Bayer HealthCare
Bayer Schering Pharma

Dr Eric Abadie
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11 December 2009

Withdrawal of the Marketing Authorization Application for Recothrom

EMEA Procedure No.	**EMEA/H/C/001063**
Invented Name:	**RECOTHROM**
INN:	**thrombin alfa**
Strength:	**1,000IU/ml**

Dear Dr Abadie,

We would like to inform you that, at this point in time, Bayer Schering Pharma has taken the decision to withdraw the application for Marketing Authorisation of RECOTHROM (thrombin alfa), 1,000 IU/ml, which was intended to be used for the supportive treatment in surgery for improvement of haemostasis where standard surgical techniques are insufficient.

The withdrawal is based on the following reason:

- Concerns raised by the CHMP regarding the choice of study population for the label in general surgery as well as the choice of comparator relative to the CHMP fibrin sealant guideline.

At this time there are no ongoing clinical trials with thrombin alfa in Europe sponsored by Bayer Schering Pharma.

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Bayer Schering Pharma reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Bayer Schering Pharma agrees for this letter to be published on the EMEA website.

Yours sincerely,

[redacted]