



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Handling of Paediatric Art. 46 work sharing procedures by the CMDh Secretariat		
Applies to: CMDh secretariat within the Scientific Committee Support Section		
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1. Changes since last revision

New WIN.

2. Records

All documents relating to Paediatric Art. 46 work sharing procedures are saved electronically in the folder in DREAM:

[Old EDMS Structure\Meetings\Scientific Meetings\CMDh \(M R F G H\)\TO MOVE IN NEW ARCHITECTURE DREAM\10- CMDh Worksharing Activities\Paediatric\03- Article 46](#)

The public assessment reports for Paediatric Art. 46 work sharing procedures are saved electronically in the folder in DREAM (retention time 50 years):

[Old EDMS Structure\Meetings\Scientific Meetings\CMDh \(M R F G H\)\ TO MOVE IN NEW ARCHITECTURE DREAM\10- CMDh Worksharing Activities\Paediatric\Public PaedARs\03- Art 46 \(Post Paed Reg\)](#)

3. Instructions

The Paediatric Medicines Section in the H-Unit receives submissions of line listings and related cover letters according to Art. 46 of Regulation EC No 1901/2006 as amended and includes them in a list of all Art. 46 submissions for MRP/DCP/NAPs (Art. 46 list), which is updated by the Paediatric Medicines Section on a regular basis. The CMDh Secretariat and the Paediatric Medicines Section both work on this list with regard to work sharing procedures. It is saved under ...[10-CMDh Worksharing Activities\Paediatric\03- Article 46\List_Art46_MRP-DCP-N](#). It consists of a tab 'Line Listings' to be



populated by the Paediatric Medicines Section and a tab 'List AS' to be prepared by the Paediatric Medicines Section and partially to be filled in by the CMDh secretariat with incoming information received during the rapporteur consultation.

Abbreviations

- AD: Administrator in the CMDh secretariat
- AR: Assessment report
- AS: Active substance
- AST: Secretary in the CMDh secretariat
- CMDh: Coordination Group for Mutual Recognition and Decentralised Procedure - Human
- DCP: Decentralised procedure
- DREAM: Document Records Electronic Archive Management system
- H-Unit: Human Medicines Development and Evaluation Unit
- INN: International non-proprietary name
- MAH: Marketing authorisation holder
- MRP: Mutual recognition procedure
- MS: Member State
- NAP: Nationally authorised product
- PI: Product information
- PIP: Paediatric investigation plan
- PrAR: Preliminary assessment report
- RMS: Reference Member State
- WS: Work sharing

Step	Action	Responsibility
1.	<i>On Day -7 of each CMDh meeting (on Monday one week before the meeting)</i> Check with the Paediatric Medicines Section if the Art. 46 list is updated with the latest Paediatric Art. 46 submissions received in the Paedstudies46-nat mailbox. In the tab 'List AS', the Paediatric Medicines Section should have filled in the columns 'Active substance / INN', 'Number of Studies', 'Change to PI', 'PIP' and 'Planned ongoing variation' for any new submission since the last circulation of the list.	AD
2.	Appoint rapporteurs for all Paediatric Art. 46 submissions since the last meeting, which are listed at the bottom of the tab 'List AS' under the heading of the current month. The following criteria are applied in the given order: • In case of a MRP/DCP product (check in tab 'Line Listings' if a	AD

	MRP/DCP number is mentioned for the product), the rapporteur is the RMS;	
	• If the product is authorised purely nationally in more than one member state, the rapporteur is the same as for other procedures for the same product, e.g. Art. 45 (check published list of Art. 45 waves); • If no other rapporteur is available, one of the MSs who has received the submission (check in the tab 'Line Listings') based on statistics (MSs with statistically lower number of rapporteurships so far) and other information provided by the MSs (e.g. answers to a questionnaire on planned rapporteurships).	
3.	Include the reason for appointment in the tab 'List AS' in the column 'reason for appointment' and mention if the same MS has been appointed for the same product previously (by checking the whole list). Change the version number of the Excel file in the heading of tab 'List AS'.	AD
4.	Send out an email with the information on the appointment for the current month to the PaediatricWS mailbox (list-h-cmd-paediatricws@eudra.org) using the template email • Mention the version number of the Art. 46 list; • Attach the Excel file to the email (a ZIP file might be needed due to the size of the Excel file); • Include the appropriate dates and new information of the current month, i.e. submissions received, appointed rapporteurs and reason for appointment; • Include the deadline for responses from rapporteurs; • List all procedures for which feedback from the rapporteurs on the start of the work sharing has not yet been received from the previous month(s) (column 'feedback' not filled in).	AD
5.	Include the updated list of Paediatric Art. 46 submissions and appointments in the agenda of the joint CMDh/EMA subgroup on paediatric Regulation. Any issue relating to the work sharing, the appointment of rapporteurs or missing feedback from previous months can be mentioned and discussed during the subgroup meeting.	AST
6.	Save emails related to the rapporteur appointment under ...\10-CMDh Worksharing Activities\Paediatric\03- Article 46\<year>\<month - year>\<product> <i>Note: The CMDh secretariat does not track rapporteurs' agreement to the appointment. If no feedback is received within one week after sending out the email and no objections are presented during the joint CMDh/EMA subgroup on paediatric Regulation meeting, there will be no follow-up. In case a rapporteur cannot accept the appointment at a</i>	AST

