

**RECOMMENDATIONS ON CONTACTS  
WITH REPRESENTATIVE ORGANISATIONS**

*Doc. Ref.: CMDh/055/2006/~~Rev2~~Rev3  
~~May~~ August 2011*

**Reference: CMDh Rules of procedure, Article [1415](#)**

1. *Contacts with representative organisations may be held under the conditions to be defined by the CMDh.*
2. *The CMDh shall neither conduct any deliberations nor reach any formal positions in the presence of members of representative organisations.*

## 1. Background

Having in regard the Rules of procedure, the CMDh has decided to support its contacts with stakeholders by adoption of this guidance document. The CMDh has various stakeholders - patients, consumers and users of medicines, healthcare professionals, academia, learned societies, pharmaceutical industry. The document defines the rules and the conditions of such meetings and establishes the contacts on a transparent basis.

## 2. Scope of interaction

Communication of CMDh with representative organisations shall include general issues as CMDh guidance documents, experience with the system/ procedures, transparency issues. In these meetings individual procedures shall not be discussed.

## 3. Contacts with representative Patients' and Consumers' Organisations<sup>1</sup>

Contacts with patients' and consumers' organisations shall develop in close collaboration with the partners in the European Union (EU) Regulatory System by having CMDh observers in existing activities, namely in the EMA Human Scientific Committees Working Party with Patients and Consumers Organisations (PCWP). Nomination of observers shall be agreed in the CMDh plenary session.

A meeting of CMDh and patients' and consumers' organisations can be organised upon request of patients' and consumers' organisations or if need is identified by the CMDh.

## 4. Contacts with representative organisations of Health Care Professionals

Contacts with health care professionals shall develop in close collaboration with the partners in the European Union (EU) Regulatory System by having CMDh observers in existing activities, namely in the EMA/CHMP Working Group with Health Care Professionals. Nomination of observers shall be agreed in the CMDh plenary session.

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<sup>1</sup> Doc. Ref. EMA/14610/04/Final Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMA activities, [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/12/WC500018099.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf)

A meeting of CMDh and representative organisations of healthcare professionals can be organised upon request of representative organisations of healthcare professionals or if need is identified by the CMDh.

## 5. Contacts with representative organisations of Pharmaceutical Industry

- 5.1. A meeting of CMDh and representative organisations of the pharmaceutical industry can be organised at the request of the representative organisations of the pharmaceutical industry or if need is identified by the CMDh.
- 5.2. To ensure the dialogue is transparent and balanced all representative organisations of the European pharmaceutical industry shall as a general rule be invited at the same time.
- 5.3. At least one meeting shall be organised each year. If need is identified extra meeting(s) can be held. Decision on the date and agenda of the meeting(s) shall be taken in the CMDh plenary session, preferably two months before the meeting to allow the preparation by all parties involved.

## 6. Meetings with representative organisations shall be open to all CMDh members

CMDh may decide to delegate the preparation of the contents of the meeting to an *ad hoc group*. For this purpose the chair and members of the ad hoc group shall be agreed by the CMDh. The ad hoc group shall report to the CMDh plenary. Work of the ad hoc group shall be supported by the EMA secretariat.

- 6.1. Tasks of the ad hoc group shall include:
  - Preparation of the agenda based on communication with all parties involved
  - Report from the meeting with representative organisations to the CMDh plenary meeting.
- 6.2. Tasks of the EMA secretariat shall include:
  - Sending out invitation letter to the associations with agenda proposal and request to identify other potential points to the agenda.
  - Circulation of documents and presentations in advance, if possible.
  - Taking the minutes.
  - Circulation of the minutes to all participants after the meeting.
- 6.3. Preparatory meetings on individual topics can be organised as bilateral ones between the ad hoc group and one of the representative organisations, e.g. a pharmaceutical association, but this should be an exception.

7. The CMDh shall neither conduct any deliberations nor reach any formal positions in the presence of members of representative organisations.
8. To ensure the transparency of the dialogue, key points of the discussion and agreements shall be included in the CMDh press release.