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): Deleobuvir
Invented name: n/a

Latest Decision number(s): 1) P/0240/2013

Corresponding PIP number(s): 1) EMEA-001389-PIP01-12

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Treatment of chronic viral hepatitis C

☒ 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: The Phase III data in adults are below expectations and inferior to those recently presented by other companies; see description.)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:
Following an assessment of the blinded Phase III trial patient disposition data from HCVerso 1 and 2 for the combination of deleobuvir, faldaprevir and ribavirin, Boehringer Ingelheim has decided to halt further development of deleobuvir containing hepatitis C regimens.
Compared to other therapies in development, the combination showed a higher rate of premature discontinuations which may result in a lower efficacy rate than anticipated. Boehringer Ingelheim has concluded that the expected therapeutic value of the deleobuvir containing regimen would not justify further development.

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

Date: 21 February 2014

Contact for inquiries from interested parties:

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