EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Processing requests for inclusion in the list of substances not falling within the scope of Regulation EC 470/2009 (out of scope)		
Applies to: Veterinary Medicines		
Status: **PUBLIC**		Document no.: WIN/V/4151
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1. Changes since last revision

New WIN.

2. Records

Electronic copies of all correspondence and documents related to each request are saved in the appropriately labelled folder in DREAM: Cabinet 01 – Evaluation of Medicines\V-Maximum Residue Limits\V – MRL General\Out of scope\Requests for out of scope.

3. Instructions

3.1. Purpose, scope and responsibilities

This WIN serves to provide guidance on the management and assessment of requests for inclusion of a substance in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009. The WIN applies to any staff member of the Animal and Public Health Service in the Veterinary Medicines Division working on request(s) for 'out of scope'. It is the responsibility of the Head of Department, delegated to the Head of Animal and Public Health Service to ensure that this procedure is adhered to.

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3.2. Documents needed for this WIN

- Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (EMA/CVMP/519714/2009)
- Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/516817/2009)
- Procedure checklist (EMA/153767/2017; 2nd tab)
- Tracking table for requests for inclusion of substances in the out of scope list (EMA/192534/2013)
- Procedure templates in X:\Templates\Others\Vet\MRLs

3.3. Definitions

AA	Administrative assistant (here: AA in vet.applications team)
Applicant	A person submitting a request for out of scope
CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	Document records and electronic archive management system
EC	European Commission
EFTA	European Free Trade Association
HSer	Head of Service (here: HSer of Animal and Public Health)
MRL application	Application for the establishment of maximum residue limits
PC	Procedure Coordinator, typically an Assistant, assigned to the management of the procedure
S/CL	Scientific administrator assigned as the scientific/content lead for the procedure
WIN	Work instruction

3.4. Instructions

Step	Action	Responsibility
1.	Request **received** in vet.applications inbox: Forward to HSer.	AA
2.	Appoint (and inform) procedure team.	HSer
3.	*Following the detailed steps described in the procedure checklist*: In liaison with S/CL, **check** that the request and supporting documents are in line with the Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009. If deficiencies are identified, **inform** the applicant and request additional information/ documentation, if appropriate, or inform the applicant of the non-acceptance of request.	PC
4.	**Create** a folder (name of substance) in DREAM for every new request and **save** received correspondence and supporting documents (using *Guide to naming specific documents in DREAM/MMD*). **Update** the tracking table in DREAM with the new request.	PC PC
5.	**Inform** applicant on approximate month of discussion at the CVMP (next meeting or the one after), depending on when the request has been submitted. **Prepare** the template for the CVMP report and **save** in the appropriate folder. Inform S/CL.	PC PC
6.	**Complete** the draft CVMP report and **forward** to HSer for review and agreement.	S/CL
7.	1st CVMP mailing: under section 8.1, **table** the request from applicant and the draft CVMP report, if available, following agreement from HSer, for the relevant CVMP meeting for decision.	PC
8.	**Update** document, as appropriate, following CVMP discussion.	S/CL
9.	Did CVMP make a recommendation for inclusion of the substance in the out of scope list? If **yes**, go to 10 If **no**, go to 15	
10.	**Revise** the 'Substances considered as not falling within the scope of Regulation (EC) No. 470/2009 ("out of scope list"), with regard to residues of veterinary medicinal products in foodstuffs of animal origin' document with a new revision number (EMA/CVMP/519714/2009–Rev.*x+1*) and **include** the new entry for the substance for which CVMP report has been agreed (using track-changes) as per recommendation from the CVMP report.	PC

Step	Action	Responsibility
	Send to S/CL for review.	
11.	**Table** the revised 'out of scope list' for adoption during the CVMP meeting (with track-changes) for adoption.	PC
12.	Update CVMP press release to include CVMP decision and adoption of the revised "out of scope list".	S/CL
13.	Following the CVMP meeting, usually on Thursday afternoon, **accept** all track-changes in the 'out of scope list' and **send** to CVMP secretariat team member dealing with publication of press release and other relevant documents. **Send** the CVMP outcome to the applicant (i.e. positive response: inclusion of the substance in the out of scope list).	PC
14.	Once the revised out of scope list has been published, **send** an email to the EC and EFTA with the link to the published document. [END]	PC
15.	**Send** the CVMP outcome to the applicant (negative reponse: recommendation for a request for scientific advice or for submission of a MRL application). [END]	PC