



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Handling of Art. 29(1) referrals to the CMDh (60 day procedure) by the CMDh secretariat (incl. Article 13 referrals for variations)		
Applies to: CMDh secretariat within the Scientific Committee Support Section		
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1. Changes since last revision

New WIN.

2. Records

All documentation relating to Article 29(1) referral procedures to the CMDh (60 day procedure) is saved electronically in the following folder in DREAM:

[01. Evaluation of medicines\Referrals\H - Art29 Referrals to CMDh](#)

The following documents are kept as a record for 30 years (by AST):

- Notification of referral by RMS
- Final List of Questions
- Responses from MAH to LoQ
- Final AR
- Day 60 Final outcome

3. Instructions

Abbreviations

- AD: Administrator in the CMDh secretariat

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- AR: Assessment report
- AST: Secretary in the CMDh secretariat
- CHMP: Committee for Medicinal Products for Human Use
- CMDh: Coordination Group for Mutual Recognition and Decentralised Procedure - Human
- CMS: Concerned Member State
- CTS: Communication and Tracking System software
- DCP: Decentralised procedure
- DREAM: Document Records Electronic Archive Management system
- LoQ: List of questions
- MAH: Marketing authorisation holder
- MRP: Mutual recognition procedure
- OE: Oral explanation
- RMS: Reference Member State
- V-PD-BUS: Product and Application Business Support Section

Templates for the handling of Article 29 referral procedures to the CMDh can be found in the following folder in DREAM:

- Timetables: [01. Evaluation of medicines\Referrals\H - Art29 Referrals to CMDh\04-TEMPLATES\01- Timetables](#)
- Correspondence to applicant/MAH(s): [01. Evaluation of medicines \Referrals\H - Art29 Referrals to CMDh\04-TEMPLATES\03- Letters CMDh Sec to Applicant \(New Applications\) and ...\04-Letters CMDh Sec to Applicant \(Variation\)](#)
- Grounds and Outcomes from RMS for publication: [01. Evaluation of medicines\Referrals\H - Art29 Referrals to CMDh\04-TEMPLATES\05- Grounds&Outcomes](#)

For **statistical and tracking data**, the files and information can be found in the following folder in DREAM: [01. Evaluation of medicines\Referrals\H - Art29 Referrals to CMDh\01-New Applications\STATISTICS and ...\02-Variation\STATISTICS](#)

Guidance documents are available from the CMDh website: <http://www.hma.eu/26.html>

All dates in the table below relate to the standard timetable for a 60-day procedure, as published on the CMDh website.

Referrals to the CMDh for type II variations as foreseen in Article 13 of Regulation (EC) No.1234/2008 will be handled via the same procedure and with the same templates. Referrals to the CMDh procedures for initial applications are saved under [01. Evaluation of medicines\Referrals\H - Art29 Referrals to CMDh\01-New applications](#) and referrals to the CMDh procedures for variation applications are saved under [01. Evaluation of medicines\Referrals\H - Art29 Referrals to CMDh\02-Variations](#).

Step	Action	Responsibility
1.	Receive a request for referral to the CMDh via the CMDh referrals functional eudranet mailbox sent by the CMS (optional).	AD
2.	Receive an official notification of referral to the CMDh at the latest 7 days after the official end of procedure via the CMDh referrals	AD

Step	Action	Responsibility
	functional eudranet mailbox sent by the RMS. Check with the RMS if the notification has not been received after 7 days.	
3.	Create a folder for the product in DREAM (H - Art29 Referrals to CMDh\01-New Applications or ... \02-Variation) applying the following folder name structure: <year>_<month> <Procedure number> <Product name> , e.g. 10_02 PTH181 01 MR Ciclosporin.	AST
4.	Create the following subfolders: 01 Notification 02 Timetable 03 LoQ 04 Updated AR 05 CMDh Meeting 2 06 Outcome Correspondence	AST
5.	Save the request(s) (if applicable) and official notification for referral to the CMDh in the subfolder 01 Notification .	AST
6.	Perform a quality check of the official notification received from the RMS against CTS: <ul style="list-style-type: none"> • Check if the contact details of the applicant/MAH (contact name, postal address, phone and fax numbers and e-mail address) have been mentioned in the official notification; • Ensure that the contact details on the official notification correspond with the details in CTS; • Check the listed CMSs; • Ensure that the status of procedure in CTS reads 'CMD'. <p>If necessary, contact the RMS Contact point mentioned at the top of the notification, requesting clarification, and save the reply in the subfolder 01 Notification of the procedure.</p>	AST
7.	Update the Tracking table – Art. 29 Referrals to CMDh/Art. 13 referral to CMDh Variation (for internal use) in the STATISTICS folder with the newly referred procedure. Inform AD. Update the rationale for the referral in the tracking table.	AST AD
8.	Select the relevant timetable for the given month from the TEMPLATES folder in DREAM (in accordance with the overview published on the CMDh website).	AST

