To:

Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
London E14 5EU
United Kingdom
paediatrics@ema.europa.eu

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

Actives substances(s): Betrixaban

Invented name: Dexxience

Latest Decision number(s): 1) P/0168/2018 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001834-PIP02-16-M01 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of venous 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:)

☐ manufacturing / quality problems

☒ other regulatory action (please specify: refusal to grant the marketing authorization) (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:

The CHMP issued a negative opinion recommending the refusal of marketing authorization applicable for betrixaban.

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

Date: 24 April 2019

Contact for inquiries from interested parties: Portola Netherlands B.V.

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