13 January 2010
EMA/23476/2010
Press Office

Press release

Wyeth Consumer Healthcare withdraws its marketing authorisation application for Ibuprofen/Diphenhydramine Hydrochloride Wyeth

The European Medicines Agency has been formally notified by Wyeth Consumer Healthcare of its decision to withdraw its application for a centralised marketing authorisation for the medicine Ibuprofen/Diphenhydramine Hydrochloride Wyeth 200 mg/25 mg soft capsules.

This medicine was intended to be used for the short-term treatment of mild to moderate pain in adults who experience sleeplessness as a result of the pain.

The application for the marketing authorisation for Ibuprofen/Diphenhydramine Hydrochloride Wyeth was submitted to the Agency on 4 December 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 its decision to withdraw the application was based on CHMP's view that the data provided do not allow the Committee to conclude on a positive benefit-risk balance.

More information about Ibuprofen/Diphenhydramine Hydrochloride Wyeth 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 18-21 January 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

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