European Medicines Agency

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

I. Introduction

Since its creation in 1995 the EMEA has engaged in a dialogue and interaction with its various stakeholders. Among them, the interaction with patients and consumers has achieved a high level of formalisation and structure, and the successful model used by the EMEA to build up such interaction has been considered as a reference to reach other groups of EMEA stakeholders.

In September 2005 the EMEA Management Board endorsed a specific framework in the field of interaction between EMEA and Patients' and Consumers' Organisations (EMEA/354515/2005-Final). This framework defines the objectives to be achieved in order to better structure and formalise the interaction and to tackle new challenges as derived from the implementation of new pharmaceutical legislation as well as the implementation of the EMEA Road Map to 2010.

II. Report on the progress of the interaction with Patients' and Consumers' Organisations

Further to the endorsement of the framework of interaction with Patients' and Consumers' Organisations, the Management Board requested the EMEA to present a report on the outcome and progress made at the end of each year as regards the level of implementation of the interaction. A first report was presented to the Management Board at its June 2008 meeting.

The conclusions from the report show that the work achieved so far has established the grounds towards a more systematic interaction and involvement of patients and consumers at different levels of the Agency's work. However, there is still a need to formalise the procedures which have been established and to further enhance the level of interaction in the different areas. This will have to be particularly considered for activities at the level of the different EMEA Scientific Committees.

It is concluded that patients and consumers are ideally situated to provide a valid contribution to the activities of the EMEA Scientific Committees and their Working Parties, and therefore further emphasis should be given in order to foster their involvement and participation at this level.

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Identified next steps within this report comprise the preparation of a "Reflection Paper" which will propose a framework with specific actions to further develop this more systematic interaction and involvement of patients and consumers at the level of the EMEA Scientific Committees and their Working Parties. The proposal for participation in the PhVWP will be part of the content of this "Reflection Paper" and will, therefore, be developed at a later stage. The current document foresees for a pilot exercise where patients/consumers will participate as observers in to 2 to 3 consecutive meetings of the PhVWP, to gain experience. This experience and its subsequent analysis will be utilised for the development of the more general strategy to further involve patients/consumers at the level of the EMEA (which, among others, will include a formal proposal for involvement and participation of patients/consumers at the level of the PhVWP).

III. 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) Nº 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) Nº 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) Nº 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) Nº 726/2004 widened the scope of involvement of patients in EMEA activities:

- Article 78 of Title IV of Regulation (EC) Nº 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."*

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

After having considered the outcome of the report mentioned in Section II., a discussion at the level of the Patients' and Consumers' Organisations Working Party (PCWP) has been held on how to foster 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 was highlighted as one of the first initiatives to be explored in this respect. The following reasons supported it:

- The initiative is in line with provisions already in the mandate, objectives and rules of procedure for the CHMP PhVWP (EMEA/CHMP/PhVWP/88786/04). Section VI.9 "Contacts with Interested Parties" states:
    - *"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".*
    - *"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".*
- Positive experience already exists on the 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. Additionally it can be explored which PhVWP activities can benefit from patient input.
- The European Commission's legislative proposals to strengthen and rationalise the EU system of pharrmacovigilance foresee the establishment of a Committee within the EMEA to replace the existing PhVWP. It is proposed that the composition of the Committee comprises two representatives of Patients' Associations as full members. Participation of patients and consumers in the current PhVWP could be an opportunity to allow both members of the Working Party and patients/consumers to get used to work together. This would facilitate a smoother integration of patients and consumers as full members of the Committee, once the future legislation is implemented.
- The PCWP Work Plan for 2008 includes an action for exploring further interaction between the PCWP and the EMEA Scientific Committees/Working Parties.

V. Some examples of existing experience 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.

VI. Proposal for "pilot" participation of patients' / consumers' representatives as observers to the PhVWP

After having discussed the proposal for involvement of patients' / consumers' representatives in the PhVWP meetings at the level of the PCWP and the PhVWP, it has been agreed that many practical aspects still require further analysis. Therefore, a pilot phase is being proposed. In this aspect, elaboration of a clearer proposal will need to be built upon the experience acquired from the pilot phase in which patients / consumers should attend 3 consecutive meetings of the PhVWP.

In addition to the experience acquired from this pilot phase, the above-mentioned experience of similar models at national level (i.e. the "Commission Nationale de Pharmacovigilance" in France and the "Pharmacovigilance Expert Advisory Group" in the United Kingdom), will also be considered.

Following the pilot phase, the EMEA Secretariat, together with patients/consumers having attended the PhVWP and with the collaboration and input from members of the PhVWP will draft a report analysing the outcome of the pilot exercise, and putting it in perspective with the experience already existing at national level. The report will identify "pros and cons" of the planned interaction, and will 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 to attend (patients as experts in specific therapeutic areas participating on a case-by-case and selected from the EMEA network of patient experts *vs.* general patients' / consumers' representatives who could attend more regularly).
- Explore resource and workload implications (for Patients' / Consumers' Organisations, the PhVWP and the EMEA).

VII. Next steps

Following agreement of this proposal by the PhVWP in its May 2008 meeting, by the PCWP in June 2008, by the CHMP in October 2008 and by the ERMS Facilitation Group in November 2008, the proposal will be provided to the HMA in January 2009 and the EMEA Management Board in March 2009 for their agreement. Once agreement has been obtained implementation is expected from April 2009 onwards.

The report which will be drafted to analyse the experience obtained during the pilot phase will be used for the development of a more general strategy on how to further involve patients / consumers in EMEA activities.

ANNEX 1

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

Two patients/consumers will participate to 3 consecutive meetings of the PhVWP as observers. The following rules of participation will apply during the pilot phase:

- Patients/consumers participating in the pilot phase will be members of Patients' / Consumers' Organisations which fulfil the EMEA eligibility criteria (see annex 2) which allow involvement in EMEA activities.

- Patients/consumers will be selected based on a call of expression of interest among eligible Organisations. Priority will be given to those Organisations which are currently members of the PCWP.

- The EMEA will decide on the most adequate candidates who have expressed an interest and will nominate them. Candidates' background and experience, as well as capacity to potentially contribute to the work of the PhVWP will be taken into account.

- Patients/consumers acting as observers to the PhVWP may attend the whole PhVWP meeting, participate in the discussions, express their views, but cannot take part in the conclusion process.

- Patients/consumers are bound by confidentiality and will 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. Patients/consumers by no means are allowed to disclose nor discuss any document or information with any third party, as they remain bound by confidentiality.

- 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 observers 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 meting.

- Following finalisation of the pilot phase, patients/consumers will participate together with the EMEA Secretariat and PhVWP members in the preparation of the above-mentioned report which will analyse the pilot exercise. The report will not contain any confidential information.

ANNEX 2

European Medicines Agency
Evaluation of Medicines for Human Use

London, 7 February 2005
Doc. Ref. EMEA/14610/04/Final
Approved by MB 29 September 2005

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.

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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.