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): vorapaxar sulphate

Invented name: Zontivity

Latest Decision number(s): 1) P/0131/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000778-PIP02-12-M01 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of arterial thromboembolism

☒ 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: Zontivity has never been marketed in the European Union Member States or any countries in the European Economic Area and the Marketing Authorisation of Zontivity has been withdrawn in the European Union as well as Iceland, Norway and Liechtenstein.)

☐ 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:

Discontinuation of PIP EMEA-000778-PIP02-12 M01 founded in the notification to EMA (dated 17-May-2017) and to the Commission (dated 18-May-2017) declaring its intention to withdraw the MA of Zontivity. The MA withdrawal has been approved on 23 June 2017.

Name and signature of the PIP contact point: Ann Debbaudt

Date: 1st August 2017

Contact for inquiries from interested parties: Merck Sharp & Dohme Europe

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