EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Research and Development Support Division

Re-examination procedure of paediatric investigation plan and/or waiver opinions by the Paediatric Committee (PDCO)

Legal Basis

In accordance with Article 25 of Regulation (EC) No 1901/2006 as amended, the EMA shall transmit, within 10 days of its receipt, the opinion of the Paediatric Committee to the applicant. Within 30 days following receipt of the opinion of the Paediatric Committee, the applicant may submit to the Agency a written request, citing detailed grounds, for a re-examination of the opinion.

Within 30 days following receipt of a request for re-examination, the Paediatric Committee, having appointed a new rapporteur, shall issue a new opinion confirming or revising its previous opinion. The rapporteur shall be able to question the applicant directly. The applicant may also offer to be questioned. The rapporteur shall inform the Paediatric Committee without delay in writing about details of contacts with the applicant. The opinion shall be duly reasoned and a statement of reasons for the conclusion reached shall be annexed to the new opinion, which shall become definite.

Re-examination procedure

Upon adoption of an opinion on a paediatric investigation plan and/or waiver, the EMA will forward the opinion to the applicant together with a copy of the PDCO Summary Report.

In order to facilitate planning, it is recommended that the person authorised to communicate with the EMA gives written notice, by email to paediatrics@ema.europa.eu, of any intent to request the re-examination of the opinion within 10 days of receipt of the opinion (date of mail delivery record).

In case re-examination is requested, the applicant should submit detailed grounds for re-examination within 30 days of receipt of the opinion to the EMA as PDF and Word documents.

The EMA strongly recommends using the eSubmission Gateway or the eSubmission Web Client as the submission method. More information on how to register and connect to the Gateway / Web Client can be found in the eSubmission website and detailed information on the required naming conventions and file formats can be found in European Medicines Agency eSubmission Gateway.

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The Agency will still accept applications sent on CD or DVD accompanied by a cover letter. Applications by Eudralink, to paediatrics@ema.europa.eu, will be accepted to meet the submission deadline; however, they should be followed by the CD or DVD shortly after.

Please indicate the Agency's procedure number (PIP number) clearly on the cover letter and on the CD or DVD.

The grounds for the re-examination should be based only on the original information and scientific data provided in the application for a PIP and/or waiver and/or request for modification which were previously available to the PDCO and on which the initial opinion is based. This may include new analysis of the same data, or a compromise proposal, e.g. minor protocol amendments to a previously proposed study. Significant changes to the previous plan cannot be part of the re-examination process.

In all cases, the EMA will refer the request and grounds for re-examination to the PDCO. The PDCO will appoint a new rapporteur and a new peer reviewer for the re-examination procedure. The PDCO may involve, if necessary, additional experts. The paediatric co-ordinator will remain the same for the re-examination.

A teleconference may be held with the applicant, the newly appointed rapporteur and the peer reviewer, the EMA and experts (if appointed) immediately after their appointment.

The summary report will be updated on the basis of the assessment of the grounds for re-examination by the paediatric co-ordinator followed by the rapporteur and peer reviewer.

In the frame of the re-examination procedure, the applicant may be heard by the rapporteur and peer reviewer directly. The EMA should be systematically involved. The Paediatric Committee and the EMA should be informed in writing about the details of any contact with the applicant.

The applicant will receive the draft revised summary report including comments of the paediatric co-ordinator, the rapporteur and peer-reviewer around Day 20 for information only.

The applicant may be invited to an oral explanation in front of the PDCO during the re-examination procedure.

Where possible, the expert(s) involved in the application will be invited to attend the PDCO discussion.

The PDCO, having reviewed the detailed grounds for re-examination and having heard the oral explanation of the applicant, if applicable, will consider whether its opinion should be revised and will adopt a final PDCO opinion by Day 30.

However, as the end of the 30-day period may not coincide with a PDCO meeting, there may be no opportunity for oral explanation in front of the PDCO once the grounds have been fully assessed, and the PDCO opinion will be adopted by a written procedure only. To allow for a possible oral explanation, the applicant might consider requesting the matter to be discussed and the opinion adopted at the following PDCO meeting.

In case of withdrawal of the re-examination request by the applicant, the previous opinion will become final.

The opinion, annexes and appendix (summary report) will be notified to the contact person authorised by the applicant.

The decision of the EMA will be adopted within 10 days of receipt of the final opinion.

The decision of the EMA will be made public according to the rules of transparency.