Step	Action	Responsibility
	Save the timetable in the subfolder 02 Timetable of the procedure.	
9.	Prepare the letter to the applicant/MAH using the template letter 01- Template_Letter Timetable to Applicant which is to be sent to the applicant/MAH together with the timetable, in order to inform him of the start of the procedure and relevant deadlines. Save the letter in the subfolder 02 Timetable of the procedure.	AST
10.	Check the letter against the information in the official notification and CTS.	AD
11.	2-3 calendar days prior to the start of the procedure (day 1) Send the letter and timetable (both in pdf format) to the applicant/MAH by e-mail using the template e-mail 01- Template_Email TT to Applicant , adding also as an attachment the flow-chart for the 60-day procedure CMDh-028-2006_Rev2- Clean_Flow Chart from the DREAM folder: documentum\Docbases\EDMS\Products\Referrals\H - Art29 Referrals to CMDh\GUIDANCE DOCUMENTS . Save the e-mail in the subfolder 02 Timetable of the procedure.	AST
12.	Forward the letter and timetable to the CMDh referrals functional eudranet mailbox (AllHumanCMD-REFERRALS@ema.europa.eu).	AST
13.	Day 1 Check if the draft LoQ has been circulated by the RMS for agreement by written procedure to the CMDh referrals functional eudranet mailbox. Liaise with the RMS if the draft LoQ has not been circulated on time according to the timetable.	AD AST
14.	Save the draft LoQ and all comments received from CMSs in the subfolder 03 LoQ of the procedure.	AST
15.	Day 8 Receive the final LoQ sent to the CMDh referrals functional eudranet mailbox by the RMS. Liaise with the RMS in case the final LoQ has not been sent by the deadline set in the timetable.	AD AST
16.	Save the final LoQ in the subfolder 03 LoQ .	AST
17.	Prepare the letter to the applicant/MAH using the template 02- Template_Letter LoQ to Applicant and the final LoQ using the template 02- Template_LoQ . Save the letter and final LoQ in the subfolder 03 LoQ .	AST

Step	Action	Responsibility
18.	Check the letter and final LoQ if all comments have been included and liaise with RMS for clarification if needed.	AD
19.	Day 10 Send the letter and final LoQ (both in pdf format) to the applicant/MAH by e-mail using the template email 02- Template_Email LoQ to Applicant Save the e-mail in the subfolder 03 LoQ .	AST
20.	Forward the letter and final LoQ to the CMDh referrals functional eudranet mailbox.	AST
21.	Day 25 Receive the response to the LoQ and notification of oral explanation or written procedure sent by the applicant/MAH to all Member States in accordance with the list of contact points for submission of Responses to List of Questions for Applications referred to the CMDh published on the CMDh website. Liaise with the applicant/MAH and/or RMS if the response to the LoQ has not been sent within the deadline set in the timetable.	AD AST
22.	Save the response to the LoQ in the subfolder 03 LoQ . If the applicant/MAH requests an oral explanation, save the request in the subfolder 05 CMDh meeting 2 of the procedure.	AST
23.	Around Day 35 Receive the updated AR sent to the CMDh referrals functional eudranet mailbox by the RMS. Liaise with the RMS if not sent within the deadline set in the timetable.	AD AST
24.	Save the updated AR and all comments received from CMSs in the subfolder 04 Updated AR of the procedure.	AST
25.	If an oral explanation has <u>not</u> been requested , continue with step 32. If an oral explanation has been requested , prepare the letter to the applicant/MAH using the template 03- Template_Letter to Applicant OE in accordance with the timeslot agreed by the CMDh Members. Save the letter in the subfolder 05 CMDh meeting 2 .	AST
26.	Check the letter.	AD
27.	11 calendar days prior to the start of the CMDh meeting Send the letter (in pdf format) to the applicant/MAH by e-mail	AST

