EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: EMA decision-making process for decisions on Paediatric Committee opinions		
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1. Purpose

This SOP describes the tasks to be carried out to issue EMA decision following adoption of the Paediatric Committee opinion issued according to Regulation (EC) No 1901/2006[1].

2. Scope

This SOP concerns EMA decision on paediatric investigation plan (PIP), deferral, product-specific waiver, modification of an agreed PIP and class waiver.

It applies to the Executive Director, Head of Divisions, Head of Legal Department, Paediatric Medicines Office in Product Development Scientific Support Department and Online and Corporate Design Service in Communication Department.

3. Responsibilities

It is the responsibility of the Executive Director and the 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.

1 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

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4. Changes since last revision

Minor revision and update following current EMA organigram.

5. Documents needed for this SOP

Templates are located in relevant folder DREAM:

- PedRA procedural timelines and templates checklist
- Appropriate decisions templates and translations

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/3457	Modification of an agreed paediatric investigation plan
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

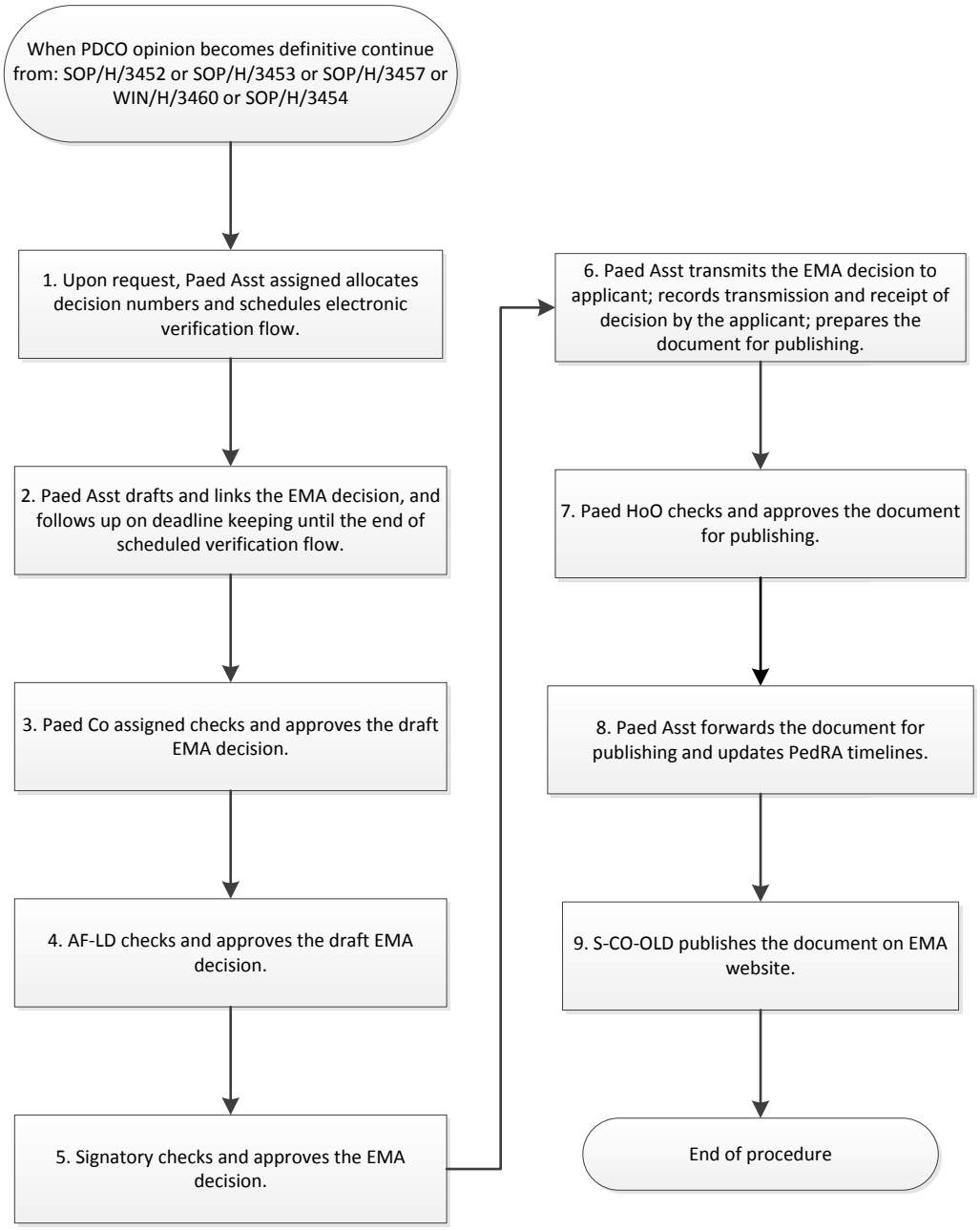
Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents (EMEA/45422/2006):
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004043.pdf

