EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Rectifying errors in PDCO opinions and EMA decisions		
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1. Purpose

This SOP describes the tasks to be carried out in order to rectify an editorial or a content error in the PDCO opinion and an editorial error in the EMA decision pertaining to PDCO opinion.

Steps to be taken to rectify a content error in an EMA decision pertaining to PDCO opinion are not described in this SOP and will be individually designed by Legal Department.

2. Scope

This SOP applies to Paediatric Medicines Office in Product Development Scientific Support Department, Regulatory Affairs Office in Scientific and Regulatory Management Department, Legal Department, the Executive Director (Head of Division or Head of Department as per delegation of the Executive Director) and Scientific Committees Secretariat in Committees and Inspections Department.

3. Responsibilities

It is the responsibility of the Executive Director and the respective Head of Division, Head of Department and Head of Office in charge 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.

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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
- Correction / Corrigendum letter template
- Revision letter template
- Transmission slip corrigendum.

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

- 20 - Opinion to applicant
- 28 - Error to chairman and Rapp and Peer
- 29 - Error revision information to applicant
- 30 - Error correction or corrigendum to applicant.

6. Related documents

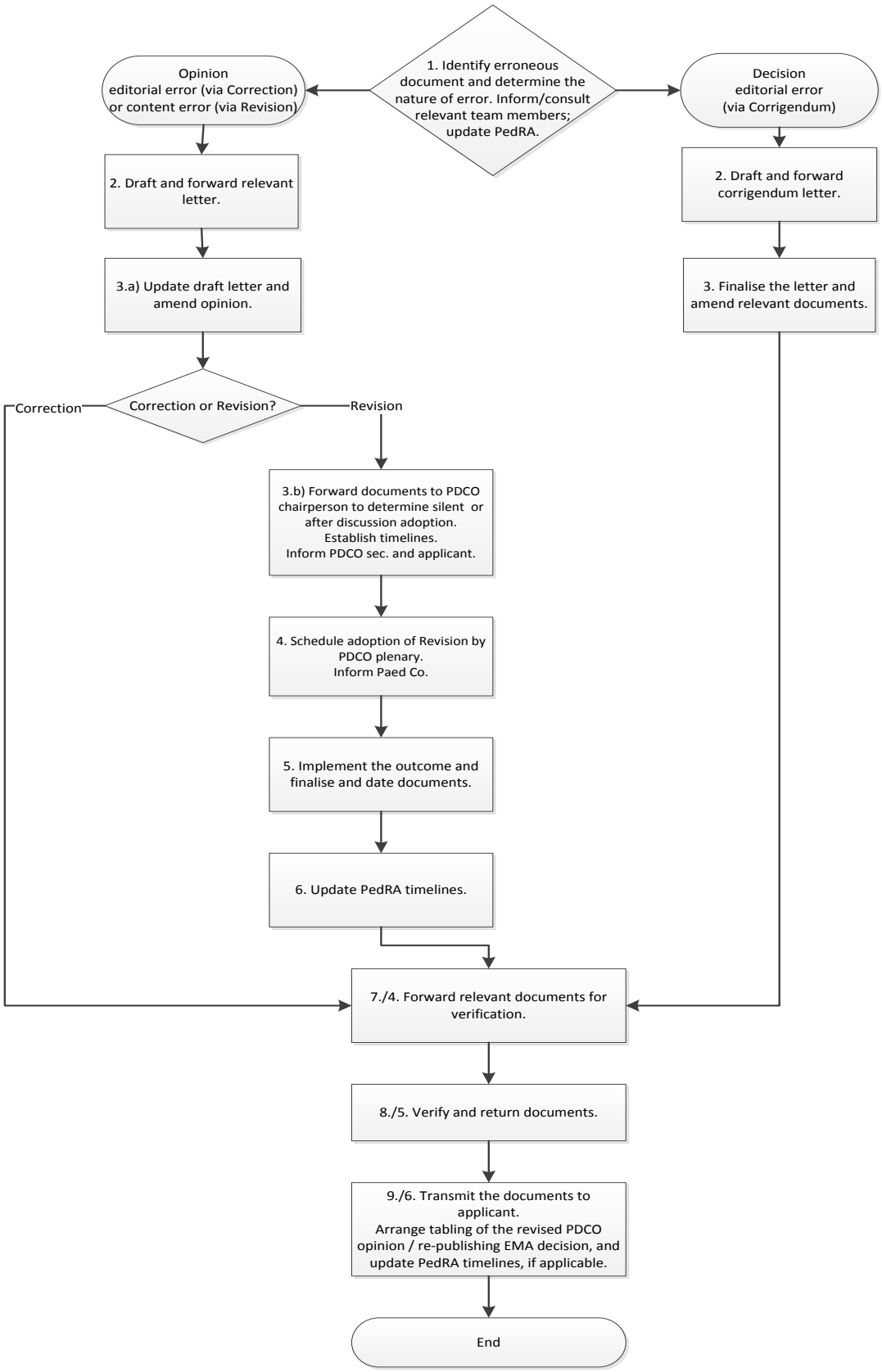
SOP/EMA/0040	Evaluation of conflicts of interests of experts for involvement in Agency activities
SOP/EMA/0101	Standard operating procedure for conducting checks for conflicts of interest when assigning medicinal products for human or veterinary use to a product / project team leader / member or project manager
SOP/H/3452	Paediatric investigation plan or a waiver from start of procedure to clock-stop or PDCO opinion
SOP/H/3453	Paediatric investigation plan from re-start of procedure to PDCO opinion
SOP/H/3454	Re-examination of Paediatric Committee opinions
SOP/H/3456	Compliance check of an agreed paediatric investigation plan
SOP/H/3457	Modification of an agreed paediatric investigation plan
SOP/H/3455	EMA decision-making process for decisions on Paediatric Committee opinions
WIN/H/3460	Review of product-specific or class waivers granted by the Paediatric Committee

