EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of requests from a NCA to the CMDh for a recommendation on the classification of an unforeseen variation under Article 5 of Commission Regulation (EC) No 1234/2008		
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1. Purpose

To describe the support provided by the CMDh secretariat to the CMDh for the handling of requests from NCAs for recommendations on the classification of unforeseen variations in the frame work of Article 5 of Commission Regulation (EC) No 1234/2008.

2. Scope

This SOP applies to the CMDh secretariat within the Committee Secretariat Service (P-CI-SCS).

3. Responsibilities

It is the responsibility of the Head of Service to ensure that this procedure is adhered to within P-CI-SCS. 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

Change of mailboxes used according to the update of the relevant Best Practice Guide.

5. Documents needed for this SOP

- **Templates** for the handling of Article 5 requests to the CMDh can be found in the following Dream folders:

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5505
Send a question via our website www.ema.europa.eu/contact

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  - Compilation of comments from Members States: Cabinets/02b. Administration of Scientific Meeting/CMDh – Administration/3. Other Activities/06. Procedures/04- Variations - Art5/TEMPLATES/03- Compilation of Comments
  - Grounds and Outcomes from RMS for publication: Cabinets/02b. Administration of Scientific Meeting/CMDh – Administration/3. Other Activities/06. Procedures/04- Variations - Art5/TEMPLATES/04- Outcome Recommendation

- User manual for CMDh activities (EMA/221153/2016)

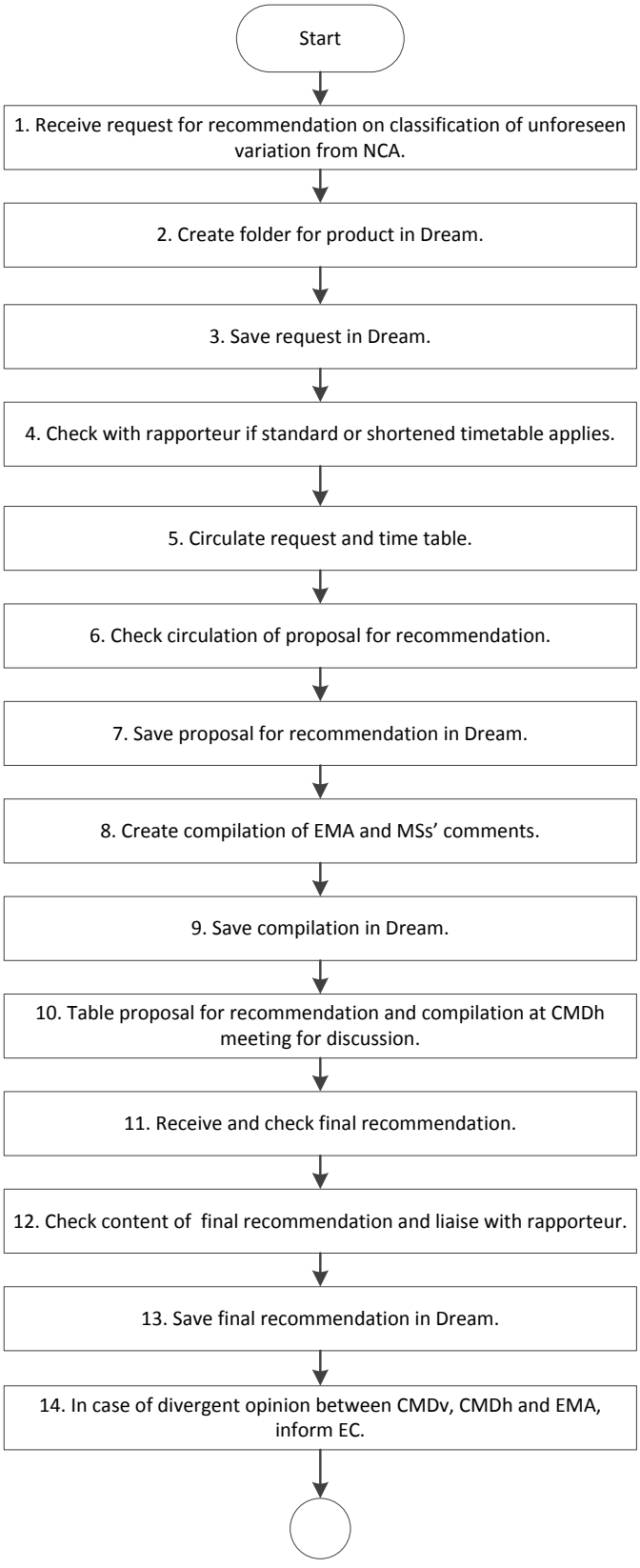
6. Related documents

- Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (http://ec.europa.eu/health/files/eudralex/vol-1/index en.htm).
- Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 (http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm).
- **Guidance documents** are available on the CMDh website: http://www.hma.eu/293.html

