EMA/241572/2025

Human Medicines Division

Version 1

Additional information

Applicant’s clarifications following Paediatric Committee (PDCO) discussions or re-discussions

<Active substance(s)>

<Case number> - Include case number before uploading this document (e.g. EMA/PE/0000123456)

When the summary report is sent after each discussion not involving a clock-stop, under “Paediatric Committee discussion” a request for clarification or further question(s) to be addressed by the applicant may be present.

**If there is such an explicit request,** the submission will be reopened in the IRIS portal so that you can upload a file with additional information. The response should be in Word (.docx) format, named: "Additional information". Any other documents that were not requested may not be accepted.

The requested additional information must be provided within the time frame indicated in the request, and using this template.

If there is no such explicit request from the PDCO, additional information may not be accepted or taken into account.

1. Clarifications

Provide responses to the questions including justification where clarification is needed.

You may add subtitles and supporting references if not previously submitted.

<Text>

For EMA use only (do not amend or delete)

Comments

|  |
| --- |
| **EMA Scientific Officer:**  <Text>  **PDCO Rapporteur:**  <Text>  **PDCO Peer Reviewer:**  <Text> |