



European Medicines Agency
Veterinary Medicines and Inspections

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**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
(CVMP)**

**PROCEDURE TO BE FOLLOWED TO FACILITATE COMMUNICATION AND
DIALOGUE BETWEEN THE CVMP AND THE INTERESTED PARTIES**

ADOPTION BY CVMP FOR RELEASE FOR CONSULTATION	16 June 2004
START OF CONSULTATION	17 June 2004
END OF CONSULTATION	17 September 2004
FINAL ADOPTION BY CVMP	13 October 2004
DATE INTO EFFECT COMING	18 October 2004

¹ Revised to update the Annex including the list CVMP Interested Parties

PROCEDURE TO BE FOLLOWED TO FACILITATE COMMUNICATION AND DIALOGUE BETWEEN THE CVMP AND THE INTERESTED PARTIES

Background

The new Community legislation places additional responsibilities on the Agency, its Management Board and its scientific committees to develop contacts with its various stakeholders to facilitate greater communication and dialogue on matters of common interest relating to the authorisation of medicines.

In particular, Article 78 (1) and 78 (2) in Title IV of the new Regulation 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.*

In general terms, the Agency considers that such new responsibilities indicate a need for the committees and their working parties to facilitate opportunities for discussion between the CVMP and the interested parties themselves. The types of exchanges with interested parties that may occur are presentations by a senior representative of the interested parties to the CVMP, discussions of interested parties with CVMP on the work programmes of its working parties and scientific advisory group(s) and/or exchanges with CVMP and/or its working parties and scientific advisory group(s) on specific scientific or technical issues, as well as Info days and Focus group meetings. It should however be borne in mind that meetings with interested parties do not take up too much time of the CVMP, its working parties and scientific advisory group(s) and must not hinder the conduct of their business. In agreeing on a meeting further to a request by an interested party the CVMP may therefore consider the urgency of the matter and the Committee's workload and time constraints. Interested parties should, where possible, make arrangements for joint representations, e.g. for discussions on guidelines.

In order that suitable arrangements can be put in place to organise such exchanges, whilst ensuring that the work of the committee is not hindered by excessive requests for meetings on an overly frequent basis, the following procedures are proposed:

Procedures

1. Presentations by a senior representative of the interested parties

On one occasion in each calendar year senior representatives of each of the agreed interested parties (listed in the Annex) shall, at the discretion of the Committee, have an opportunity to address the CVMP and to engage in a dialogue, which shall not in total exceed one hour.

The request to meet with the committee shall be submitted to the secretariat of the Veterinary Unit of the EMEA not less than two whole months preceding the intended meeting.

2. Discussions on work programmes of CVMP working parties and scientific advisory group(s)

Each calendar year, preferably during the first quarter of the year, interested parties may request the opportunity to meet with the CVMP, to obtain information on the work programmes of its working parties and scientific advisory group(s) for the particular year and to exchange in a question and answer session which in total shall not exceed 60 minutes. The interested parties should agree to participate together at one meeting, in which case they shall agree the agenda and discussion points jointly. The discussion may also be arranged within a regular meeting of the CVMP with interested parties. In any event, the request for such a meeting and the proposals for topics or comments for discussion shall be submitted to the Veterinary Unit secretariat of the EMEA at least two months in advance of the scheduled meeting of the CVMP. Alternatively, the Committee may agree as appropriate to undertake such discussion at an Info day.

3. Exchange of views between interested parties regarding guidelines on requirements for testing and quality of veterinary medicines

A critically important role for the Committee and its working parties is to consider the need for development of new guidelines, and where appropriate the updating of existing ones for testing and quality. The Committee now requires the preparation of a concept paper prior to its agreement for a working party to draft new guidelines. These concept papers are seen to be an important reference point for dialogue between the CVMP and its interested parties prior to their final adoption and approval being given for work to begin on a new or updated guideline by a working party. To facilitate such dialogue interested parties shall be given an opportunity for an exchange of views between technical experts of the interested parties and the CVMP working parties in the consultation phase foreseen prior to finalisation of the concept paper by the Committee.

During the drafting of an actual guideline, the interested parties may request a meeting with the CVMP working party concerned on specific points, or alternatively the working party may foresee the need to consult with technical experts of the interested parties.

4. Discussions of interested parties with working parties or scientific advisory groups on specific technical/scientific issues upon request of interested parties

The interested parties may consider that there are issues that they wish to discuss with the CVMP and / or its working parties or the scientific advisory groups of the CVMP, on specific technical/scientific issues during the course of the year. These issues should not concern guidelines under consultation, for which normally no further exchange with interested parties is foreseen. The request for such a meeting and the proposals for topics for discussion shall be submitted to the Veterinary Unit secretariat of the EMEA at least two months in advance of the scheduled meeting of the working party or scientific advisory group concerned, for consideration and agreement by the CVMP.

5. Invitation by CVMP, its working parties or scientific advisory group(s) to interested parties on specific technical/scientific issues

The CVMP or its working parties or scientific advisory_group(s) may consider there to be specific issues of a scientific or technical nature on which it wishes to consult with the interested parties (one, some or all of them). In such an instance CVMP may invite representatives of such interested parties to attend a meeting of the CVMP; alternatively it may request the appropriate working party or scientific advisory group to invite the relevant experts from the parties concerned for discussion at a forthcoming meeting and the working party would then report the outcome of such discussions to the next plenary meeting of the Committee.

6. Info days, Focus Groups and Bilaterals

The CVMP and the interested parties shall continue to organise different *fora* such as Info days and Focus groups which have proved successful in past years for a full and frank exchange of views/opinions on the work of the Agency, CVMP and its working parties and scientific advisory groups. At these meetings CVMP members are encouraged to attend and participate when at all possible. Interested parties shall be given the opportunity to hold bilateral meetings between their appointed representatives and the secretariat of the Veterinary-Inspections unit at EMEA on 1-2 occasions in any one calendar year.

CVMP interested parties

Association of Veterinary Consultants (AVC)

Bureau Européen des Unions de Consommateurs (BEUC)

Comité des Organisations Professionnelles Agricoles de l'Union Européenne - Confédération Générale des Coopératives Agricoles de l'Union Européenne (COPA COGECA)

European Association for Veterinary Pharmacology and Toxicology (EAVPT)

European Group for Generic Veterinary Products (EGGVP)

Federation of Veterinarians of Europe (FVE)

Groupement Pharmaceutique de l'Union Européenne (GPUE)

International Federation for Animal Health - Europe (IFAH-Europe)

International Council on Animal Protection at ICH (ICAPI)

European Federation of Honey Packers and Distributors (F.E.E.D.M.)