

To:

Head of Paediatric Medicines
European Medicines Agency
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Cadazolid

Invented name:

Latest Decision number(s): 1) P/0186/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001108-PIP02-15 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of Clostridium difficile infection

- 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:)
 manufacturing / quality problems
 other regulatory action (please specify:) (e.g. suspension, revocation of M.A.)
 other reason (please specify: decision not to file)

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

Company decision has been made to discontinue cadazolid development in the Treatment of Clostridium difficile infection. Cadazolid has never been registered in the EU Member States or any country in the EEA.

Name and signature of the PIP contact point: Mian Saeed

Date: 09 May 2018

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