



Standard operating procedure

Title: Modification of an agreed paediatric investigation plan		
Status: PUBLIC		Document no.: SOP/H/3457
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1. Purpose

This SOP describes the handling of an application for modification of an agreed paediatric investigation plan (PIP) from receipt to adoption of the PDCO opinion.

2. Scope

This SOP applies to Paediatric Medicines Office in Product Development Scientific Support Department and Scientific Committees Secretariat in Committees and Inspections Department.

3. Responsibilities

It is the responsibility of the Head of Paediatric Medicines Office to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of paragraph 9. Procedure.

4. Changes since last revision

Minor revision and update following current EMA organigram



5. Documents needed for this SOP

Templates and deadline documents are located in DREAM: Cabinets/02b. Administration of Scientific Meeting/PDCO - Administration/1. Governance/10. Templates/ PME - Paediatric templates and timelines:

- PedRA procedural timelines and templates checklist
- Appropriate PDCO opinion template
- <Year> <Q1-4> Timelines (EMA/690732/2015).

Modification summary report template – generated by PedRA

Eudralink message templates in PedRA (numbers are related to the message in the application):

- 01 - Acknowledgment of receipt
- 02 – Appointment of Rapp and Peer
- 03 - Start of procedure – Modification
- 10 - Summary report to Rapp and Peer
- 13 - Summary report Day 30 - Modification to applicant
- 18 - Draft opinion to Rapp and Peer
- 19 - Draft opinion to applicant
- 20 – Opinion to applicant.

6. Related documents

SOP/EMA/0040	Evaluation of conflicts of interests of experts for involvement in Agency activities
SOP/EMA/0101	Standard operating procedure for conducting checks for conflicts of interest when assigning medicinal products for human or veterinary use to a product / project team leader / member or project manager
SOP/H/3454	Re-examination of Paediatric Committee opinions
SOP/H/3455	EMA decision-making process for decisions on Paediatric Committee opinions
WIN/H/3459	Paediatric master files

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004:

http://ec.europa.eu/health/files/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf

Rules of procedure of the Paediatric Committee (PDCO)

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004749.pdf

Roles and responsibilities of members and alternates, rapporteur and peer reviewers, experts and observers of the Paediatric Committee (PDCO)

