



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of requests for confirmation of the applicability of an EMA decision on class waivers		
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1. Purpose

This SOP describes the handling of requests from applicants seeking confirmation of whether the scope of the EMA decision on a class waiver for a condition is applicable to their medicinal product or not.

This SOP does not address the procedure for adoption of a PDCO opinion on a class waiver initiated by the PDCO of its own accord.

2. Scope

This SOP applies to the PDCO and the Paediatric Medicines Section in the Human Medicines Special Areas Sector.

3. Responsibilities

It is the responsibility of the PDCO chairperson to ensure that this procedure is adhered to by the PDCO.

It is the responsibility of the Section Head to ensure that this procedure is adhered to within the Paediatric Medicines Section.

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

New SOP.



5. Documents needed for this SOP

All templates are located at: X:\Templates\Others\H - Paediatric Templates\11 Confirmation on the applicability of class waivers

- Form 1: Request confirmation on the applicability (applicant to fill in)
- Template 1: Confirmation on applicability to rapporteur
- Template 2: Confirmation letter of the applicability of waiver on conditions (General)
- Template 3: Confirmation letter of the applicability of waiver on conditions (in case PIP or waiver was submitted)
- Template 4: Confirmation letter to applicant via Eudralink.

6. Related documents

N.A.

7. Definitions

DREAM: Document records and e-archive management (EMA electronic repository)

MMD: Managing meeting documents system

Paed AA: Paediatric administrative assistant

Paed Co: Paediatric coordinator responsible for the activity described in this SOP. If the class waiver request is submitted in parallel with a PIP application the paediatric coordinator for the PIP procedure is also responsible for the class waiver request.

Paed Inbox: Generic e-mail inbox (paediatrics@ema.europa.eu) managed by Paed AA.

