

# Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision<sup>i</sup>

Actives substances(s): trazodone (hydrochloride)

Latest Decision number(s): 1) P/0396/2017

Corresponding PIP number(s): 1) EMEA-002142-PIP01-17

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 insomnia

has been discontinued

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

(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 PIP discontinuation is connected to the decision to proceed with the anticipated EoT notification for the study 4 "Multi-Centre, randomised, single blind, single and repeated doses PK/PD study" due to the not fully encouraging results of the interim analysis performed with regards to development continuation to whom it concerns mainly:

- the high variability in PK parameters observed in all age groups
- the considerable dispersion of data observed (individual variability in the study population was greater than that observed in adult population)
- the not evident correspondence between administered dose, exposure achieved in individual subjects and PKPD parameters observed

Based on these interim results, to achieve the same exposure as in adults, it would be necessary to increase the dose without evidence that this would lead to a substantial increase in efficacy and with potential unsatisfactory safety profile in the investigated paediatric population.

Considering the above, it was decided to prematurely close the trial and consequently to discontinue the PIP.

Date: 19 January 2026

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