EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Evaluation procedure for CVMP Scientific Advice requests		
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1. Purpose

This SOP serves to describe the procedure for the evaluation of requests for scientific advice for veterinary medicinal products.

2. Scope

This SOP applies to the appointed procedure teams for the evaluation of CVMP scientific advice requests, within the Veterinary Medicines Division.

3. Responsibilities

It is the responsibility of the Head of the Veterinary Medicines Department (delegated to the relevant Head of Service) to ensure that this procedure is adhered to within their own Department/Service. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

New SOP.

New SOP/WIN structure implemented in the Division; this SOP implements the revised procedures for the evaluation of scientific advice requests for veterinary medicinal products.

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5. Documents needed for this SOP

- Checklist for processing scientific advice requests for veterinary medicines, incl. organisation of the CVMP Scientific Advice Working Party (EMA/268710/2017)
- CVMP scientific advice tracking table (EMA/711072/2013)
- Templates to be used during CVMP scientific advice procedures (*Cabinets/01. Evaluation of Medicines/V - SA/Guidance - Templates/Templates*)

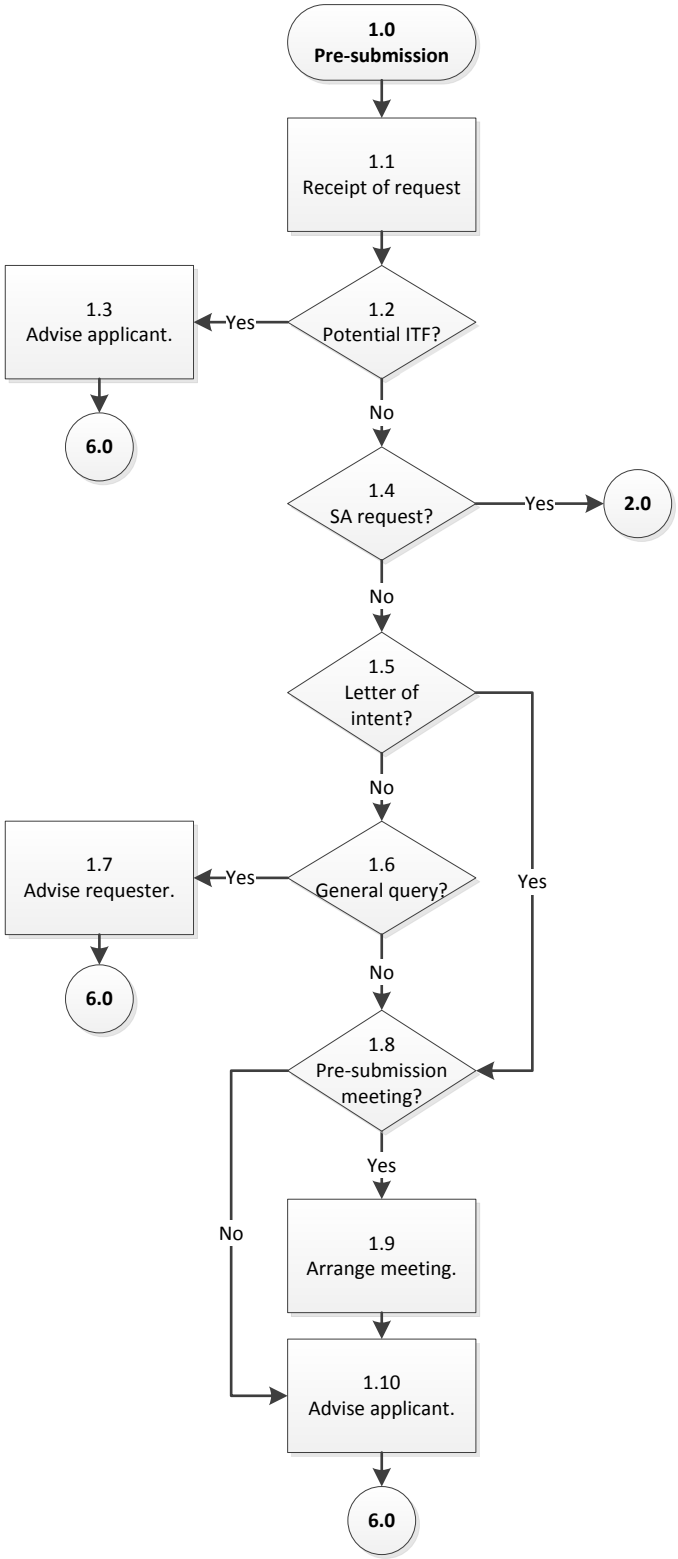
6. Related documents

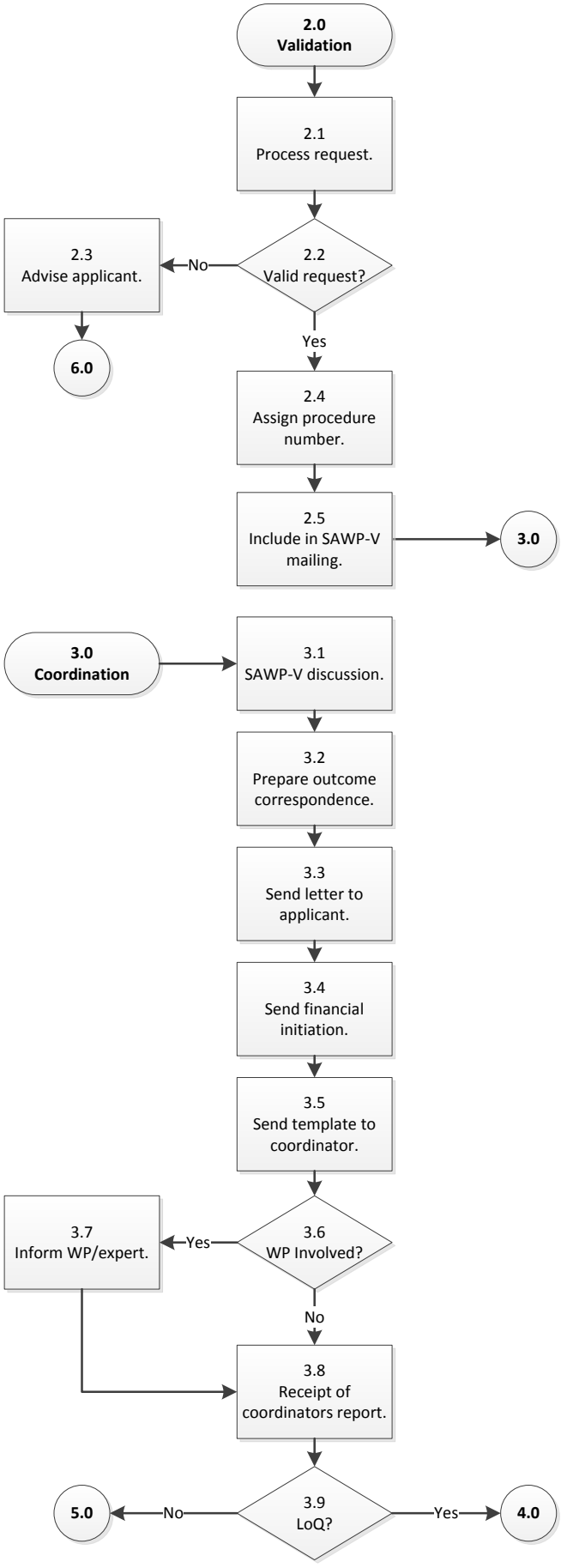
- Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- Regulation (EC) No. 297/95 on fees payable to the European Medicines Agency (Art. 10), as amended; and
  Explanatory note on fees payable to the European Medicines Agency (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp&mid=WC0b01ac058002d89e);
- EMA guidance for companies requesting scientific advice, incl. templates for letter of intent and scientific advice request (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000250.jsp&mid=WC0b01ac058002d4ef);
- SOP/H/3044 on the Organisation of Innovation Task Force briefing meetings (medicines for human/veterinary use); and
  Checklist on additional administrative actions for processing ITF queries and requests for ITF briefings for veterinary medicines (EMA/728325/2017)