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

7. Definitions

Editorial error:	An error that is typographical in nature or is the result of an editing mistake as evidenced by for example: the application distributed to all PDCO member states or summary report or PDCO opinion.
Content error:	An error that does not fall under the above definition of an editorial error.
Correction:	Procedure to rectify an **editorial** error in PDCO opinion **before** the adoption of EMA decision pertaining to the opinion. Adoption of the corrected document(s) by the PDCO is not required; date of the PDCO opinion and further timelines remain unchanged.
Revision:	Procedure to rectify a **content** error in PDCO opinion **before** the adoption of EMA decision pertaining to the opinion. Adoption of the revised opinion by the PDCO is required; date of the revised PDCO opinion will change correspondingly to the date of adoption by the PDCO.
Corrigendum:	For the purpose of this document this term is used to describe procedure to rectify an **editorial** (only) error in EMA decision (including in annexes and appendices). Date of the EMA decision and its annex remain unchanged.
AF-LD	Legal Department
D-DS-PME	Paediatric Medicines Office in Product Development Scientific Support Department
DREAM	Document records electronic archive management
E-SR-REA	Regulatory Affairs Office in Scientific and Regulatory Management Department
ED	Executive Director
Eudralink	The European medicines regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
MMD	Managing Meeting Documents system
Paed Asst	Paediatric procedure assistant in D-DS-PME
Paed Co	Paediatric coordinator (scientific officer in D-DS-PME)
Paed HoO	Head of Paediatric Medicines Office
PDCO Secr	Secretariat of the PDCO in Scientific Committees Secretariat in Committees and Inspections Department
PDCO	Paediatric Committee
PedRA	Paediatric Record Application (database)

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.*

Rectifying editorial or content error in a PDCO opinion including its appendix (summary report) before the adoption of EMA decision via Correction or Revision

