



Title: Requests for advice from CMD(v) to CVMP		
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1. Purpose

CMD(v) may request CVMP for advice on scientific matters, for the benefit of the conduct of its duties and to promote consistency between decentralised and centralised procedures. This procedure describes how CVMP deals with these requests for advice.

2. Scope

This procedure covers scientific questions submitted by CMD(v) to CVMP and applies to EMEA staff in the veterinary sectors of the Veterinary Medicines and Inspections Unit, CVMP members, alternates and members of CVMP working parties.

3. Responsibilities

It is the responsibility of the Head of Sectors VMAP and SVM to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right hand column in Section 9.

4. Changes since last revision

NA

5. Documents needed for this SOP

NA

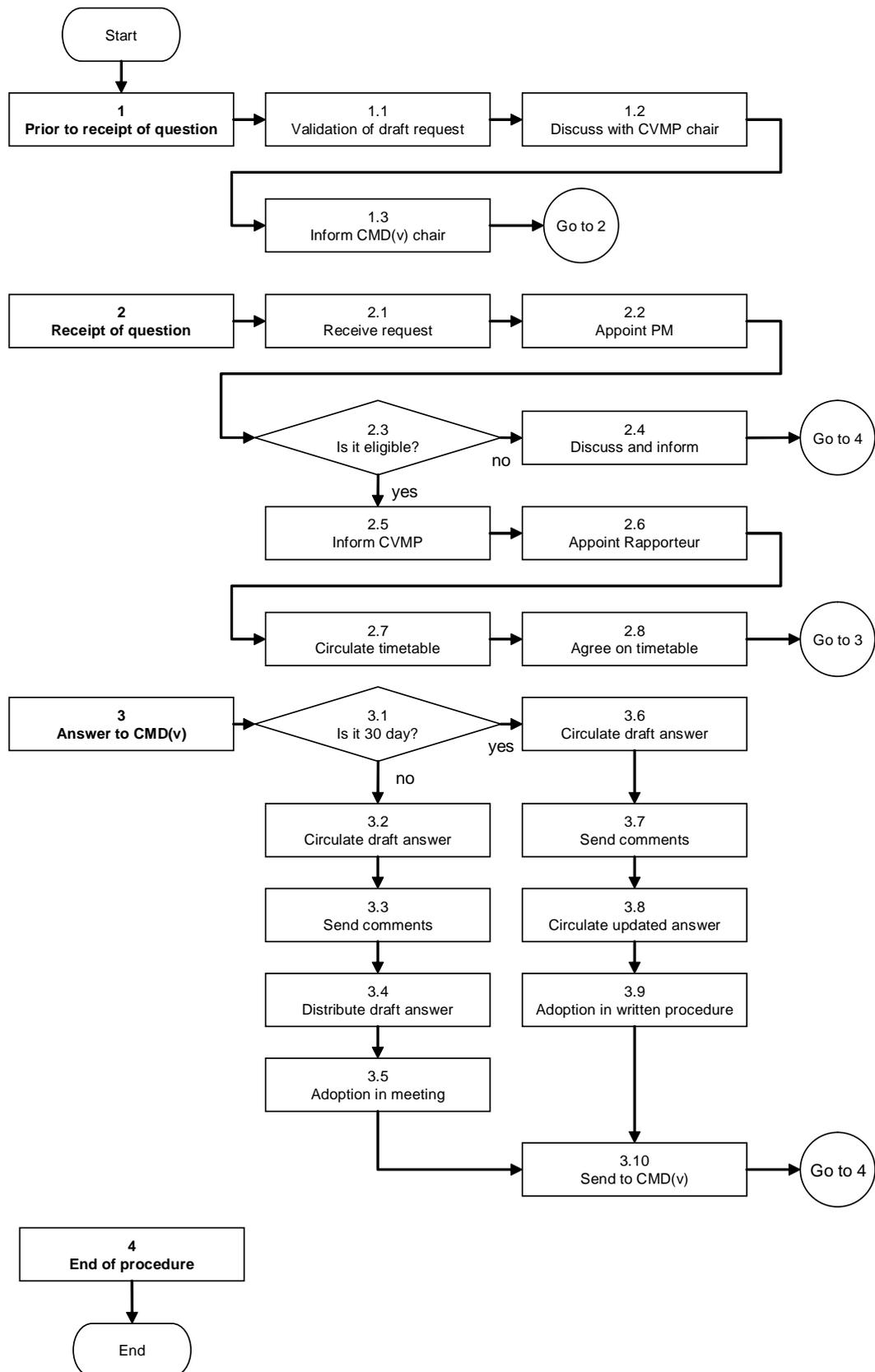
6. Related documents

NA

7. Definitions

CMD(v)	Coordination group for Mutual recognition and Decentralised procedures (veterinary)
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
EDMS	Electronic Document Management System
HoS	Head of Sector
MRP	Mutual Recognition Procedure
PM	Project Manager
SC	Secretary CMD(v)

8. Process Map(s)/ Flow Chart(s)



9. Procedure

Step	Action	Responsibility
1.0	Prior to receipt of a question	
1.1	<p>Discuss draft CMD(v) request for advice with the relevant HoS to:</p> <ul style="list-style-type: none"> • check whether the question is clear; • establish eligibility • identify the need for involvement of a Working Party; • consider a feasible timeframe for a response in relation to the urgency of the matter. <p>A request for advice is eligible if:</p> <ol style="list-style-type: none"> 1. The question is of a <u>scientific</u> nature in relation to the application of European Community legislation relevant to veterinary medicinal products. 2. The answer would benefit Member States in resolving an issue with wider implications, e.g. with relevance to a range of products or future applications. <p>Requests for legal advice are not eligible.</p> <p>Questions that could be addressed under the provisions for fee payable scientific advice may be rejected.</p>	SC