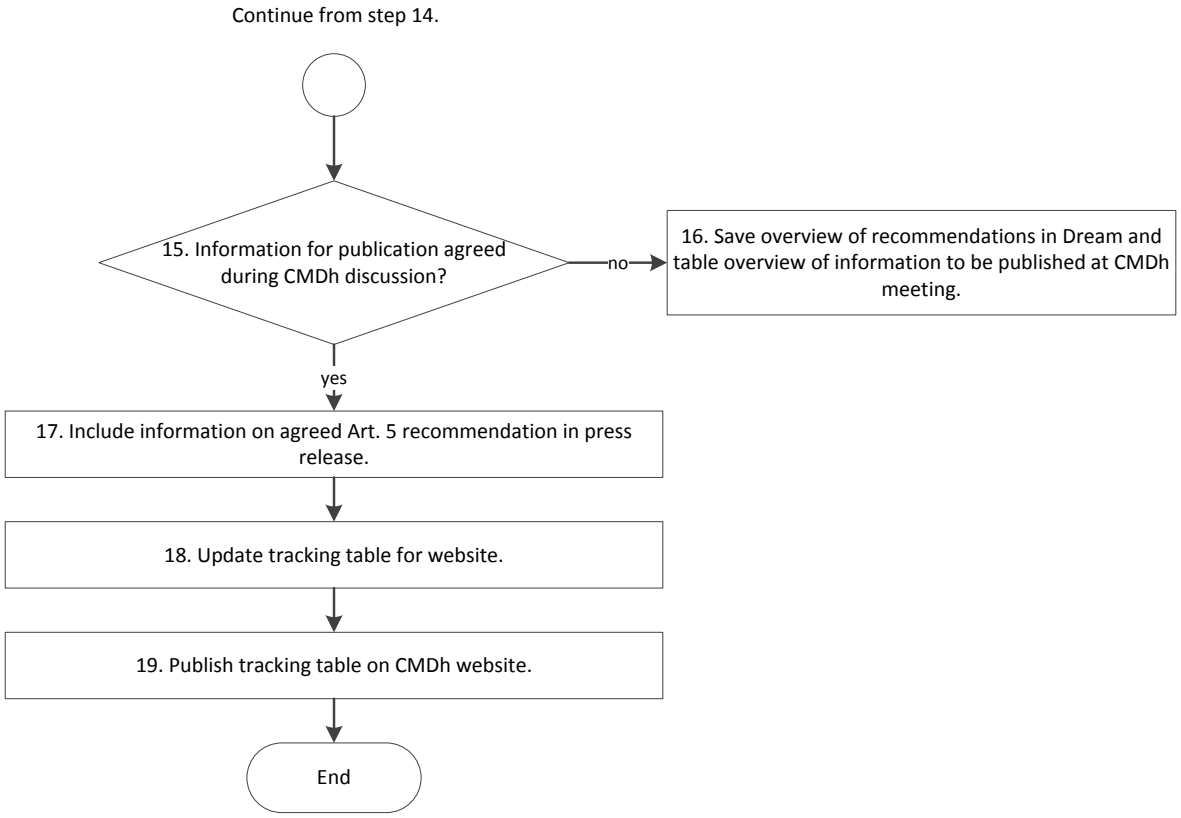
7. Definitions

- ClAG: Classification Advisory Group
- CMDh: Coordination Group for Mutual Recognition and Decentralised Procedure – Human
- CMDv: Coordination Group for Mutual Recognition and Decentralised Procedure – Veterinary
- Dream: Document records and e-archive management system
- EC: European Commission
- EMA: European Medicines Agency
- NCA: National competent authority
- MS: Member state
- P-CI-SCS: Committee Secretariat Service
- RMS: Reference member state

8. Process map



Continue with step 15.


