EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Re-examination of Paediatric Committee opinions		
Status: **PUBLIC**		Document no.: SOP/H/3454
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Signature: On File	Signature: On File	Supersedes: SOP/H/3203 (07-OCT-15) TW4550
Date: 1-Dec-2017	Date: 1-Dec-2017	TrackWise record no.: 4865

1. Purpose

This SOP describes the procedure for the handling of a re-examination of an opinion of the Paediatric Committee on a paediatric investigation plan, a product-specific waiver, or a modification of an agreed paediatric investigation plan (in accordance with Article 25 of Regulation (EC) No 1901/2006).

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 part 9. Procedure.

4. Changes since last revision

Minor revision and update following current EMA organigram.

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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
- <Year> <Q1-4> Timelines (EMA/690732/2015)

Eudralink message templates in PedRA:

- 02 – Appointment of Rapp and Peer
- 24 – Re-examination start of procedure
- 25 – Re-examination SR and opinion to applicant
- 26 - Re-examination opinion

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/3452	Paediatric investigation plan or a waiver from start of procedure to clock-stop or PDCO opinion
SOP/H/3453	Paediatric investigation plan from re-start of procedure to PDCO opinion
SOP/H/3457	Modification of an agreed paediatric investigation plan
SOP/H/3212	Decision-making process for Paediatric Committee opinions on paediatric investigation plans and product-specific waivers
WIN/H/3255	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

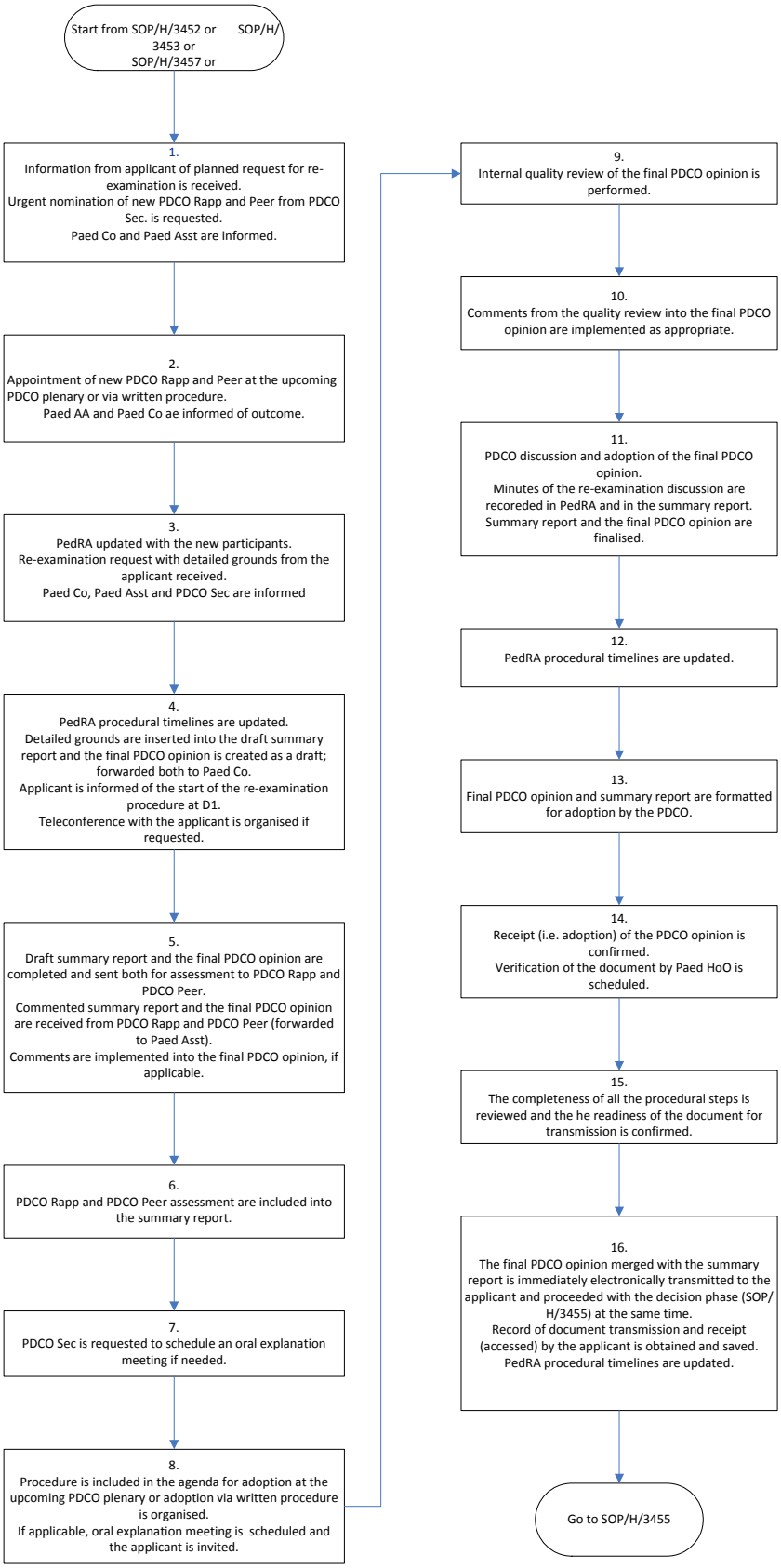
Procedural advice:

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

7. Definitions

EudraLink	The European medicines regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
Paed AA	Paediatric administrative assistant (in D-DS-PME)
Paed Asst	Paediatric procedure assistant (in D-DS-PME)
Paed Co	Paediatric coordinator (scientific officer 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
PedRA	Paediatric Record Application (database)
PedRA template	Eudralink template available in Paediatric Record Application (database)
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 PedRA template when 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 before, during and after PDCO plenary by PDCO Sec.*
- *To facilitate planning, it is recommended that the applicant gives written notice of an intent to request re-examination within 10 days of receipt of the opinion. Detailed grounds for re-examination must be provided within 30 days of receipt of the opinion.*
- *If the end of the 30-day period does not allow discussion in a PDCO meeting, the final opinion needs to be adopted by written procedure.*

Step	Action	Responsibility
	Continue from *SOP/H/3452 or* *SOP/H/3453 or* *SOP/H/3457*	
	Pre and D1 (From the date of delivery of the opinion up to 30 calendar days)	
1.	• Receive information from applicant of planned request for re-examination (letter of intent) • Request for urgent nomination of new PDCO Rapp and Peer from PDCO Sec. • Inform Paed Co and Paed Asst. *Note: Nominated persons must be different from the PDCO Rapp and Peer of the procedure for which re-examination is requested.*	Paed AA
2.	• Ensure the appointment of new PDCO Rapp and Peer at the upcoming PDCO plenary or via written procedure. • Inform Paed AA and Paed Co of outcome.	PDCO Sec
3.	• Update PedRA with the new participants. • Receive the re-examination request with detailed grounds from the applicant. • Inform Paed Co, Paed Asst and PDCO Sec.	Paed AA
4.	• Update procedural timelines in PedRA. • Insert detailed grounds into the draft summary report and create the final PDCO opinion as a draft; forward both to Paed Co.	Paed Asst

	• Inform the applicant of the start of the re-examination procedure at D1. • If requested, organise a teleconference with the applicant. *Note: The procedure starts on the following day after receipt of the grounds for re-examination. The final PDCO opinion must be adopted within 30 calendar days. If the applicant requests an oral explanation and no PDCO meeting is scheduled within 30 calendar days, the start of procedure may be postponed at the request of the applicant.*	
	From D1 to post D30	
5.	• Complete the draft summary report and the final PDCO opinion and send both for assessment to PDCO Rapp and PDCO Peer (set short deadlines). • Receive the commented summary report and the final PDCO opinion from PDCO Rapp and PDCO Peer and forward to Paed Asst if not in copy. • Implement comments into the final PDCO opinion, if applicable.	Paed Co
6.	Include the PDCO Rapp and PDCO Peer assessment into the summary report.	Paed Asst
7.	• If needed, request PDCO Sec to schedule an oral explanation meeting.	Paed Co
8.	• Include the procedure in the agenda for adoption at the upcoming PDCO plenary or organise the adoption via written procedure. • If applicable, schedule and invite the applicant for an oral explanation meeting.	PDCO Sec
9.	Perform an internal quality review of the final PDCO opinion.[1]	Paed Co (assigned)
10.	Implement comments from the quality review into the final PDCO opinion as appropriate.	Paed Co
11.	• Participate in the PDCO discussion and adoption of the final PDCO opinion. • Record the minutes of the re-examination discussion in PedRA and in the summary report. • Finalise the content of the summary report and the final PDCO opinion.[1]	Paed Co
12.	Update procedural timelines in PedRA.	Paed AA
13.	Format the final PDCO opinion and summary report for adoption by the PDCO.	Paed Asst
14.	• Confirm the receipt (i.e. adoption) of the PDCO opinion[1]. • Schedule the verification of the document by Paed HoO.	Paed Asst (assigned)

15.	Review the completeness of all the procedural steps and confirm the readiness of the document for transmission[1]. *Note: if required, obtain immediately further clarification from Paed Co.*	Paed HoO
16.	• Transmit electronically the final PDCO opinion merged with the summary report to the applicant immediately and proceed with the decision phase (SOP/H/3455) at the same time. • Obtain and save the record of document transmission and receipt (accessed) by the applicant. • Update the procedural timelines in PedRA. *Note: The final PDCO opinion becomes definitive immediately upon its adoption, hence the decision is due 10 calendar days afterwards.*	Paed Asst
	Continue to SOP/H/3455	

10. Records

All original documents are filed in the master file. Electronic records are saved in the appropriately labelled folders in DREAM and on N:\ drive.

[1] Completeness is indicated by labelling the document version in DREAM appropriately.