<i>later stage, a new rapporteur will have to be appointed.</i>		
7.	If feedback is received from a rapporteur that the work sharing should be started, go to step 8. If feedback is received from a rapporteur that the work sharing should NOT be started, go to step 9.	AD
8.	- Enter the information in the tab 'List AS' in the column 'feedback' with the date of the receipt of the email and a summary of the information provided, if applicable, e.g. procedure number, proposed start date etc. <i>(Note: the letters requesting the submission of the data to the rapporteur should be sent by Paediatric Medicines Section at least one month in advance of the intended start of the procedure);</i> - Change the background colour of the cell to light green to indicate that feedback has been received; - Save the email in the corresponding folder in DREAM under ...\10-CMDh Worksharing Activities\Paediatric\03- Article 46\<year>\<month - year>\<product>; - Enter 'N/A' in the column 'MAH informed of procedure on (Date) Feedback Letter', highlight the cell 'Date of requesting data' in light yellow (to indicate to the Paediatric Medicines Section that a letter needs to be sent) and include a proposed date for the sending in brackets, if applicable (brackets are used to distinguish between dates where letters have already been sent and proposed dates for letters to be sent); - Inform the Paediatric Medicines Section that a request letter needs to be sent to the MAH. <i>(Once the letter is sent, the Paediatric Medicines Section is responsible for entering the date when the letter has been sent in the respective cell).</i> Go to step 10	AD AD AST AD AD
9.	- Enter the information in the tab 'List AS' in the column 'feedback' with the date of the receipt of the email and a summary of the information provided, i.e. reason for not starting the work sharing (e.g. upcoming or ongoing variation); - Change the background colour of the cell to light green to indicate that feedback has been received; - Save the email in the corresponding folder in DREAM under 10-CMDh Worksharing Activities\Paediatric\03- Article 46\<year>\<month - year>\<product>; - Enter 'N/A' in the column 'Date of requesting data' and highlight the cell 'MAH informed of procedure on (Date) Feedback Letter' in light yellow (to indicate to the Paediatric Medicines Section that a letter needs to be sent); - Inform the Paediatric Medicines Section that a letter informing the	AD AD AST AD

	MAH needs to be sent. <i>(Once the letter is sent, the Paediatric Medicines Section is responsible for entering the date when the letter has been sent in the respective cell).</i>	AD
	<i>Note: Sometimes rapporteurs give oral feedback during the joint CMDh/EMA subgroup on paediatric Regulation meeting. This information should likewise be entered, but ideally rapporteurs should be reminded to confirm their position in writing.</i>	
10.	For started procedures, save emails relating to the different steps of the work sharing procedure which are not circulated through the Paediatric WS-Mailbox in DREAM under (... 10-CMDh Worksharing Activities\Paediatric\03-Article 46\<year>\<month - year>\<product>) and track the following information in the tracking table 'Art. 46 WS' (located in 10-CMDh Worksharing Activities\Paediatric\03-Article 46):	AST
	• Start of procedure; • PrAR ; • Clock-stop; • Restart; • End of procedure (final AR); • Public AR, if applicable.	
11.	When a public AR is received	
	Table the public AR at the next CMDh plenary meeting.	AD
12.	Check consistency in format provided in the public AR.	AST
13.	Include reference to the public AR in the CMDh press release.	AD
14.	Publish the public AR on the CMDh website after the CMDh meeting.	AST
15.	Every 3 months	
	Prepare statistics on Member States acting as rapporteurs in Paediatric Art. 46 work sharing procedures to be tabled for information at the next joint CMDh/EMA subgroup on paediatric Regulation meeting.	AST
	Check the statistics before tabling.	AD
16.	Every year (in January)	
	Prepare statistics on Member States acting as rapporteurs in Paediatric Art. 46 work sharing procedures for the previous year.	AST
	Check the statistics before tabling at the January meeting.	AD
	Publish the annual statistics on the CMDh website after agreement by the joint CMDh/EMA subgroup on paediatric Regulation and the CMDh plenary.	AST