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004754.pdf

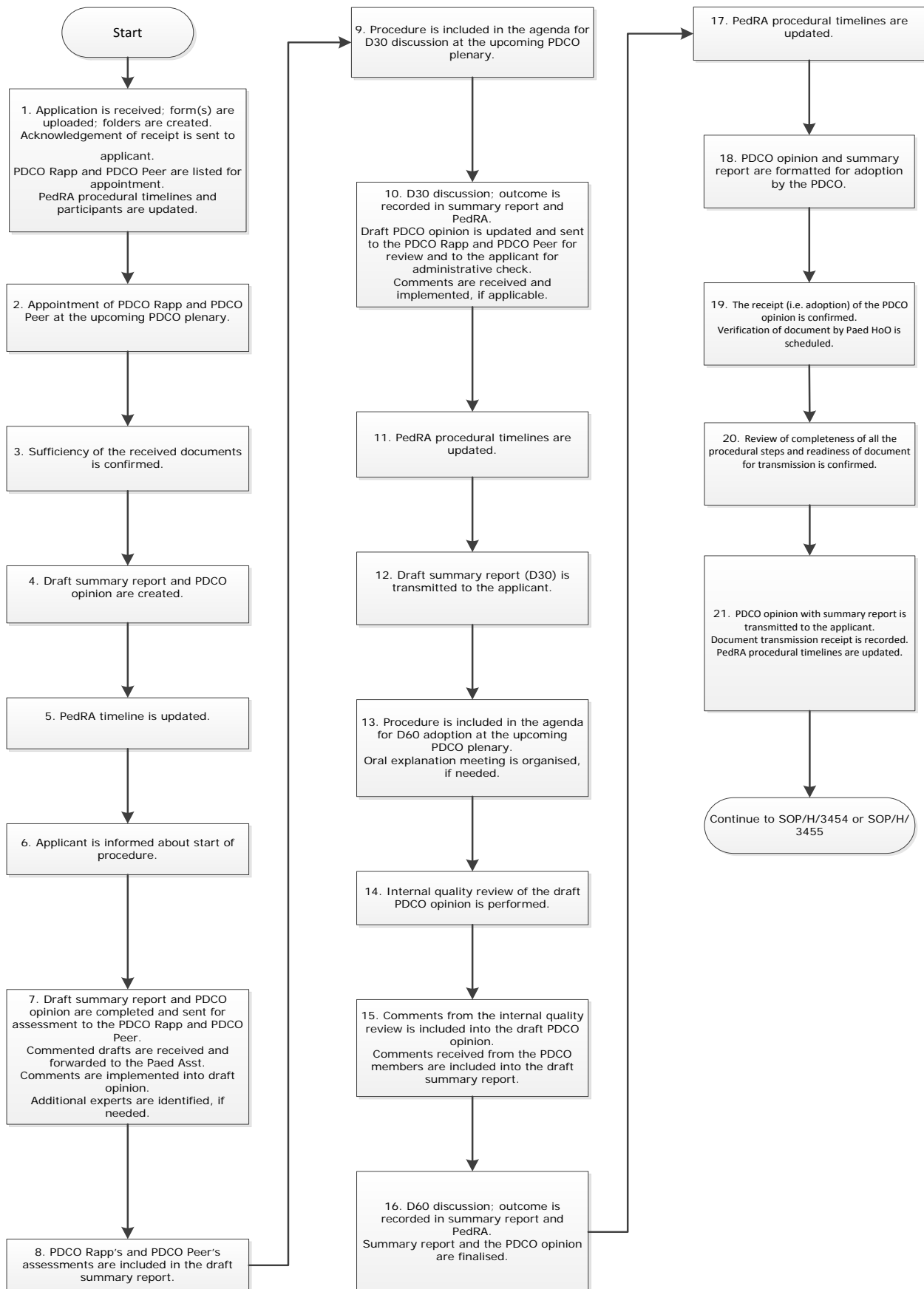
Procedural advice

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000608.jsp&mid=WC0b01ac0580925b1b

7. Definitions

D1	Start of procedure date
D30	First discussion at PDCO meeting
D60	Second discussion and adoption of opinion at PDCO meeting
D-DS-PME	Paediatric Medicines Office in Product Development Scientific Support Department
DREAM	Document records electronic archive management
Eudralink	The European medicines regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
MMD	Managing meeting documents system
N-drive	Internal repository for PME
OEM	Oral explanation meeting
Paed AA	Paediatric administrative assistant (in D-DS-PME)
Paed Asst	Paediatric assistant (in D-DS-PME)
Paed Co	Paediatric coordinator (scientific officer in D-DS-PME)
Paed Asst (assigned)	Paediatric procedure assistant assigned to complete a specific task (assistant in D-DS-PME)
Paed Co (assigned)	Paediatric coordinator assigned to complete a specific task (scientific officer in D-DS-PME)
Paed HoO	Head of Paediatric Medicines Office
PDCO	Paediatric Committee
PDCO Peer	PDCO peer reviewer
PDCO Rapp	PDCO rapporteur
PDCO Sec	Secretariat of the PDCO in Scientific Committees Secretariat in Committees and Inspections Department
PedRA	Paediatric Record Application (database)
PedRA template	Eudralink template available in PedRA
PIP	Paediatric investigation plan

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



9. Procedure

Notes:

- Declarations of interest are checked and evaluated for all staff before involvement according to SOP/EMA/0101 and SOP/EMA/0040 listed under "Related documents".
- All messages containing confidential information must be sent via EudraLink, using the appropriate PedRA template if available.
- All procedural timelines and application guidance are published on the EMA website.
- All meeting documents are linked to appropriate DREAM meeting folders by Paed Asst prior meeting and regularly tabled in MMD by PDCO Sec, before during and after PDCO plenary.

