

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): human fibrinogen / human thrombin

Invented name: RAPLIXA

Latest Decision number(s): 1) P/0276/2017 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001340-PIP01-12 2) EMEA- 3) EMEA- 4)
EMEA-

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

Treatment of haemorrhage resulting from a surgical procedure

☒ 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☒ commercial reasons (please specify: Marketing Authorisation has been withdrawn in the EEA)

☐ 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:

The Marketing Authorisation for RAPLIXA has been withdrawn in the EEA. The product has not and will not be marketed in Europe.

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

Date: 20 February 2018