EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Evaluation procedure for CVMP MUMS/limited market classification requests		
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1. Purpose

This SOP serves to describe the procedure for the evaluation of requests relating to the Agency policy on classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market. The procedure applies equally to requests for reclassification.

2. Scope

This SOP applies to the appointed procedure teams for the evaluation of MUMS classification requests within the Veterinary Medicines Division.

3. Responsibilities

It is the responsibility of the Head of the Veterinary Medicines Division (delegated to the relevant Head of Service) to ensure that this procedure is adhered to within their own Division/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, following implementation of new SOP/WIN structure in the Division.

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5. Documents needed for this SOP

- Template for a request to the CVMP to classify a veterinary medicinal product as minor use minor species (MUMS)/intended for use in a limited market, to be completed by the applicant http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001762.jsp&mid=WC0b01ac058002d89f
- Checklist for CVMP MUMS classification request procedure (EMA/728378/2017)
- MUMS tracking table (located in DREAM *Cabinets/01. Evaluation of Medicine/V - MUMS*)
- Templates for CVMP recommendation and letters to applicant (located in DREAM *Cabinets/01. Evaluation of Medicine/V – MUMS/MUMS templates*)
- CVMP press release template wording (located in DREAM *Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/2. Meeting Organisation/MEETINGS/Press Releases*)

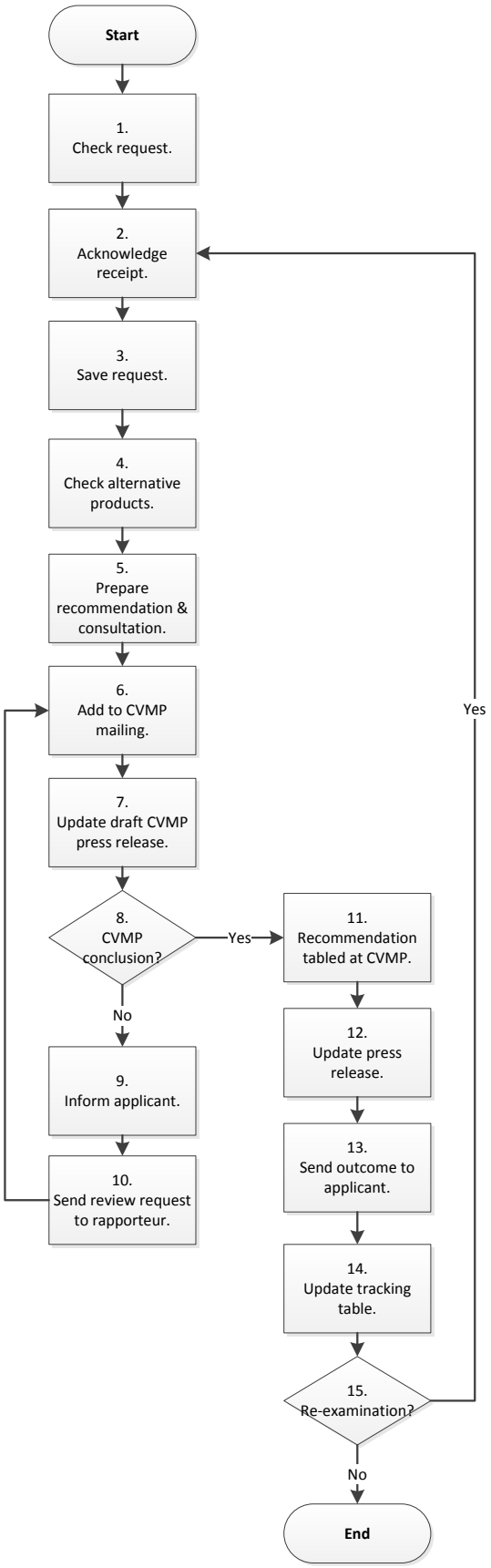
6. Related documents

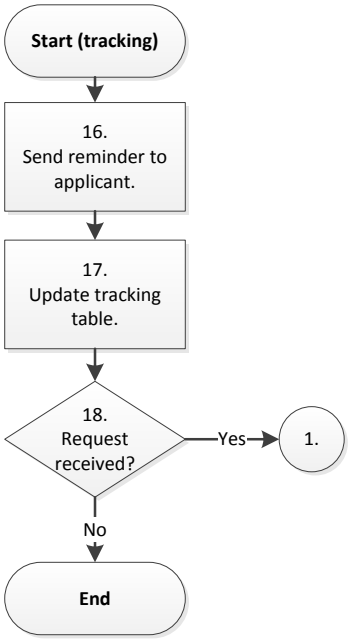
- Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market (EMA/308411/2014)
- Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS)/limited market (EMA/CVMP/388694/2014)
- Q&A - EMA guidance for companies requesting classification for products/indication as Minor Use Minor Species (MUMS)/limited market (EMA/CVMP/370663/2009)

7. Definitions

CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	Electronic Document Management System
MUMS	minor use minor species
PC	Procedure coordinator, Assistant in the Veterinary Medicines Division assigned to processing MUMS classification requests
Q&A	Questions and Answers (guidance), usually published on the EMA website
S/CL	Scientific administrator appointed to processing of MUMS classification requests

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




Start (tracking)
16.
Send reminder to applicant.
17.
Update tracking table.
18.
Request received?
Yes
1.
No
End

9. Procedure

Step	Action	Responsibility
1.	Following receipt, review request for MUMS/limited market (re-)classification from applicant and ensure it is in the correct format (template completed) and sufficient information is provided for CVMP to form a judgement.	S/CL
2.	Acknowledge receipt to applicant informing them of the timetable for evaluation of the request.	PC
3.	Create folder in DREAM for application and save request and related supporting documents.	PC
4.	Check if alternative product is authorised in any EU Member State (internet search, reference publications).	S/CL
5.	Prepare recommendation for CVMP in consultation with Head of Service and subject matter experts (scientific administrators), as applicable.	S/CL
6.	Add request, supporting documents and draft recommendation to first mailing for next CVMP meeting under appropriate agenda point. *Note: if the time between the arrival of the MUMS classification request and the first mailing for a CVMP meeting does not allow for the internal consultation, the recommendation may be included in the second CVMP mailing.*	PC
7.	Include proposed recommendation in draft CVMP press release entry using template wording.	S/CL
8.	CVMP considers the (re-)classification, making a decision if MUMS data requirements and/or financial incentives apply, or appoints rapporteur to review request in more detail. Has CVMP agreed classification? If yes, go to 11. If no, go to 9.	
9.	Inform applicant of further considerations and request additional information, if appropriate.	S/CL
10.	Send email detailing classification review to appointed rapporteur and agree deadline for completion. Upon receipt of rapporteur's response: Proceed to 6.	S/CL
11.	Convert the recommendation into CVMP conclusions in line with CVMP outcome and table to CVMP.	PC
12.	Update draft CVMP press release, as necessary.	S/CL

Step	Action	Responsibility
13.	Prepare letter to applicant detailing the CVMP classification (based on template letter) and send to applicant following internal review and sign-off.	PC
14.	Update MUMS tracking table with outcome.	PC
15.	Has applicant requested re-examination? If yes, go to 1. If no, go to 16.	
16.	*Approx. 6 months prior to expiry of classification* Prepare reminder letter and send to applicant.	PC
17.	Update MUMS tracking table to indicate reminder letter has been sent.	PC
18.	Request for reclassification[1] received within 6 months? If yes, go to 1. If no, go to 19.	
19.	*End of procedure*	

10. Records

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

[1] Note that depending on the scope, some reclassification requests are simplified. Refer to the advice given in the reminder letter and Q&A guidance.