European Medicines Agency
Press office

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PRESS RELEASE
Sanofi-Aventis withdraws marketing authorisation application for MULTAQ

The European Medicines Agency has been formally notified by Sanofi-Aventis of their decision to withdraw the application for a centralised marketing authorisation for the medicinal product MULTAQ.

The indication applied was for rhythm and rate control in patients with atrial fibrillation or atrial flutter (abnormalities of the heartbeat), to maintain normal sinus rhythm or to decrease ventricular rate.

The application for marketing authorisation for MULTAQ was submitted to the EMEA on 20 July 2005. 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 withdrawal letter, the company stated that the withdrawal of MULTAQ was due to the fact that the additional clinical data requested by the CHMP cannot be provided within the timeframe of the current procedure.

More information about MULTAQ and the current 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, after the next meeting of the CHMP on 18-21 September 2006.

--ENDS--

NOTES

1. The active substance of MULTAQ is dronedarone hydrochloride.
2. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu

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