Paed Secr: Paediatric secretary coordinating the activity described in this SOP

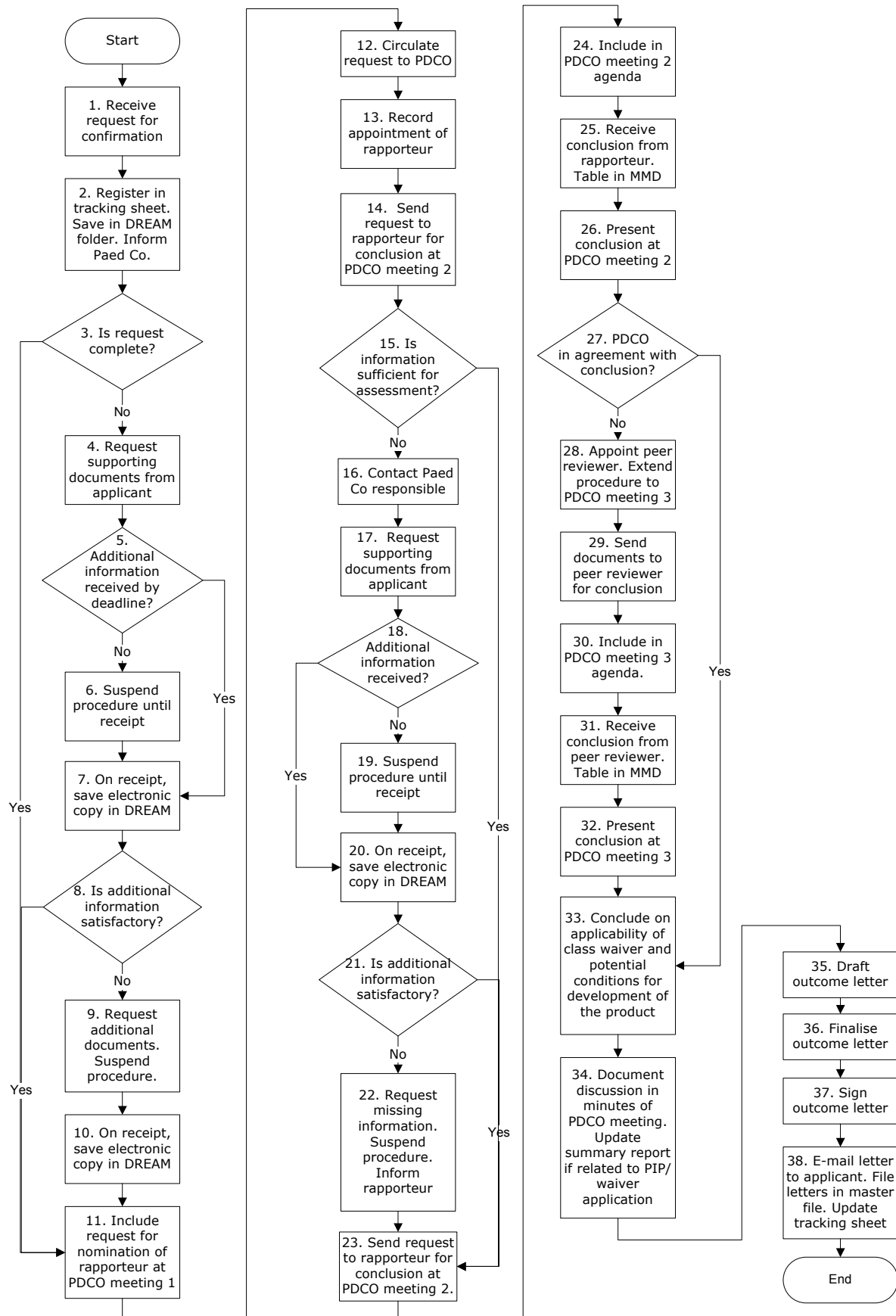
PDCO: Paediatric Committee

PDCO Secr: Paediatric Committee secretary

PIP: Paediatric investigation plan

SH: Section Head

8. Process map(s)/ flow chart(s)



9. Procedure

Note: All e-mails mentioned in this procedure must be sent using Eudralink or a similarly secure EMA system.

Step	Action	Responsibility
1	Receive from applicant request for confirmation on the applicability of the EMA decision on class waivers (form 1) together with supporting documents in Paed Inbox or receive request submitted in parallel with an application for a PIP and/or waiver.	Paed AA
2	Add the request to the Excel tracking sheet (PIP intents and submission) located in DREAM and allocate a procedure number. Create a folder with the allocated number in DREAM to save the request. Identify and inform the assigned Paed Co.	Paed AA
3	Check whether the request is complete (i.e. supporting document submitted preferably in the form of an investigator brochure) or not. If no, go to step 4. If yes, go to step 11.	Paed AA
4	Contact the applicant to request supporting documents by email within a short (defined) timeframe.	Paed AA
5	Check that the supporting document has been received from the applicant by the deadline indicated in the e-mail. If no, go to step 6. If yes, go to step 7.	Paed AA
6	If the additional information has not been received by the deadline indicated in the e-mail suspend the procedure until the receipt of the responses. Inform the Paed Co accordingly. Postpone the resumption of the procedure to the next possible PDCO meeting.	Paed AA
7	Upon receipt of the documents save an electronic copy in the allocated area in DREAM.	Paed AA
8	Check that additional information is satisfactory If no, go to step 9. If yes, go to step 11.	Paed AA
9	If the responses are not satisfactory send a new e-mail to the applicant requesting additional information. Suspend the procedure until the receipt of the responses. Postpone the resumption of the procedure to the next possible	Paed AA

