European Medicines Agency

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RULES OF INVOLVEMENT OF MEMBERS OF PATIENTS' / CONSUMERS' AND HEALTHCARE PROFESSIONALS' ORGANISATIONS IN COMMITTEES RELATED ACTIVITIES*

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***This document is a revision of 'Rules of involvement of members of Patients' and/or Consumers' Organisations in Committees related activities' (EMEA/483439/2008) to make these rules also applicable to Healthcare Professionals' Organisations.**

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Rules of involvement of members of Patients'/Consumers' and Healthcare Professionals' Organisations in Committees related activities

1. Background and legal basis

The new Community legislation gives additional responsibilities to the Agency, its Management Board and its Scientific Committees to develop contacts with its various stakeholders. The objective is to provide better information and facilitate communication and dialogue on matters of common interest relating to medicinal products.

> Article 78 (1) and 78 (2) in Title IV of Regulation (EC) No 726/2004 provide as follows:
> *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.*
> *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.*

The objective of this procedure is to define different types of consultation, on an advisory basis, of specific Patients'/Consumers' and Healthcare Professionals' Organisation(s) on product, disease or treatment area specific issues.

- by the Scientific Committees (CXMP[1]);
- by the Working Parties or the Scientific Advisory Groups;
- by the Rapporteurs.

2. Conditions for the consultation

General conditions

The consultation will follow the Rules of Procedure of the CXMP/Working Party/Scientific Advisory Group.

The need for a given consultation should be agreed by the CXMP and should be channelled through the EMEA secretariat for organisation.

The CXMP should decide beforehand whether the Committee wishes to consult Patients'/Consumers' and Healthcare Professionals' Organisations by inviting a representative acting on behalf of that organisation, or a member of a given organisation acting as an individual expert.

In both cases, the scope of the consultation should be clearly defined and questions to be addressed should be adopted by the Committee. This will help the organisations to identify the right member(s) to attend the discussion and facilitate the preparation of such consultation.

[1] CXMP refer to CHMP, COMP, HMPC, PDCO and CAT.

The EMEA will send the request to the contact person of the organisation for nomination of either member(s) who will represent the organisation or member(s) who will act as individual expert(s). As far as possible the request should be sent well in advance of the meeting to allow the organisation to make the necessary arrangements.

In order to make sure that the EMEA establishes contacts only with the appropriate organisations, and that it gets contributions which are representative of the members of the organisation at European level,, the consulted organisation(s) will have to fulfil certain criteria defined by the Agency and its Committees[2]. In exceptional cases, if justified, the CXMP may decide to consult an organisation not fulfilling the criteria. However such an organisation should still be fully transparent with regard to its activities and funding.

The member(s) nominated by the organisation to participate either as representative(s) of the organisation or as expert(s), will have to adhere to the EMEA Code of Conduct and to the provisions defined in the EMEA policy on the Handling of Conflict of Interests. Additional specific conditions will apply, depending on whether the organisation's member(s) are invited as representative(s) of their organisation or acting as individual expert(s).

Specific conditions

Patients/consumers or healthcare professionals as representatives of their organisation

Patients/consumers or healthcare professionals representing their organisation will have the responsibility to liaise with the organisation as necessary in order to deliver the position of the organisation on the questions to be addressed.

In case of involvement in a product related activity, the applicant/sponsor/MAH will be informed in advance about the Stakeholder Organisation consultation and of any list of questions being put to them. In this case, confidential data could be brought to the knowledge of the concerned organisation. The agreement of the applicant/sponsor/MAH should be sought prior to disclosure of these confidential data.

In case the applicant/sponsor/MAH does not agree to a consultation with representative(s) of a Patients'/Consumers' or Healthcare Professionals' Organisation, this will be made public at the end of the evaluation procedure as part of the usual publication on outcomes (e.g. EPAR, publication on withdrawal or negative opinion). Where the applicant/sponsor/MAH submits reasons for this refusal, these will also be published.

Patients/consumers or healthcare professionals as experts

Patients/consumers or healthcare professionals may be invited as an individual expert, and therefore not representing his/her organisation. He/she will have to adhere to the same rules as all other experts participating in EMEA activities, especially with regard to confidentiality undertaking and will have to adhere to the EMEA Code of Conduct.

No documentation will be sent prior having received the signed form(s) (i.e. declaration of interest and confidentiality undertaking).

The balance between confidentiality and the need for sharing the information within the organisation concerned is recognised. Therefore if for technical reasons the member needs the opinion of colleagues from his/her organisation in order to prepare for the discussion, he/she should inform the

[2] For patients' and consumers' organisations: "Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMEA Activities" (EMEA/14610/04/Final).
For healthcare professionals' organisations: "Criteria to be fulfilled by Healthcare Professionals' Organisations involved in EMEA Activities"(EMEA//)

EMEA Secretariat and send the names of the additional members with whom the information would be shared. They would have to respect the same rules before they could have access to any information, in particular all the members would have to sign the confidentiality undertaking.

In case of involvement in product related activity, the applicant/sponsor/MAH will be informed of the names of the person(s) in accordance with the same rules as for any other expert consulted. In case the person acting as expert is approached by the applicant/sponsor/MAH, he/she should immediately contact the EMEA.

In accordance to article 62(2) of Regulation (EC) No 726/2004, when involved as expert, the member of the patients'/consumers' and healthcare professionals' organisation will be entered in the EMEA EU experts' database.

3. Consultation

Within the patients'/consumers' and healthcare professionals' organisations, most members are subject to constraints in terms of time, budget and availability for travelling to the EMEA. Therefore the relevance of their involvement in such CXMP activities will be carefully assessed before any decision on their involvement can be taken. In addition, alternative tools for interaction will be envisaged as far as possible including written procedure, video link or teleconference. However when the presence as experts or as representatives of patients'/consumers' and healthcare professionals' organisations is deemed necessary, the meeting will take place at the EMEA offices in London.

As far as possible, the EMEA will send the relevant documentation well in advance of the meeting to allow sufficient time for preparation. The timeframe will be adapted to the procedure involved.

In accordance with the Rules of Procedures, the Committee/ Working Party/Scientific Advisory Group shall neither conduct any deliberations nor reach any formal opinions or decisions in the presence of representatives from any organisation. This does not apply to the situation when such representatives are involved as individual experts.

Whether the patient(s)/consumer(s) or healthcare professional(s) were invited as representative of their association or as expert, the relevant section of the minutes will be circulated to them for comments, excluding the section on the deliberations or any formal opinions or decisions reached by Committee/ Working Party/Scientific Advisory Group. The minutes or the outcome of the discussion will be forwarded to the Committee
In case of consultations taking place directly with a Rapporteur or a Working Party/Scientific Advisory Group, a report on the outcome of such contacts should be provided to the Committee.

If the organisations' representatives wish to keep some information confidential (such as private information which cannot be anonymised) from the company concerned, they should state it clearly and this should be recorded in the minutes of the meeting.

If the organisations' representative(s) were consulted on a centralised procedure, this consultation will be reflected in the public assessment report (e.g. EPAR, withdrawal assessment report).

Expenses related to travel and accommodation regarding the meeting (i.e. travel arrangement, hotels, daily allowance) will be covered by the EMEA in accordance to the EMEA rules for reimbursement. In case of patients and consumers, specific implementation rules may apply.