Step	Action	Responsibility
	using the template email <i>03- Template_Email to Applicant OE</i> . Save the e-mail in the subfolder <i>05 CMDh meeting 2</i> .	
28.	<i>Wednesday prior to the start of the CMDh meeting</i> Receive the list of representatives of the applicant/MAH attending the OE sent to the CMDh secretariat and RMS by the applicant/MAH. Liaise with the applicant/MAH if the list is not received within the deadline given in the letter.	AST
29.	Save the list of representatives of the applicant/MAH in the subfolder <i>05 CMDh Meeting 2</i> . Submit the request for 'Industry' passes ('red badges') to Reception (via the Visitor Request form on the Intranet).	AST
30.	<i>Friday prior to the start of the CMDh meeting</i> Receive the presentation to be given at the OE sent to the CMDh Secretariat and RMS by the applicant/MAH. Liaise with the applicant/MAH if the presentation is not received within the deadline given in the letter.	AST
31.	Save the presentations from the applicant/MAH (if applicable) and RMS/CMSs in the subfolder <i>05 CMDh Meeting 2</i> . Circulate the presentations in the Preamail2 or Late documents mailing (see WIN/H/3322 – CMDh agenda premail-postmail and rolling plan).	AST
32.	Follow the scientific discussions on the referral during the CMDh meeting	AD
33.	<i>After the scientific discussions at the CMDh meeting</i> Prepare the template for grounds/outcome (<i>complete all sections using CTS except the grounds and outcome sections</i>) (use the template <i>MMYY PR_Outcome referrals MMY</i>). Send the template by e-mail to the RMS for completion in advance of the adoption by the CMDh at the following CMDh meeting (use the template e-mail <i>Template_Email to RMS Grounds&Outcome</i>). When returned by the RMS, save the completed template in the Press Release folder of the next CMDh meeting.	AST
34.	<i>CMDh meeting + 1 day to 1 week</i> Receive the proposed day-60 outcome sent to the CMDh referrals functional eudranet mailbox by the RMS for written agreement (optional).	AD

Step	Action	Responsibility
	Save the proposal for agreement and all comments/final positions received from MSs in the subfolder 06 Outcome of the procedure.	AST
35.	Day 60 - End of the referral procedure	
	Receive the final outcome sent to the CMDh referrals functional eudranet mailbox by the RMS.	AD
36.	Save the day-60 final outcome (Agreement reached or Notification for arbitration to the CHMP) in the subfolder 06 Outcome .	AST
37.	If a notification for arbitration to the CHMP is received, forward the notification for information to the Community Procedures Section, CHMP Secretariat and V-PD-BUS by e-mail.	AD
38.	Update the Tracking table – Art. 29 Referrals to CMDh/Art. 13 referral to CMDh Variation (for internal use) in the STATISTICS folder with the outcome of the procedure. Update the statistics sheet in the tracking table.	AST
39.	CMDh meeting month + 1	
	Present the proposals from the RMSs for information to be published on the ground and outcome of CMDh referral(s) at the CMDh meeting. Are any comments received? If Yes: go to 39.1. If No: go to 40.	AD
39.1	Implement the comments received at the CMDh meeting in track change mode.	AD
40.	Perform a quality check of information to be published (including name of the product in the RMS, active substance, pharmaceutical form, procedure number, CMS, legal basis, grounds for referral to CMDh, Day 60 and outcome of the procedure).	AD
41.	Send the information on applications referred to the CMDh together with the draft press release (see WIN/H/3321 CMDh press release and minutes) to 'All Human CMD' for written agreement within 48h.	AST
42.	Once the grounds/outcomes have been agreed upon, update the Tracking table 'For website – Art. 29 Referrals to CMDh/Art. 13 referral to CMDh Variation' in the STATISTICS folder in DREAM.	AST
43.	One week following the CMDh meeting month + 1 Publish the tracking table referrals on the CMDh website.	AST