Step	Action	Responsibility
1.	• Determine whether the nature of the error in PDCO opinion (before the adoption of EMA decision) is: – **editorial** - to be rectified via **Correction** OR – **content** - to be rectified via **Revision**. *Note: Consult with Paed HoO and classify as content error if in doubt.* • Add and describe the event in PedRA timelines (expected date). • Inform: – Paed Asst, providing clear instruction on which procedure to follow; and, in case of Revision: – E-SR-REA; – AF-LD.	Paed Co
2.	Using relevant template, draft and forward to Paed Co correction or revision letter. In case of Revision, link documents to appropriate folder in DREAM.	Paed Asst
3.	• Update the draft correction or revision letter. • Implement amendments into the PDCO opinion and **In case of correction:** • Record "Corr" next to the PDCO opinion document reference number; insert actual date of correction event in PedRA; • Go to step 6. **OR** **In case of revision:** • Record "Rev" next to the PDCO opinion document reference number.	Paed Co

Step	Action	Responsibility
	• Consult AF-LD and E-SR-REA to determine timelines of Revision. • Forward drafts revision letter and revised PDCO opinion to PDCO chairperson and obtain his/her decision whether the drafts are to be scheduled for PDCO discussion or silent adoption. • Request PDCO Sec to include the adoption of Revision and revised opinion in the next PDCO plenary agenda or via written procedure. • Inform: – Paed Asst and Paed AA; and – the applicant using the relevant PedRA template.	
4.	• Include the Revision in the PDCO plenary agenda or arrange written procedure. • Table the relevant linked documents in MMD. • In case of written procedure, inform Paed Co about the date and the outcome.	PDCO Secr
5.	• Implement outcome of the written procedure or the PDCO discussion and finalise the content of the summary report and revised PDCO opinion, date the PDCO opinion and revision letter accordingly to PDCO adoption (i.e. the date of adoption during PDCO plenary or of concluding the written procedure). • Inform Paed Asst.	Paed Co
6.	• Update PedRA procedural timelines with the actual date of correction or adoption of the revision and revised PDCO opinion, stating the date of the erroneous PDCO opinion in comment box of the event. • Format and forward the correction or revision letter to Paed HoO, together with the corrected or revised PDCO opinion.	Paed Asst
7.	Verify and return the documents Paed Asst.	Paed HoO
8.	• Process and transmit electronically the correction or revision letter and corrected or revised PDCO opinion to the applicant. • Obtain and save in DREAM the record of document transmission and receipt (access) by the applicant and, for revision update the relevant PedRA procedural timelines stating the transmission and receipt date of the erroneous PDCO opinion in comment box. • Ensure that the corrected or revised PDCO opinion is tabled in MMD.	Paed Asst
	End of procedure. *Continue to SOP/H/3455, once applicable.*	

Rectifying editorial error in an EMA decision including its annexes (i.e. definitive PDCO opinion and summary report) via Corrigendum

Step	Action	Responsibility
1.	• Confirm with AF-LD and E-SR-REA the **editorial** nature of the error. • Add and describe the relevant event in PedRA procedural timelines (expected date). • Inform: – Paed Asst; – Paed HoO.	Paed Co
2.	• Draft and forward the corrigendum letter to Paed Co.	Paed Asst
3.	• Finalise the draft corrigendum letter and amend the EMA decision including its annexes, leaving the dates of adoption of the EMA decision and its annexes unchanged. Record 'Corr' next to the EMA decision and annexes (if applicable) document reference number(s). • Inform Paed Asst.	Paed Co
4.	Create a transmission slip using template and format and forward the documents for verification.	Paed Asst
5.	Verify and, if applicable, forward the documents to the next person on the transmission slip. *Note: Last person on the transmission slip will return documents to Paed Asst.*	Paed HoO E-SR-REA AF-LD HoDIV[1] (by ED delegation)
6.	• Update decision for publishing after corrigendum; link the document to a dedicated DREAM folder. • Process the EMA decision with annexes after corrigendum and the corrigendum letter. • Transmit electronically the EMA decision with annexes, corrigendum letter and decision for publishing to applicant. • Obtain and save in DREAM the record of documents transmission and receipt (accessed) by the applicant; update the relevant PedRA procedural timeline (actual date). • Ensure the documents after corrigendum are tabled in MMD and published on the EMA website.	Paed Asst
	End of procedure.	

[1] The EMA decision signatory is included in the signature line only in case when the decision signature page is affected.

10. Records

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