

To:

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

Actives substances(s): Thrombin alfa

Invented name: RECOTHROM

Latest Decision number(s): 1) P/62/2008 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000163-PIP01-07 2) EMEA- 3) EMEA- 4)
EMEA-

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

Haemorrhage complicating 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:)

☐ 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:

According to the agreed PIP, a study of thrombin alfa with the paediatric population was to be started only after a positive benefit-risk relationship had been established in adults.

However, the marketing authorization application for Recothrom (EMEA/H/C/001063) was withdrawn in December 2009 in view of the CHMP's concerns on the efficacy of using thrombin alfa in adults for supportive treatment in surgery for improvement of haemostasis.

Since no positive benefit-risk relationship was established for thrombin alfa in adults, the paediatric study was not started and its completion by January 2012 as per the agreed PIP was not possible.

Name and signature of the PIP contact point: Juergen Weber

Date: 15.12.2017

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