

28 May 2010
EMA/342273/2010 corr.*
Press Office

Press release

Wyeth Europa Limited withdraws its marketing authorisation application for Brilence

The European Medicines Agency has been formally notified by Wyeth Europa Limited of its decision to withdraw its duplicate application for a centralised marketing authorisation for the medicine Brilence (bazedoxifene), 20 mg film-coated tablets.

This medicine was intended to be used for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

The application for the marketing authorisation for Brilence was submitted to the Agency on 2 October 2009. At the time of 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 reason for the withdrawal of the application was that no co-marketing partner had been identified prior to the CHMP opinion.

More information about Brilence 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 21-24 June 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. 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.

* The dosage has been corrected from 200 mg to 20 mg.

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu