

To:

Head of Paediatric Medicines  
European Medicines Agency

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

Actives substances(s): Metformin (hydrochloride)

Invented name: n/a

Latest Decision number(s): 1) P/0244/2014

Corresponding PIP number(s): 1) EMEA-001352-PIP01-12-M01

Date of initial marketing authorisation granted: no application for MA was ever submitted

Date of authorisation of new indication, pharmaceutical form or route of administration: n/a

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

Treatment of polycystic ovary syndrom (PCOS)

has been discontinued

has been suspended/put on long-term hold (with possible re-start at a later time)

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: wide and inexpensive availability of API; even if the product is registered under a PUMA, it could only be marketed at a financial loss due to the limited appeal of the PUMA concept, as national healthcare systems place different values on it and the exclusivity incentive has little or no value due to reimbursement issues (20150918 Response to EC )

manufacturing / quality problems

other regulatory action (please specify: ) (e.g. suspension, revocation of M.A.)

other reason (please specify: )

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

with the termination of the financial support under FP7-Health2013-Innovation-1 in 2015, also the project was terminated. A clinical study protocol was discussed with the FDA (IND), but since it was rejected resp. a Clinical Hold letter issued, no trial was ever started.

Please note that 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 to the PIP in question:

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.

Name and signature of the ~~PIP~~-contact point: Signature on file

Date: 7 September 2023

Contact for inquiries from interested parties: n/a

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