Continue from step 14.
15. Information for publication agreed during CMDh discussion?
no
16. Save overview of recommendations in Dream and table overview of information to be published at CMDh meeting.
yes
17. Include information on agreed Art. 5 recommendation in press release.
18. Update tracking table for website.
19. Publish tracking table on CMDh website.
End

9. Procedure

Step	Action	Responsibility
1	Receive from a NCA (=the rapporteur) a request for a recommendation on the classification of an unforeseen variation under Article 5 of Commission Regulation (EC) No 1234/2008 to the CMDh.	CMDh Assistant
2	Create a folder for the product in Dream (under Cabinet/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/04- Variations - Art5/<YEAR>) applying the following folder name structure: <year> <month> - <Product name>	CMDh Assistant
3	Save the request in Dream.	CMDh Assistant
4	Check with the rapporteur if the standard timetable as published on the CMDh website should be applied or if a shorter timetable can be applied, if not already specified in the request. *Note: At least 1 week should be given between the circulation of the rapporteur's proposal for classification and the discussion of the recommendation in the CMDh meeting in order to allow CMDh members, CMDv members and EMA to comment.* *Note: The standard timetables can be found under Cabinets/02b. Administration of Scientific Meeting/CMDh – Administration/3. Other Activities/06. Procedures/04- Variations - Art5/TEMPLATES/01- Timetables and in the CMDh external website*	CMDh Assistant
At the latest at Day 0 of the procedure		
5	Circulate the request together with the timetable for the procedure to: • CMDh members (via the CMDh Eudranet mailbox All Human CMD <list-h-cmd@eudra.org>); • CMDv secretariat; • CMDv members (via the CMDv Eudranet mailboxAll Veterinary CMD (<list-v-cmd@eudra.org>); • CLAG. Save the e-mail in Dream.	CMDh Assistant
Day 25 or appropriate day according to shortened timetable		
6	Check if the proposal for a recommendation has been circulated to the CMD Eudranet mailboxes (human and veterinary) by the rapporteur for comments. Liaise with the rapporteur in case the proposal for a recommendation has not been circulated by the deadline set in the	CMDh Committee manager

Step	Action	Responsibility
	timetable.	
7	Save the proposal for a recommendation from the rapporteur in Dream.	CMDh Assistant
Day 32 or appropriate day according to shortened timetable		
8	Create a compilation with comments received from EMA and all MSs for internal use using the template ***Template_Compiled comments*** from the Templates folder.	CMDh Assistant
9	Save the compilation in Dream.	CMDh Assistant
10	Table the rapporteur's proposal for a recommendation and the compilation of comments received at the CMDh meeting for discussion.	CMDh Assistant
Following CMDh meeting – at the latest days 44/45 or appropriate day according to shortened timetable		
11	Receive the final recommendation from the rapporteur. Check that the following points are ticked/completed in the final recommendation received from the rapporteur (usually inserted under Conclusions), unless justified through the nature of the recommendation (e.g. out of the scope of the Variation Regulation) or the discussion in the CMDh (e.g. agreement not to publish the outcome): • Rapporteur's proposal for classification; • Justification for the proposed classification; • Relevant sentences in the conclusion; • Table for publication. Bring missing points to the attention of the CMDh Committee manager, if necessary.	CMDh Assistant
12	Check the content of the recommendation and liaise with the rapporteur for clarification, if necessary.	CMDh Committee manager
13	Save the final recommendation in Dream.	CMDh Assistant
14	In case of a divergent opinion between CMDv, CMDh and EMA, send the recommendation including the arguments to the EC for information.	CMDh Committee manager
15	If the information for publication was already agreed during the CMDh discussions, continue with step 17. In exceptional circumstances, when the information for publication was not agreed during the meeting, continue with step 16.	CMDh Committee manager
CMDh meeting month +1		

Step	Action	Responsibility
16	Save the overview of recommendations in Dream and table the overview of information to be published on the recommendations from the rapporteur at the CMDh meeting.	CMDh Assistant
After the CMDh meeting month +1		
17	Include information on the agreed Art. 5 recommendation in the press release (see User manual for CMDh activities).	CMDh Committee manager
18	Update the tracking table entitled ***FOR WEBSITE_Tracking Table - Article 5*** saved in Dream under **06. Procedures/04-Variations - Art5/Rapporteurships and tracking table** (section of classification guideline, date issued, summary of proposed change, proposed classification, proposed conditions where relevant).	CMDh Assistant
19	After publication of the press release, publish the tracking table ***FOR WEBSITE_Tracking Table - Article 5*** on the CMDh website (see User manual for CMDh activities).	CMDh Assistant

10. Records

All documentation relating to Article 5 requests to the CMDh are saved electronically in the following folder in Dream:

Cabinets/02b. Administration of Scientific Meeting/CMDh – Administration/3. Other Activities/06. Procedures/04- Variations - Art5

The following documents are kept as a record in Dream (retention time 50 years):

- Request for a recommendation
- Final recommendation
- Published outcome