Step	Action	Responsibility
	PDCO meeting.	
10	Upon receipt of the documents save electronic copy in the allocated area in DREAM.	Paed AA
11	List all requests received prior to a PDCO meeting in the line listing for nomination of rapporteur at the PDCO meeting (PDCO meeting 1). If the class waiver applicability request is submitted in parallel with a PIP application, propose the same rapporteur for the PIP procedure.	Paed Secr
12	Circulate the request to the PDCO for appointment of rapporteur.	PDCO Secr
13	During the PDCO meeting (PDCO meeting 1) record appointment of rapporteur.	PDCO Secr
14	Upon appointment of the rapporteur, send the request, the supporting documents and the presentation template to the rapporteur by e-mail (using template 1) requesting them to prepare the conclusion for the next PDCO meeting (PDCO meeting 2).	Paed Secr
15	Check if information is sufficient for assessment. If no, go to step 16. If yes, go to step 23.	Rapporteur
16	If the request does not contain sufficient information for assessment contact the Paed Co to liaise with the applicant.	Rapporteur
17	Contact the applicant by email (cc Paed AA) to request supporting documents within a short (defined) timeframe.	Paed Co
18	Check that the supporting documents have been received from the applicant by the deadline indicated in the e-mail. If no, go to step 19. If yes, go to step 20.	Paed Co
19	If the additional information has not been received by the deadline indicated in the e-mail suspend the procedure until the receipt of the responses. Inform the rapporteur and the Paed AA accordingly. Postpone the resumption of the procedure to the next possible PDCO meeting.	Paed Co
20	Upon receipt of the documents save electronic copy in the allocated area in DREAM.	Paed AA
21	Check that additional information is satisfactory. If no, go to step 22. If yes, go to step 23.	Paed Co

Step	Action	Responsibility
22	Send an e-mail to the applicant requesting the missing information. Suspend the process until the receipt of the responses and inform the rapporteur and the Paed AA accordingly.	Paed Co
23	Send the responses received from the applicant to the rapporteur by e-mail requesting them to prepare the conclusion for the next PDCO meeting (PDCO meeting 2). Ask the PDCO Secr to include request for confirmation of applicability in the agenda of the PDCO meeting.	Paed Co
24	Include request for confirmation of applicability in the agenda of the PDCO meeting (PDCO meeting 2).	PDCO Secr
25	Receive slides with the conclusion from the rapporteur and table them in MMD.	PDCO Secr
26	Present at PDCO meeting 2 the conclusion (max 2 slides) focussing on: - the applicability of the class waiver - potential conditions in which development of the product would be of interest and for which the applicant could be encouraged to submit a PIP application.	Rapporteur
27	Is the PDCO in agreement with the rapporteur's conclusion? If no, go to step 28. If yes, go to step 33.	PDCO chairperson
28	Appoint a peer reviewer to assess the application and extend the procedure until the following PDCO meeting (PDCO meeting 3).	PDCO chairperson
29	Send the request together with the supporting documents to the peer reviewer (template 1) by e-mail requesting them to prepare the conclusion for the next PDCO meeting (PDCO meeting 3).	Paed Secr
30	Include request for confirmation of applicability in the agenda of the PDCO meeting (PDCO meeting 3).	PDCO Secr
31	Receive slides with the conclusion from the peer reviewer and table them in MMD.	PDCO Secr
32	Present at PDCO meeting 3 the conclusion focussing on: - the applicability of the class waiver - potential conditions in which development of the product would be of interest and for which the applicant could be encouraged to submit a PIP application.	Rapporteur/Peer reviewer
33	Conclude on: - the applicability of the class waiver - potential conditions in which development of the product would	PDCO chairperson

Step	Action	Responsibility
	be of interest and for which the applicant could be encouraged to submit a PIP application.	
34	Reflect the outcome of the PDCO discussion in minutes of the PDCO meeting. If request related to application for PIP and/or waiver insert conclusion in summary report.	Paed Co
35	Draft outcome letter using relevant template (template 2 or template 3).	Paed Secr
36	Finalise outcome letter based on the minutes of the PDCO meeting.	Paed Co
37	Sign letter.	SH
38	Send letter to applicant by e-mail using template 4 and save correspondence in the relevant electronic folder. File signed letter in the master file for confirmation letters. Update the Excel tracking sheet (PIP intents and submission) located in DREAM to reflect positive/negative outcome and date of the letter.	Paed Secr

10. Records

When completed and approved the original, signed hard copy of the form and of the outcome letter is filed in the master file.

Electronic copies are saved in the appropriately labelled folder in DREAM.