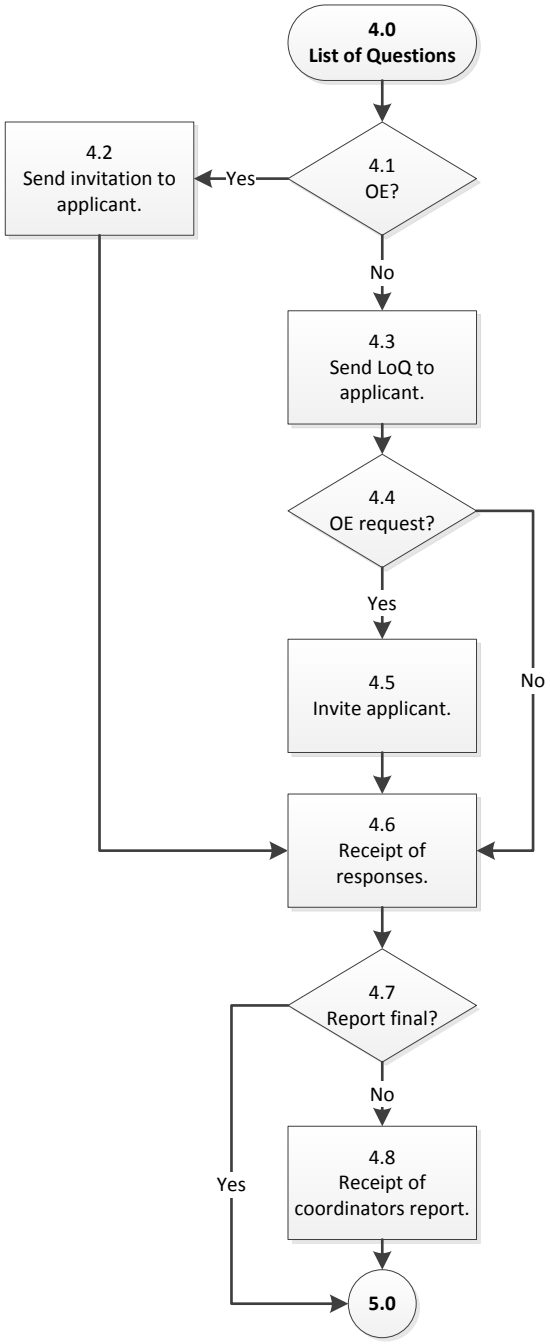
7. Definitions

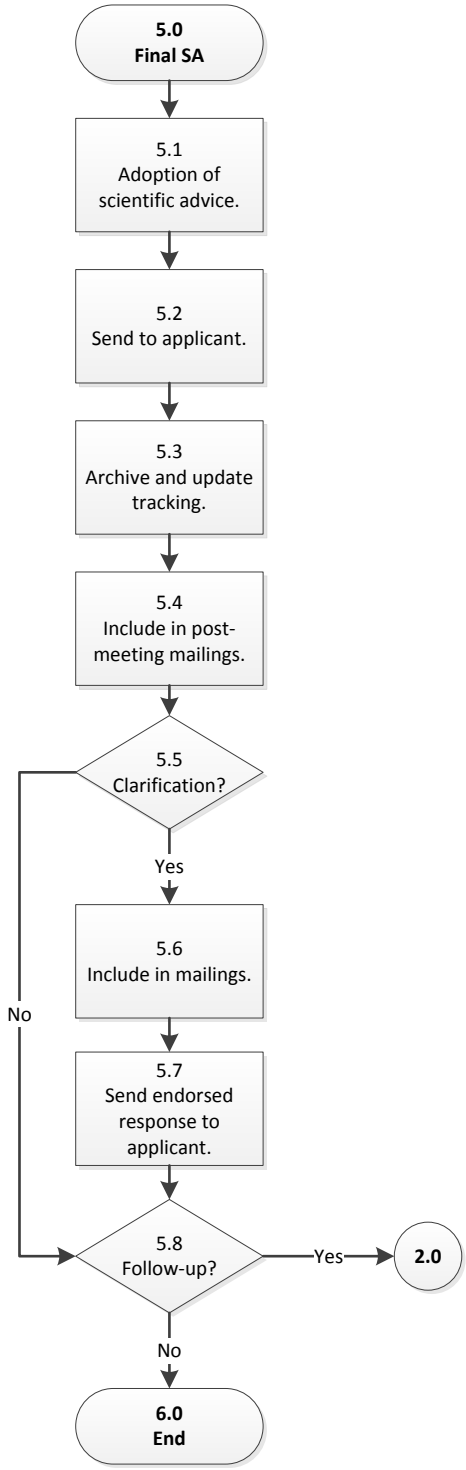
CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	Document Records Electronic Archive Management
ITF	Innovation Task Force
LoQ	List of Questions
PC	Procedure coordinator
SA	Scientific Advice
SAWP-V	Scientific Advice Working Part (Veterinary)
S/CL	Scientific lead
SOP	Standard Operating Procedure
HSer	Head of Service
WP	Working Party