1.2	Discuss the request with the CVMP chairperson	HoS/SC
1.3	Inform the CMD(v) chairperson of the outcome and provide advice on how to proceed.	SC
2.0	Receipt of a question	
2.1	Receive the request for scientific advice from CMD(v).	HoS
2.2	Appoint a project manager	HoS
2.3	Check eligibility If eligible proceed to 2.5	PM
2.4	If not eligible, discuss with HoS, inform CMD(v) chairperson and SC in writing, indicating ineligibility and go to 4.0	PM
2.5	Inform CVMP	PM
2.6	Appoint a rapporteur A rapporteur can be (alternate/co-opted) member of CVMP or one of its Working Parties	CVMP chairperson
2.7	Circulate a draft timetable CVMP will adopt an answer to a question at the third meeting after the receipt of the question. However, if the need for advice is urgent,	PM

Step	Action	Responsibility
	e.g. in the case of an ongoing MRP/DCP or CMD(v) referral, an answer will be delivered within 30 calendar days after receipt of the question by EMEA.	
2.8	Agree on the timetable	CVMP chairperson Rapporteur
3.0	Answer to CMD(v)	
3.1	In case of a 30 day timetable go to 3.6, otherwise go to 3.2	
3.2	Circulate a draft answer to CVMP one week before the first mailing of the second meeting after receipt of the question.	Rapporteur
3.3	Send comments before the first mailing of the second meeting after receipt of the question.	CVMP
3.4	Update the answer and distribute with the second mailing	Rapporteur
3.5	Adopt the answer at the meeting, go to 3.10	CVMP
3.6	Circulate a draft answer to CVMP within 2 weeks after receipt of the question.	Rapporteur
3.7	Send comments within 3 working days.	CVMP
3.8	Circulate an updated answer for adoption within 2 working days	Rapporteur
3.9	Adoption of the answer through a written procedure by day 30 after receipt of the question.	PM/CVMP
3.10	Send the answer to CMD(v) via the SC on day 30.	PM/SC
4.0	End of procedure	

10. Records

Electronic copies are saved in the appropriately labelled folder in EDMS.