Related information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/pip_search.jsp&mid=WC0b01ac058001d129

7. Definitions

AF-LD	Legal Department
D-DS-PME	Paediatric Medicines Office in Product Development Scientific Support Department
DREAM	Document records electronic archive management
ED	Executive director of the European Medicines Agency
EudraLink	The European medicines regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
HoDiv	Head of Division
MMD	Managing meeting documents system
Paed Asst	Paediatric procedure assistant (in D-DS-PME)
Paed Asst (assigned)	Paediatric procedure assistant assigned to complete a specific task
Paed Co	Paediatric coordinator (scientific officer in D-DS-PME)
Paed Co (assigned)	Paediatric coordinator assigned to complete a specific task
Paed HoO	Head of Paediatric Medicines Office
PDCO	Paediatric Committee
PedRA	Paediatric Record Application (database)
PedRA template	Eudralink template available in Paediatric Record Application (database)
PIP	Paediatric investigation plan
S-CO-OLD	Online and Corporate Design Service in Communication Department

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; PedRA templates must be used, if available.*
- *All procedural timelines and application guidance are published on the EMA website.*
- *Decisions are tabled in MMD.*

Step	Action	Responsibility
	Continue from: • *SOP/H/3452 or SOP/H/3453 or SOP/H/3457 or WIN/H/3460 (if no re-examination of PDCO opinion was requested);* *or* • *SOP/H/3454 (if re-examination of PDCO opinion was requested).*	
1.	On request of Paed Asst (after receipt of PDCO opinion by applicant): • update the relevant procedural timelines in PedRA to assign decision number; • schedule the EMA decision electronic verification flow for HoO, AF-LD and HoDiv.	Paed Asst (assigned)
2.	• Draft the EMA decision using relevant template in English, and where requested by the applicant in the applicable EU language; complete the draft by merging with annex and appendix (PDCO opinion and summary report); link the document to a dedicated DREAM folder; confirm the step completion by labelling appropriately the document version in DREAM. *Note: If applicable, information for cross-referencing to other EMA decision(s) is to be requested from and provided by Paed Co.* • Follow up on the completion of the decision electronic verification flow within the scheduled deadlines; if needed, address any comments immediately.	Paed Asst

Step	Action	Responsibility
3.	By the deadline established in the decision electronic verification flow, check correctness, completeness and consistency of the draft EMA decision with PDCO opinion and summary report and approve; confirm the step completion by labelling appropriately the document version in DREAM. *Note: If amendment of the draft EMA decision is needed, notify Paed Asst by the deadline established in the scheduled decision electronic verification flow by labelling appropriately the document version in DREAM.*	Paed Co assigned (by Paed HoO delegation)
4.	By the deadline established in the decision electronic verification flow, perform the legal check of the draft EMA decision, and confirm the legitimacy by labelling appropriately the document version in DREAM. *Note: If amendment of the draft EMA decision is needed, notify Paed Asst by the deadline established in the scheduled decision electronic verification flow by labelling appropriately the document version in DREAM.*	AF-LD
5.	Within ten days of the PDCO opinion becoming definitive, check and sign-off the EMA decision by labelling appropriately the document version in DREAM. *Note: If amendment of the draft EMA decision is needed, notify Paed Asst by the deadline established in the scheduled decision electronic verification flow by labelling appropriately the document version in DREAM.*	HoDiv (by ED delegation)
6.	• Create and link decision for publishing (without confidential information) to a dedicated DREAM folder. • Process the EMA decision. • Transmit electronically the EMA decision 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 timelines.	Paed Asst
7.	Check and confirm the correctness of the EMA decision for publishing by labelling the document version in DREAM appropriately.	Paed Asst (assigned) (by HoO delegation)
8.	Process and forward the decision for publishing to S-CO-OLD; once available, update the relevant PedRA procedural timelines.	Paed Asst (assigned)
9.	Publish the decision on the EMA website	S-CO-OLD
	End of procedure.	

10. Records

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

The progress of decision electronic verification flow is recorded by labelling individual versions of the document in DREAM.