European Medicines Agency
Press office

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PRESS RELEASE
Wyeth Europa Ltd withdraws its marketing authorisation application for Pristiqs (desvenlafaxine)

The European Medicines Agency (EMEA) has been formally notified by Wyeth Europa Ltd of its decision to withdraw the application for a centralised marketing authorisation for the medicine Pristiqs (desvenlafaxine) 50mg and 100mg prolonged release tablets.

Pristiqs was expected to be used for the treatment of vasomotor symptoms associated with menopause.

The application for marketing authorisation for Pristiqs was submitted to the EMEA on 4 October 2006. 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 Pristiqs was based on its plans to conduct additional clinical studies that would address the CHMP's questions regarding the benefit-risk profile of Pristiqs as a treatment for vasomotor symptoms.

More information about Pristiqs 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 EMEA website in due course.

-- ENDS --

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 EMEA, can be found on the EMEA website: www.emea.europa.eu

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