



Work instructions

Title: Review of granted paediatric product-specific and class waivers		
Applies to: Paediatric Medicines Office in Product Development Scientific Support Department in Human Medicines Research and Development Support Division		
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Lead Author	Approver	Effective Date: 15-Feb-2017
Name: Gunter Egger	Name: Ralph Bax	Review Date: 15-Feb-2020
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1. Changes since last revision

Changes following audit comments and procedure improvement.

2. Records

All records for class waivers are saved in DREAM:

Cabinets/02b. Administration of Scientific Meeting/PDCO - Administration/3. Other activities/05.
General topics/Other opinions adopted/List of Class Waivers

All records for product specific waivers are saved in DREAM in the appropriate product folder:

Cabinets/01. Evaluation of Medicines/H-P Paediatric Medicines

Documents needed for this WIN 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:

1. Opinion Template 2d - Review ex officio of the granted W (product specific)
2. Opinion Template 2e - Class Waiver on conditions - granting, review or revocation
3. Summary Report - Review of a granted Class Waiver



3. Related documents

SOP/H/3455 Decision-making process for Paediatric Committee opinions

SOP/H/3454 Re-examination of Paediatric Committee opinions

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/EMA/0040 Evaluation of conflicts of interests of experts for involvement in Agency activities - Evaluation of conflicts of interests of experts for involvement in Agency activities

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

4. Definitions

D30	First discussion at PDCO meeting
D60	Second discussion and adoption opinion at PDCO meeting
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
MMD	Managing meeting documents system
Paed AA	Paediatric administrative assistant (in D-DS-PME)
Paed Asst	Paediatric assistant assigned for class waiver procedures (in D-DS-PME)
Paed Co	Paediatric coordinator assigned for class waiver procedures (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 Paediatric Committee
 PedRA Paediatric Record Application (database)

5. 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.
- Procedures for reviewing a granted product-specific waiver and for reviewing a class waiver are similar but different templates are used for opinions.
- New summary report will be generated for class waiver; initial summary report will be updated for product-specific waiver.
- PDCO will adopt an opinion only in case a waiver is revoked.
- In case of major change in the class waiver a public consultation is considered.
- Time schedule of the procedure shall be planned by PDCO Rapporteur, PDCO Peer Reviewer.

Step	Action	Responsibility
1.	When a review is requested (e.g. by PDCO, applicant, general public) either for a granted product-specific or a class waiver, appoint and inform Paed Co. Note: If available, appoint the same Paed Co as for initial procedure for product-specific waiver.	Paed HoO
2.	<ul style="list-style-type: none"> • Inform PDCO Sec; Paed AA and Paed Asst of the review request. For review of product-specific waiver only: Identify all applicants (using PedRA) concerned by the revision and inform them of the start of procedure of the review.	Paed Co
3.	Ensure the appointment of PDCO Rapp and PDCO Peer at the next PDCO plenary or in writing.	PDCO Sec
4.	Update procedural timelines in PedRA (for product specific waiver).	Paed AA
5.	Create new summary report (for class waiver) or update existing summary report (for product-specific waiver); prepare draft opinion and forward to Paed Co.	Paed Asst

Step	Action	Responsibility
6.	<ul style="list-style-type: none"> • Prepare draft summary report and PDCO opinion and send for assessment to PDCO Rapp and PDCO Peer. • Implement comments into draft documents if applicable. • Identify the need and, if agreed by PDCO, organise the involvement of additional experts. • If applicable, ensure internal quality review of draft opinion. 	Paed Co
7.	<ul style="list-style-type: none"> • Include the procedure in the agenda for discussion or adoption at the upcoming PDCO plenary. 	PDCO Sec
8.	<ul style="list-style-type: none"> • Participate in PDCO discussion. • Record the minutes in PedRA (for product-specific waiver) and in the draft summary report. <p><i>Note: Ensure discussion(s) at the next PDCO meeting(s) until PDCO conclusion is reached.</i></p>	Paed Co
9.	<p>Is the product-specific or class waiver revised or revoked?</p> <ul style="list-style-type: none"> • No: opinion is not needed. <i>End of procedure.</i> • Yes: opinion is adopted refer to opinion steps in SOP/H/3453 and decision for class waivers in SOP/H/3455. 	

Note: Class waiver summary report is also published once the decision is issued.