

CMDv/BPG/013

BEST PRACTICE GUIDE

for

CONTACT WITH REPRESENTATIVE ORGANISATIONS

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BEST PRACTICE GUIDE For Contacts with Representative Organisations	CMDv/BPG/013
	Ed.: 01
	Page 2 of 5

TABLE OF CONTENTS

- 1. INTRODUCTION**
- 2. SCOPE**
- 3. REFERENCES AND RELATED DOCUMENTS**
- 4. GENERAL**
 - 4.1 Abbreviations**
 - 4.2 Definition**
- 5. DESCRIPTION OF THE MEETING**
 - 5.1 Place and time of the meetings**
 - 5.2 Support**
 - 5.3 Meetings with representative organisations**
 - 5.4 Meetings with Interested Parties**

BEST PRACTICE GUIDE	CMDv/BPG/013
For	Ed.: 01
Contacts with Representative Organisations	Page 3 of 5

1. INTRODUCTION

In accordance with Article 31 Paragraph 3 of Directive 2001/82/EC as amended by 2004/28/EC, the CMDv has agreed on its Rules of Procedures. Under Article 14 of the Rules of Procedure it is stated that "Contacts with representative organisations may be held under the conditions to be defined by the CMDv".

2. SCOPE

In order to ensure that a good cooperation is established between CMDv and the veterinary pharmaceutical industry and other representative organisations, meetings between those groups are envisaged. This BPG describes how these meetings should be handled to ensure an effective and efficient running.

Regular meetings with the main representative organisations of Industry (IFAH-Europe and EGGVP) also called interested parties, are also described in this BPG.

Discussions will be focused on regulatory issues of common interest.

3. REFERENCES AND RELATED DOCUMENTS

Rules of Procedure of CMDv (EMEA/CMDv/37111/2006)

Directive 2001/82/EC as amended by Directive 2004/28/EC

EMA policy on the Handling of Conflicts of Interest for Committee members and experts (also applicable for members of the CMDv) (EMEA/H/31653/03/Rev2).

SMP002 for The role and responsibilities of the chairperson, vice chairperson and secretariat of the CMDv (EMEA-CMDv-126125-2006)

Meeting dates for CMDv, www.hma.eu/cmdv.html

4. GENERAL

4.1 Abbreviations

CMDv Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

EMA European Medicines Agency

IFAH-Europe International Federation for Animal Health – Europe

EGGVP European Group for Generic Veterinary Products

AVC: Association of Veterinary Consultants

BEST PRACTICE GUIDE	CMDv/BPG/013
For	Ed.: 01
Contacts with Representative Organisations	Page 4 of 5

4.2 Definition

In this BPG, “interested parties” are considered delegates of IFAH-Europe, EGGVP or AVC.

5. DESCRIPTION OF THE MEETING

5.1 Place and time of meetings

Meetings will take place at the EMA-building in connection with a CMDv-meeting and will in general take no longer than 2 hours.

5.2 Support

The CMDv secretariat will make sure that a meeting room is available and will prepare the agenda and any other relevant documentation.

5.3 Meetings with representative organisations

5.3.1 General principles

The CMDv may, on its own initiative or on the request of third parties, decide to have a meeting with representative organisations other than IFAH-Europe, EGGVP or AVC. Such a meeting will not be held on a regular basis.

5.3.2 Rules

- i) Any member of CMDv can attend the meeting.
- ii) The number of delegates from the representative organisation should be restricted to 5 persons.
- iii) Attendance should be confirmed beforehand to the CMDv secretariat.
- iv) The meeting is chaired by the Chairperson of the CMDv or in his/her absence by the Vice-Chair of CMDv.
- v) The agenda of the meeting is approved beforehand at the plenary CMDv-meeting.
- vi) The CMDv shall neither conduct any deliberations nor reach any formal positions in the presence of members of representative organisations.
- vii) Minutes of the meeting will be prepared by the CMDv Secretariat or the representative organisation (to be agreed at each meeting), and will also be put on the agenda of the subsequent plenary CMDv-meeting.

BEST PRACTICE GUIDE	CMDv/BPG/013
For	Ed.: 01
Contacts with Representative Organisations	Page 5 of 5

5.4 Meetings with interested parties

5.4.1 General principles

An Interested Parties Meeting will be held on regular basis, mostly every 3 months. The goal of this meeting is to exchange information between CMDv and representative organisations from Industry and other stakeholders.

5.4.2 Rules

- i) Any member of CMDv can attend the Interested Parties Meeting.
- ii) A core group consisting of the CMDv Chair, the former, present and future Vice-Chair will endeavour to attend every Interested Parties Meeting. Chairs of CMDv subgroups will endeavour to attend the Interested Parties meeting when the agenda points of a meeting are related to that subgroup.
- iii) The number of delegates from the interested parties should normally be restricted to 5 persons.
- iv) Attendance should be confirmed beforehand to the CMDv secretariat.
- v) The meeting is chaired by the Chairperson of the CMDv or in his/her absence by the Vice-Chair of CMDv.
- vi) Items for the agenda of the meeting may be proposed by the Interested Parties. The agenda of the meeting is approved beforehand at the plenary CMDv-meeting.
- vii) The CMDv shall neither conduct any deliberations nor reach any formal positions in the presence of members of the interested parties.
- viii) To ensure the transparency of the dialogue, minutes of each Interested Parties Meeting will be prepared by the interested parties, and will also be put on the agenda of the subsequent plenary CMDv-meeting. The minutes of the agenda points included by the CMDv will be prepared by the CMDv Secretariat.