EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Paediatric investigation plan or a waiver from pre-submission to start of procedure		
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1. Purpose

This SOP describes the handling of an application for a paediatric investigation plan (PIP) or a waiver from the receipt of the letter of intent in pre-submission phase to the start of procedure.

2. Scope

This SOP applies to Paediatric Medicines Office in Product Development Scientific Support Department, Regulatory Affairs Office in Scientific and Regulatory Management 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).

Summary Report draft is generated by Business Intelligence (Oracle Fusion Middleware Online Documentation Library.

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

- 01 - Acknowledgment receipt
- 02 - Appointment of Rapp and Peer for info to applicant
- 03 - Validation issues
- 04 - Validity of PIP/waiver request not verified 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/3452	Paediatric investigation plan or a waiver from start of procedure to clock-stop or PDCO opinions
WIN/H/3459	Paediatric core master files and numbering

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 located at: 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

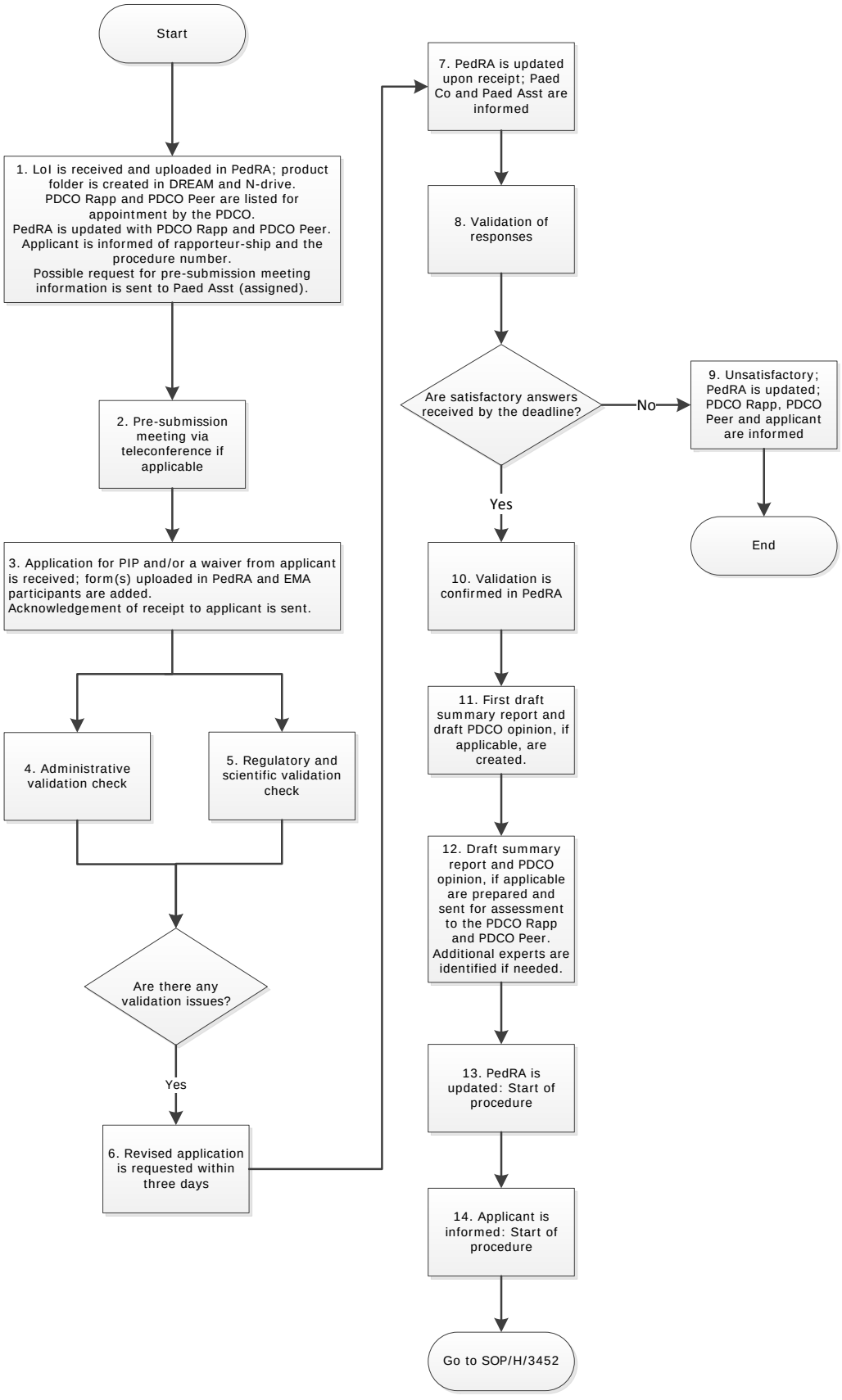
Roles and responsibilities of members and alternates, rapporteur and peer reviewers, experts and observers of the Paediatric Committee (PDCO) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004754.pdf