Step	Action	Responsibility
Pre D1		
1.	<ul style="list-style-type: none"> • Receive application for modification on an agreed PIP from applicant; upload form(s) in PedRA create folder in DREAM and N-drive. • Send an acknowledgment of receipt to the applicant. • List PDCO Rapp and PDCO Peer for appointment by the PDCO. • Update procedural timelines and participants in PedRA. <p><i>Note: If available, participants should be the same as it was for the related procedure.</i></p>	Paed AA
2.	Ensure the appointment of PDCO Rapp and PDCO Peer at the upcoming PDCO plenary.	PDCO Sec
3.	Confirm the sufficiency of the submitted documents to Paed Asst	Paed Co
4.	Create draft summary report and PDCO opinion; forward both to Paed Co.	Paed Asst
5.	Update procedural timelines in PedRA.	Paed AA
Pre and post D30		
6.	Inform applicant of the start of procedure at D1.	Paed Asst
7.	<ul style="list-style-type: none"> • Complete the draft summary report and PDCO opinion and send both for assessment to the PDCO Rapp and PDCO Peer. • Receive the commented draft summary report and PDCO opinion from the PDCO Rapp and PDCO Peer and forward to Paed Asst if not in copy. • Implement comments into draft opinion, if applicable. • Identify the need and, if agreed by PDCO, organise the involvement of additional experts. 	Paed Co

8.	Include the PDCO Rapp and PDCO Peer assessment into the summary report.	Paed Asst
9.	<ul style="list-style-type: none"> • Include the procedure for D30 discussion in the upcoming PDCO plenary. 	PDCO Sec
10.	<ul style="list-style-type: none"> • Participate in the D30 discussion. • Record the minutes of the D30 discussion in PedRA and in the draft summary report.¹ • Update the draft opinion accordingly and send it to the PDCO Rapp and PDCO Peer for a review, and to the applicant for administrative check. • Receive and implement comments into draft opinion, if applicable. 	Paed Co
11.	Update procedural timelines in PedRA.	Paed AA
12.	Transmit the draft summary report (D30) to applicant for information or for clarification if requested.	Paed Asst
<i>Pre and post D60</i>		
13.	<ul style="list-style-type: none"> • Include the procedure in the agenda for adoption at the upcoming PDCO plenary. • If applicable, schedule and invite the applicant for an oral explanation meeting. 	PDCO Sec
14.	Perform an internal quality review of the draft PDCO opinion. ¹	Paed Co (assigned)
15.	<ul style="list-style-type: none"> • Implement comments from the quality review into the draft PDCO opinion as appropriate. • Include comments received from the PDCO members into the summary report as appropriate. 	Paed Co
16.	<ul style="list-style-type: none"> • Participate in the D60 discussion. • Record the minutes of the D60 discussion in PedRA and in summary report. • Finalise the content of the summary report and the PDCO opinion.¹ 	Paed Co
17.	Update procedural timelines in PedRA.	Paed AA
18.	Format the PDCO opinion and summary report for adoption by the PDCO.	Paed Asst
19.	<ul style="list-style-type: none"> • Confirm the receipt (i.e. adoption) of the PDCO opinion¹. • Schedule the verification of document for Paed HoO. 	Paed Asst (assigned)

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| 20. | Review the completeness of all the procedural steps and confirm the readiness of the document for transmission. ¹ | Paed HoO |
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Note: if required, obtain immediately further clarification from Paed Co.

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| 21. | <ul style="list-style-type: none">• Transmit electronically the PDCO opinion merged with the summary report to applicant within ten days of receipt from the PDCO (i.e. adoption date).• Obtain and save the record of document transmission and receipt (accessed) by the applicant.• Update the relevant PedRA procedural timelines. | Paed Asst |
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Continue to SOP/H/3454 or SOP/H/3455.

10. Records

Electronic records are saved in the appropriately labelled folders in DREAM and on N:\ drive.

¹ Task completion is confirmed by labelling the document version in DREAM appropriately.