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Press Office

Press release

Bayer Schering Pharma withdraws its marketing authorisation application for Recothrom (thrombin alfa)

The European Medicines Agency has been formally notified by Bayer Schering Pharma of its decision to withdraw its application for a centralised marketing authorisation for the medicine Recothrom (thrombin alfa) 1,000 IU/ml.

Recothrom was expected to be used as supportive treatment in surgery to improve haemostasis where standard surgical techniques are insufficient.

The application for the marketing authorisation for Recothrom was submitted to the Agency on 29 August 2008. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of the application was based on the concerns raised by the Committee 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.

More information about Recothrom and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 14-17 December 2009.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. The CHMP's 'Guideline on the clinical investigation of plasma derived fibrin sealant/haemostatic products (CPMP/BPWG/1089/00)' is available here: http://www.emea.europa.eu/pdfs/human/bpwg/108900en.pdf
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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