To:
Head of Paediatric Medicines
European Medicines Agency
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London E14 4HB
United Kingdom
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Doripenem monohydrate
Invented name: Doribax

Latest Decision number(s): 1) P/0071/2012 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000015-PIP01-07-M04 2) EMEA- 3) EMEA- 4) EMEA-

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

☒ 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: withdrawal of marketing authorisation) *(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:
Following a letter from the MAH, Janssen-Cilag International N.V. dated 6 July 2014 notifying the European Commission of their intention to voluntarily withdraw the product in the EU for commercial reasons, the European Commission withdrew the marketing authorisation on 31 July 2014. Subsequently the development of Doribax as per the agreed paediatric investigational plan (PIP) has been discontinued. Therefore the withdrawal of the PIP for Doribax is requested.

Name and signature of the PIP contact point: Ming Ewe

Date:

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