EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Compliance check of an agreed paediatric investigation plan		
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1. Purpose

This SOP describes the process of compliance check with fully or partially completed paediatric investigation plan (PIP), from the receipt of the request for compliance check to the transmission of the PDCO Compliance report with compliance check outcome letter and PDCO opinion if applicable.

2. Scope

This SOP applies to Paediatric Medicines Office in Product Development Scientific Support Department, Scientific Committees Secretariat in Committees and Inspections Department and Evaluation Procedures A-D Services in Procedure Management 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

Changes following audit comments and procedure improvement.

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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
- PDCO opinion on compliance check template, and
- <Year> <Q1-4> Timelines (EMA/690732/2015).
- Opinion template: Opinion on compliance +/-
- Compliance report with compliance check outcome letter

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

- 08 - Start of procedure- Compliance
- 14 – Summary report Day 30 – Compliance to applicant
- 21 - Outcome of compliance check

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
WIN/H/3516	Validation of initial MAAs and line extensions
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

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

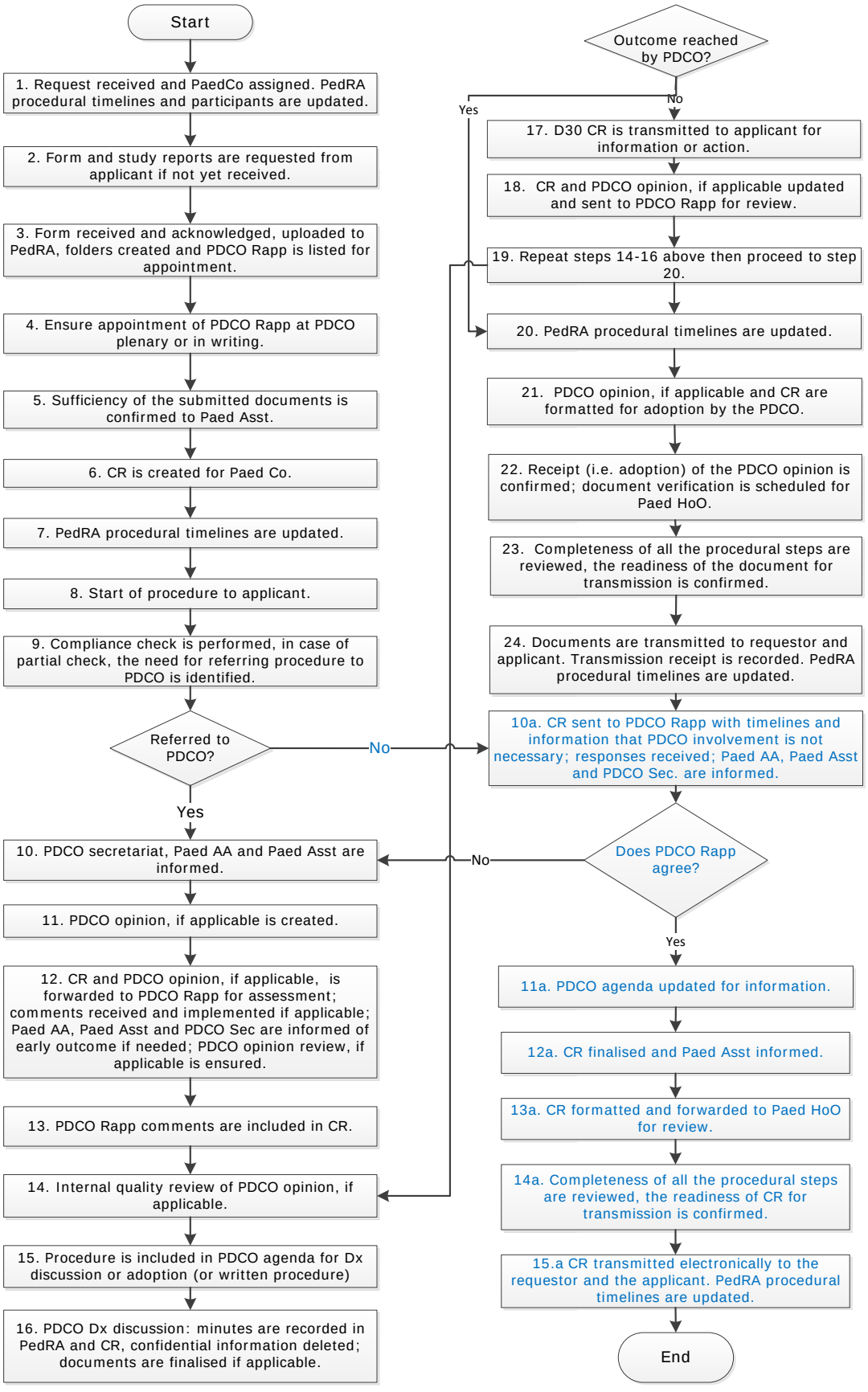
Roles and responsibilities of members and alternates, rapporteur and peer reviewers, experts and observers of the Paediatric Committee (PDCO)
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004754.pdf

Procedural advice
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000023.jsp&mid=WC0b01ac05800240cd

7. Definitions

CR	Compliance report with compliance check outcome letter (for partial compliance check)
D1	Start of procedure date
Dx	Discussion at upcoming PDCO meeting (Maximum 60 days procedure with 2 plenary discussions)
CHMP	Committee for Medicinal Products for Human Use
D-DS-PME	Paediatric Medicines Office in Product Development Scientific Support Department
DREAM	Document records electronic archive management
E-PM EP (A-D)	Evaluation Procedures A-D Services in Procedure Management Department
MAA	Marketing authorisation application
MMD	Managing Meeting Documents system
NCA	National competent authority
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 Rapp	PDCO Rapporteur
PDCO Sec	Secretariat of the PDCO
PDCO	Paediatric Committee
PedRA	Paediatric Record Application (database)

