

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decisionⁱ

Actives substances(s): Reparixin

Latest Decision number(s): 1) P/0210/2022

Corresponding PIP number(s): 1) EMEA-001693-PIP03-21

If the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

Please note that development of the medicinal product above in the following **condition(s)/indication(s)**:

Treatment of coronavirus disease 2019 (COVID-19)

X has been discontinued

for the following reason(s): (tick all that apply)

X (possible) lack of efficacy in adults

☐ (possible) lack of efficacy in children

☐ (possible) unsatisfactory safety profile in adults

☐ (possible) unsatisfactory safety profile in children

☐ commercial reasons (please specify:)

☐ manufacturing / quality problems

☐ other regulatory action (please specify:)

☐ other reason (please specify:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation:

The Paediatric Investigation Plan and a deferral (EMA-001693-PIP03-21) on Reparixin (oral formulation) for the Treatment of coronavirus disease 2019 (COVID-19) in paediatric patients aged from birth to less than 18 years of age would be initiated, with prior agreement with PDCO, following completion of the safety and efficacy studies in adults. In this regard, the Phase 3, placebo-controlled study in adults (REP0321) (Study 6 in the PIP) with oral Reparixin to evaluate pharmacokinetic, pharmacodynamic (inflammatory status), efficacy and safety data was run to support extrapolation of efficacy for patients below 18 years of age. The interim analysis of the first 250 patients of REP0321 study met the pre-specified futility criteria for the primary efficacy endpoint. Following the DMC's recommendation, Dompé farmaceutici S.p.A. terminated the study early for futility, with no safety concerns identified. The results of study REP0321 have been published on the EudraCT portal. Following the early termination of the study due to futility, the Paediatric Investigation Plan has been suspended, no paediatric studies have been initiated, and the project has been removed from the development pipeline.

Name and signature of the PIP contact point:

Date: 20/03/2026

Contact for inquiries from interested parties:

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ⁱ This form will be published to the corresponding decision available on the website of the European Medicines Agency.