EMA/241568/2025

Human Medicines Division

Version 1

Response to Paediatric Committee request for supplementary information and modification of proposed PIP (RSI)

Re-submission following clock-stop

<Active substance(s)>

<Case number> - Include case number before uploading this document (e.g. EMA/PE/0000123456) Please use this template for your submission **only** **after clock-stop**.

Name your file as “Response to PDCO RSI”

**Do not delete the comment boxes or modify the formatting/style of the template and retain existing fonts and headings.**

Note: RSI is generally adopted at Day 60 followed by the clock-stop. It applies to PIPs only and was previously referred to as “RfM”.

This change was introduced to align terminology with the Regulation and the IRIS system.

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| Text boxes with borders in this document are for **EMA use only**. **Do not delete or insert any text** within these boxes. |

Glossary

EMA - European Medicines Agency

PDCO - Paediatric Committee

PIP – paediatric investigation plan

RSI - Request for supplementary information and modification of proposed PIP, previously known as request for modification (“RfM”)

Reference

[Paediatric Regulation](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1901) Article 17.2

*“Within the 60-day period referred to in paragraph 1, the Paediatric Committee may request the applicant to propose modifications to the plan, in which case the time-limit referred to in paragraph 1 for the adoption of the final opinion shall be extended for a maximum of 60 days. In such cases, the applicant or the Paediatric Committee may request an additional meeting during this period. The time-limit shall be suspended until such time as the supplementary information requested has been provided.”*

Applicant’s response to PDCO request for supplementary information and modification of proposed PIP (RSI) - following clock-stop

Introduce section titles where applicable as presented in the received Summary report and list all the issues, followed by the responses (add responses as needed).

Waiver

PIP

*Quality*

*Non-clinical*

*Clinical*

*Modelling and Simulation, Extrapolation and Other studies*

Deferral(s) and timelines

PDCO request 1

<Text>

**Applicant’s response 1**

<Text>

Comments

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

PDCO request 2

<Text>

**Applicant’s response 2**

<Text>

Comments

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

PDCO request 3

<Text>

**Applicant’s response 3**

<Text>

Comments

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

For EMA use only (do not amend or delete)

1. Procedural information following clock-stop

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| <The assessment team for this procedure has not changed after clock-stop.>  ***OR***  <The assessment team for this procedure has changed after clock-stop as per below:  **EMA Scientific Officer:** <name>  **PDCO Rapporteur:** <name>  **PDCO Peer Reviewer:** <name>  **Additional expert:** <name>> |

1. Paediatric Committee (PDCO) – Re-discussion

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| In MONTH YEAR, the assessment team presented the applicant's revised proposal, which was reviewed by the PDCO.  The following points were highlighted:  Brief summary of the points raised in RFM and discussion on unresolved issues.  <The applicant is not required to address any of the issues at this stage and an opinion will be adopted at the next PDCO plenary meeting.>  **OR**  <The Committee concurred that the following issues would prevent them supporting the proposed plan:   * Text * Text>   <Should the applicant wish to comment on the points above, additional information will be taken into account if submitted no later than DATE.> |

Additional information received from applicant following Paediatric Committee (PDCO) – Re-discussion

Only in case clarification was requested after PDCO re-discussion, EMA may insert responses received from applicant in this report.

<Not applicable>

Comments

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

1. Feedback from other EMA committees, working parties or operational expert groups (OEGs)

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| --- |
| <No comments have been requested from other EMA committees, working parties or operational expert groups.>  <In MONTH YEAR Name of committee, working group, OEG did not identify any outstanding issues.>  <In MONTH YEAR Name of committee, working group, OEG provided comments on the following issues:   * Text> |