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

7. Definitions

D-DS-PME	Paediatric Medicines Office in Product Development Scientific Support Department in Human Medicines Research and Development Support Division
DREAM	Document records electronic archive management
EudraLink	The European medicines regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
LoI	Letter of intent
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 procedural assistant (in D-DS-PME)
Paed Asst (assigned)	Paediatric procedure assistant assigned to complete a specific task (assistant in D-DS-PME)
Paed Co	Paediatric coordinator (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 Paediatric Record Application (database)
RfM	PDCO's request for modifications to the initially submitted paediatric investigation plan

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



9. Procedure

Notes:

- *Declaration of interests 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 when available.*
- *All procedural timelines and application guidance are published on the EMA website.*

Step	Action	Responsibility
	Pre-submission	
1.	• Receive and upload LoI in PedRA to assign a procedure number – check existing product number - and create product folder in DREAM and N-drive. • List PDCO Rapp and PDCO Peer for appointment by the PDCO. • Update PedRA with names of PDCO Rapp and PDCO Peer. • Inform the applicant of rapporteur-ship and the procedure number. • In case of pre-submission meeting request is received, inform Paed Asst (assigned) *Note: Applicants are encouraged to send a LoI about 60 days before planned start of procedure in order to have procedure number allocated and PDCO Rapporteur and Peer reviewer appointed prior submission.*	Paed AA
2.	Organise pre-submission meeting via teleconference if applicable.	Paed Asst (assigned)
	Validation	
3.	• Receive application for PIP and/or a waiver from applicant and upload form(s) in PedRA, add EMA participants. • Send acknowledgement of receipt to applicant.	Paed AA
4.	Conduct validation check for administrative issues.	Paed AA
5.	Conduct validation check for regulatory and scientific issues; use "Validation issues" template as a checklist (PedRA).	Paed Co
	Are there any validation issues? If no, go to step 9. If yes, go to step 6.	
6.	Send validation issues to the applicant, requesting a revised application within three working days.	Paed Co

Step	Action	Responsibility
7.	On receipt of the revised application, upload the revised form(s) in PedRA, and inform Paed Co and Paed Asst.	Paed AA
8.	Continue the validation process by assessing the applicant's response.	Paed Co
	Are the answers to the validation issues satisfactory and received by the deadline? If no, go to step 9. If yes, go to step 10.	
9.	• The answers to the validation issues are unsatisfactory, or not received on time add "invalid" in PedRA. • Inform the PDCO Rapp, PDCO Peer and the applicant about the validation outcome. ***End of procedure.*** *Note:* *Only under exceptional circumstances, and with the agreement of the Paed HoO, an application can be suspended and re-started at a later date.*	Paed Co
	End of validation - Start of procedure	
10.	Add validity verified step in PedRA.	Paed Co
11.	Create the first draft summary report, and if applicable, the draft PDCO opinion, and forward it to the Paed Co.	Paed Asst
12.	• Prepare the draft summary report *and PDCO opinion, if applicable* and send for assessment to the PDCO Rapp and PDCO Peer. Highlight any commercially confidential information (e.g. references to non-public aspects of other applications). • Identify the need and, if agreed by PDCO, organise the involvement of any additional experts.	Paed Co
13.	Update procedural timelines in PedRA (start of procedure).	Paed AA
14.	Inform the applicant of the start of procedure at D1.	Paed Asst
	Continue to SOP/H/3452.	

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.