8. Process map(s) / flow chart(s)




2.0
Validation
2.1
Process request.
2.2
Valid request?
No
2.3
Advise applicant.
6.0
Yes
2.4
Assign procedure number.
2.5
Include in SAWP-V mailing.
3.0
3.0
Coordination
3.1
SAWP-V discussion.
3.2
Prepare outcome correspondence.
3.3
Send letter to applicant.
3.4
Send financial initiation.
3.5
Send template to coordinator.
3.6
WP Involved?
Yes
3.7
Inform WP/expert.
No
3.8
Receipt of coordinators report.
3.9
LoQ?
No
5.0
Yes
4.0


4.0
List of Questions
4.1
OE?
Yes
4.2
Send invitation to applicant.
No
4.3
Send LoQ to applicant.
4.4
OE request?
Yes
No
4.5
Invite applicant.
4.6
Receipt of responses.
4.7
Report final?
No
Yes
4.8
Receipt of coordinators report.
5.0


5.0
Final SA
5.1
Adoption of scientific advice.
5.2
Send to applicant.
5.3
Archive and update tracking.
5.4
Include in post-meeting mailings.
5.5
Clarification?
Yes
5.6
Include in mailings.
5.7
Send endorsed response to applicant.
5.8
Follow-up?
Yes
2.0
No
No
6.0
End

9. Procedure

NB: The default timetable for a scientific advice procedure is 60 days. This can be shortened to 30 days for accelerated provision of scientific advice in cases of low complexity. For requests with high complexity, this can also be extended to 90 days from the outset. If clarifications and/or a meeting with the applicant are required, the timetable can also be extended to 90 days. When the relevant stage is indicated in the text, it refers to the 30(60) day procedure.

Step	Action	Responsibility
1.0	**Pre-submission**	
1.1	Upon receipt of request in VetScientificAdvice mailbox, forward to SAWP-V secretariat.	PC
1.2	Is the request a potential item for the Innovation Task Force (ITF)? If yes, go to 1.3 If no, go to 1.4	
1.3	Advise applicant to submit ITF briefing request according to SOP/H/3044. Proceed to 6.0	SAWP-V secretariat
1.4	Is the request a complete request for scientific advice? If yes, go to 2.0 If no, go to 1.5	
1.5	Is the request a draft version of an intended scientific advice request? If yes, go to 1.8 If no, go to 1.6	
1.6	Is the request only relating to general information on the scientific advice procedure? If yes, go to 1.7 If no, go to 1.8	
1.7	Provide information/advice to the enquirer. Archive any correspondence in the relevant folder in DREAM. Proceed to 6.0	PC
1.8	Is a request for a pre-submission scientific advice meeting included? If yes, go to 1.9 If no, go to 1.10	
1.9	Arrange pre-submission meeting.	PC
1.10	Provide comments/clarifications on draft request. Advise applicant on submission dates. Archive any correspondence in the relevant folder in DREAM. Proceed to 6.0	SAWP-V secretariat
2.0	**Validation**	
2.1	Upon receipt the scientific advice request is processed following the procedural steps described in the checklist.	PC

