



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Handling of Paediatric Art. 45 work sharing procedures by the CMDh Secretariat		
Applies to: CMDh secretariat within Committees Secretariat in the Scientific Committee Support Department		
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1. Changes since last revision

- Update of the location for documents in DREAM (moved to Cabinet 2b).
- Update of the name of the Working Party (Working party instead of Subgroup).
- Deletion of the Rapporteur assignment process (previously steps 4 to 4.5).
- Deletion of task on saving e-mails not circulated via the Paediatric WS-Mailbox (step 9).
- Deletion of task on checking consistency of format of the public AR (step 11).
- Addition of steps for removal of an active substance from the Art. 45 list of paediatric studies (steps 16 to 20).

2. Records

The agreed waves of Paediatric Art. 45 work sharing procedures are saved electronically in the following folder in DREAM:

Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45

The public assessment reports for Paediatric Art. 45 work sharing procedures are saved electronically in the following folder in DREAM (retention time 50 years):

Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Public ARs



3. Instructions

Per year, up to 4 waves of Paediatric Art. 45 work sharing procedures are started, i.e. in January, April, July and October.

Abbreviations

- AD: Administrator in the CMDh secretariat
- AR: Assessment report
- AS: Active substance
- AST: Assistant in the CMDh secretariat
- CMDh: Coordination Group for Mutual Recognition and Decentralised Procedure – Human
- DREAM: Document Records Electronic Archive Management system
- EMA: European Medicines Agency
- MAH: Marketing authorisation holder
- MS: Member State
- WS: Work sharing

Step	Action	Responsibility
1	<i>Two months in advance of a new wave (in February, May, August and November, as applicable)</i> Ask MSs by e-mail or during the joint CMDh/EMA Working Party on Paediatric Regulation meeting to volunteer as rapporteur and to choose active substances for assessment from the final list of active substances compiled by the EMA or from an agreed priority list prepared by MSs.	AD
2	Check that the chosen active substance is still available in the tracking table 'Final list' in DREAM under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45 and ask the proposing MS regarding the rapporteurship for combinations of active substances if any.	AD
3	Save received agreements by MSs on rapporteurship in DREAM under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Art. 45 Waves/Wave <number>.	AST
4	Track rapporteurship appointments in the tracking table 'Final list' in DREAM under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45.	AST
5	<i>One month before the start of the wave (in March, June, September and December, as applicable)</i> Inform the Paediatric Medicines Office of the proposed substances in the wave for verification if Art 45 studies for the concerned substances	AST

	have been submitted.	
6	Put the list of selected AS and rapporteurs on the agenda of the joint CMDh/EMA Working Party on Paediatric Regulation for agreement and subsequent agreement by the CMDh. <i>Note: If no Working Party meeting is scheduled during this month, put the list directly on the agenda of the CMDh Plenary meeting.</i>	AST
7	After agreement by the CMDh, update the published document 'List of the active substances included in the work-sharing procedure' ('Article 45 - 1st to xxth waves - Table for Publication' saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Statistics & Published waves) with the new wave. Publish the updated document on the CMDh website.	AST
8	Update the published document 'List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation' (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Final List for PUBLICATION) with information on the AS in the new wave (wave number and rapporteur). Publish the updated document on the CMDh website.	AST
9	About one month after the publication Liaise with the Paediatric Medicines Office for them to send out the letters to the concerned MAHs requesting the companies to submit the data within one month after receipt of the letter. The submission is to be followed up by the rapporteur.	AD
10	After all letters have been sent Receive from the Paediatric Medicines Office a list with all studies included in the wave and requested for submission by MAHs including all MAH contact points used in the letters. Duplicate studies were sorted out from this list by the Paediatric Medicines Office. Circulate the list of studies and contact points for the started wave by e-mail to the Paediatric WS-Mailbox (list-h-cmd-paediatricws@eudra.org) for information.	AD
11	Once the rapporteur has started the Paediatric Art.45 procedure (after all data has been received) Track the following information in the document 'Tracking table - Art. 45 WS' (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45): • Start of procedure, including timetable; • Date of received preliminary AR;	AST

	• Date of clock-stop; • Date of received final AR; • End of procedure date; • Date of publication of public AR; • Date of publication of revised public AR; • Comments on publications (if any).	
12	<i>When a public AR is received</i> Table the public AR at the next joint CMDh/EMA Working Party on Paediatric Regulation and/or CMDh Plenary meeting for adoption. The deadline to submit the public AR for adoption is Preamble 2 (9am UK time, Thursday before the CMDh meeting). Public ARs received after the deadline are tabled for the next Working Party on Paediatric Regulation and/or CMDh Plenary meeting.	AD
13	If no feedback from the Chair of the joint CMDh/EMA Working Party on Paediatric Regulation was received, liaise after the meeting with the Working Party Chair if editorial changes need to be made to the public AR before publication on the CMDh website. After receipt of feedback from the Working Party Chair, liaise with the rapporteurs for updates as necessary.	AST
14	Include reference to the public AR in the CMDh press release.	AD
15	Update columns "Changes to Product information" and "Outcome of assessment" in the document 'List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation' (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Final List for PUBLICATION) with the information included in the public AR under "Summary of outcome".	AST
16	Publish the adopted public AR and the updated document 'List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation' on the CMDh website after the CMDh meeting.	AST
17	Save the published public AR in the Public ARs folder (Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Public ARs).	AST
18	Track the date of publication of the public AR in the document 'Tracking table - Art. 45 WS' (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45).	AST
19	<i>Every 6 months (January, July)</i> Prepare statistics on MSs acting as rapporteurs in Paediatric Art. 45 work sharing procedures to be tabled for information at the next joint	AST

	CMDh/EMA Working Party on Paediatric Regulation meeting (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Statistics & Published waves). Check the statistics before tabling. Publish the annual statistics (prepared in January) on the CMDh website after agreement by the joint CMDh/EMA Working Party on Paediatric Regulation and the CMDh.	AD AST
20	<i>Whenever an active substance is removed from the Art. 45 list of paediatric studies (data assessed via another regulatory procedure, product no longer marketed, product centrally authorised, etc.)</i> Save the e-mail stating that an AS is withdrawn in DREAM under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Withdrawn Studies/<Active Substance>-<MS>-<Withdrawn>. If the AS was included in a wave previously, link the above mentioned folder to the relevant wave folder.	AST
21	Strikethrough the AS in the tracking table 'Final list' (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45) and in the published document 'List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation' (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Final List for PUBLICATION). Check with the AD which reason for deletion to enter in the column "outcome of assessment" in the published document 'List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation'.	AST
22	Delete the AS from the published document 'List of the active substances included in the work-sharing procedure' ('Article 45 - 1st to xxth waves - Table for Publication' saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Statistics & Published waves). Publish the updated document on the CMDh website with the next publication for a new wave.	AST
23	If the AS was included in a wave previously, update statistics on MSs acting as rapporteurs in Paediatric Art. 45 work sharing procedures accordingly (saved under Cabinets/02b. Administration of Scientific Meeting/CMDh - Administration/3. Other activities/06. Procedures/02- Article 45/Statistics & Published waves). Publish the updated document on the CMDh website with the next	AST

publication for a new wave.
