the possibility to attend the PhVWP meetings at least 2-3 times per year (even if the member is attending as well).
- Patients/consumers from specific disease areas could be consulted as experts by the PhVWP when matters arise. Experts already in the EMEA network of patients/consumers experts should be given preference for involvement.
- Patient/consumer acting as observer/alternate to the PhVWP is expected to take an active role in the liaison and interaction with additional patients/consumers experts which might be consulted. This consultation could be done by written procedure or alternatively the patient/consumer could be invited to attend the specific discussion of the PhVWP.