Step	Action	Responsibility
2.2	Validate request by checking whether the questions are presented in a clear, unambiguous manner and are within the scope of the scientific advice procedure. Has the request been validated? If yes, go to 2.4 If no, go to 2.3	S/CL
2.3	Advise applicant on changes necessary for a valid request and advise on submission dates. Archive all relevant correspondence. Proceed to 6.0	S/CL
2.4	Assign procedure number and include in CVMP scientific advice tracking table.	PC
2.5	Include the request in the 1st mailing for the next SAWP-V meeting, calling for expressions of interest to act as coordinator. Proceed to 3.0	PC
3.0	**Coordination of response**	
3.1	**Day 0** Ensure discussion at SAWP-V covers • Appointment of coordinator • Agreement on timetable for procedure • Consideration of involvement of other CVMP working parties or experts. If agreed, the Chair of SAWP should obtain agreement from CVMP during verbal report of meeting at CVMP.	S/CL
3.2	Continue following procedural steps in checklist. Prepare letter to applicant, timetable, fee initiation email and template for coordinators report. Send to S/CL for review.	PC
3.3	Send letter to applicant incl. timetable.	PC
3.4	Send fee initiation email to financial workflow mailbox.	PC
3.5	Send template for coordinators report, timetable and any supporting documents to coordinator (including previous scientific advice, if applicable).	PC
3.6	Was the involvement of any other CVMP working party or expert agreed at the SAWP-V meeting? If yes, go to 3.7 If no, go to 3.8	
3.7	Inform relevant CVMP working party (in liaison with relevant secretariat) or other expert of impending request for comments.	PC
3.8	**Day 20(40)** Circulate draft coordinators report to SAWP-V via mailbox for comments, as well as to any other CVMP working party/expert(s) involved, if applicable. Include draft coordinators report in current mailing for next CVMP meeting.	PC

Step	Action	Responsibility
3.9	**Day 30(60)** Discussion of draft coordinators report and any comments received at the SAWP-V meeting. Was a list of questions agreed by SAWP-V? If yes, go to 4.0 If no, go to 5.0	
4.0	**List of questions / oral explanation**	
4.1	***Clock stop*** Did SAWP-V agree that the questions should be answered in an oral explanation? If yes, go to 4.2 If no, go to 4.3	
4.2	Send list of questions to applicant with an invitation to attend oral explanation meeting at one of the next SAWP-V meetings, follow procedural steps in the checklist. Proceed to 4.6	PC
4.3	Send list of questions to be answered in writing to the applicant, following procedural steps in the checklist.	PC
4.4	Did the applicant send a request to give the responses by oral explanations? If yes, go to 4.5 If no, go to 4.6	
4.5	Invite applicant for one of the next SAWP-V meetings in accordance with relevant steps in checklist.	PC
4.6	**Day 40(70)** Ensure receipt of written answers from applicant. Circulate to SAWP-V.	PC
4.7	**Day 60(90)** ***Restart clock***. Discussion of responses (and oral explanations, if applicable). Can the report be finalised during the meeting? If yes, go to 5.0 If no, go to 4.8	
4.8	**Day 75** Ensure receipt of revised coordinators report. Circulate to SAWP-V (and other CVMP WPs/experts, if applicable) for comments. Proceed to 5.0	PC
5.0	**Final scientific advice**	
5.1	**Day 30 / 60 / 90** (as applicable) Adoption of scientific advice at SAWP-V. Final scientific advice is tabled at the ongoing CVMP meeting for adoption. Update the CVMP press release as necessary.	PC S/CL
5.2	Send adopted scientific advice to applicant following the CVMP meeting, following procedural steps described in checklist.	PC

Step	Action	Responsibility
5.3	Archive all relevant correspondence and update CVMP scientific advice table.	PC
5.4	The final scientific advice report is included in the SAWP-V post-meeting mailing and also circulated to any CVMP WP or expert, who was consulted, for information.	PC
5.5	Has the applicant sent a clarification request within 6 months after the scientific advice was given? If yes, go to 5.6 If no, go to 5.8	
5.6	Ensure coordinator prepares draft response to request for clarification in time for the next SAWP-V/CVMP meeting. *NB: clarification requests do not incur a fee.*	PC
5.7	Discussion & endorsement of response to request for clarification. Send endorsed response to applicant and archive all relevant correspondence.	PC
5.8	Was a follow-up scientific advice request received in relation to the same product/substance? If yes, go to 2.0 If no, go to 6.0	
6.0	**End of procedure**	

10. Records

Electronic copies of submitted requests and all related correspondence are saved in the appropriately labelled folder in DREAM.