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.*
- *All meeting documents are linked to appropriate DREAM meeting folders by Paed Asst prior to meeting and regularly tabled in MMD by PDCO Sec.*
- *Compliance check is the verification whether the terms of a PIP have been adhered to. It is partial when one or more distinct measure(s) is/are checked; and full when all the measures included in a PIP are checked.*
- *CR is issued for partially completed PIP and PDCO opinion is adopted for fully completed PIP.*
- *Compliance check may be requested by the applicant, by the Agency, by the CHMP or by the NCA. In all cases a CR is completed and a rapporteur from PDCO is appointed although presentation and discussion at PDCO plenary may not be necessary for all partial compliance checks.*
- *Maximum length of compliance check procedure is 60 days. Length of procedure can be shortened or PDCO outcome can also be reached via written procedure if necessary.*

Step	Action	Responsibility
1.	• Receive compliance check request and ensure the assignment of Paed Co. • Update procedural timelines and participants in PedRA. *Note: If available, Paed Co should be the same as for the related procedure.*	Paed AA
2.	Ask the applicant to complete and send "Request for compliance check on an agreed paediatric investigation plan" form and study report(s), if not yet received.	Paed Co
3.	Receive and upload form in PedRA to assign a procedure number and create product folder in DREAM and N-drive. • Send acknowledgement of receipt to the requestor. • List PDCO Rapp for appointment by the PDCO. *Note: If available, PDCO Rapp should be the same as for the related procedure.*	Paed AA
4.	Ensure the appointment of PDCO Rapp at the upcoming PDCO plenary or in writing if necessary.	PDCO Sec
5.	Confirm the sufficiency of the submitted documents to Paed Asst.	Paed Co
6.	Create and forward CR to Paed Co.	Paed Asst

Step	Action	Responsibility
7.	Update procedural timelines in PedRA (start of procedure).	Paed AA
8.	Inform the applicant of the start of procedure at D1.	Paed Asst
9.	Perform the compliance check. For partial compliance check identify together with the PDCO Rapp if: • There is a need to refer for presentation and discussion at the PDCO plenary or • It is sufficient to send in writing for PDCO's information. *Note: Procedures must be referred for discussion and presentation at the PDCO plenary in case of full compliance check, possible negative outcome or need for scientific review.*	Paed Co
	Is there a need to refer the compliance check procedure for presentation and discussion at the PDCO plenary? • Yes, go to next step (10). • No, go to step 10a.	
10.	Inform PDCO Sec, Paed AA and Paed Asst accordingly including timelines.	PDCO Sec
11.	Create and forward draft PDCO opinion, if applicable, to Paed Co.	Paed Asst
12.	• Send CR and PDCO opinion, if applicable, for assessment by the PDCO Rapp. • Receive the CR and PDCO opinion, if applicable, with comments from the PDCO Rapp and forward to the Paed Asst if not in copy. • Inform Paed AA, Paed Asst and PDCO Sec if outcome (i.e. adoption) is expected at the upcoming PDCO discussion. • In case of full compliance check, implement comments into PDCO opinion and ensure that internal quality review can be performed.	Paed Co
13.	Include the PDCO Rapp assessment into CR.	Paed Asst
14.	In case of opinion, perform internal quality review of the PDCO opinion.[1]	Paed Co (Assigned)
15.	Include the procedure in the agenda for discussion or adoption at Dx at the upcoming PDCO plenary.	PDCO Sec
16.	• Participate in the Dx discussion during PDCO plenary. • Record the minutes of Dx discussion in PedRA and in the CR, delete any commercially confidential information. • Finalise the content of CR and PDCO opinion, if applicable.	Paed Co
	Has PDCO reached the outcome already at Dx discussion?	

Step	Action	Responsibility
	Yes, go to step 20 No, go to step 17.	
17.	Transmit CR (Dx) to applicant for information or action, as appropriate.	Paed Asst
18.	Update CR and PDCO opinion, if applicable and send it to the PDCO Rapp for review.	Paed Co
19.	Repeat steps 14-16 above then proceed to step 20.	
20.	Update procedural timelines in PedRA.	Paed AA
21.	Format the PDCO opinion, if applicable and CR for adoption by the PDCO.	Paed Asst
22.	In case of full compliance check, confirm the receipt (i.e. adoption) of the PDCO opinion. Schedule the verification of document for Paed HoO.	Paed Asst (assigned)
23.	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
24.	• Transmit CR (for partial check) or PDCO opinion merged with CR (for full check) electronically to the requestor and the applicant within ten calendar 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
	End of procedure	
10a	• Send CR containing partial compliance check to PDCO Rapp and inform them about: – timelines; – presentation and discussion at PDCO plenary are not considered necessary. • Receive the PDCO Rapp's response and inform, Paed AA, Paed Asst and PDCO Sec.	Paed Co
	Does PDCO Rapp agree? Yes, go to next step (11a). No, go back to step 10.	
11a	Update agenda partial compliance check procedure for information. *Note: This can be circulated to the PDCO in the pre-mail.*	PDCO Sec
12a	Finalise CR and inform Paed Asst.	Paed Co
13a	Format CR and forward to Paed HoO for review.	Paed Asst

Step	Action	Responsibility
14a	Review the completeness of all the procedural steps and confirm the readiness of CR for transmission. *Note: If required, obtain immediately further clarification from Paed Co.*	Paed HoO
15a	• Transmit CR electronically to the requestor and to the applicant. • Update the relevant PedRA procedural timelines.	Paed Asst
	End of procedure	

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