EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency reviews cardiovascular risk of Multaq

Ongoing benefit-risk assessment broadened

The European Medicines Agency (EMA) is reviewing the cardiovascular risk of the anti-arrhythmic medicine Multaq (dronedarone), from Sanofi Aventis. This follows the company's announcement on 7 July 2011 of its discontinuation of the PALLAS study, because of the occurrence of severe cardiovascular events in some patients taking Multaq.

In the PALLAS study Multaq was being investigated in patients over 65 years of age with permanent atrial fibrillation. The patient population being studied in the PALLAS study is different from the population for which Multaq is currently approved, which are patients who currently have or have had non-permanent atrial fibrillation. The study was carried out as part of the ongoing development programme for Multaq. At the time the study was stopped 3,149 patients were enrolled.

The study was looking at the rate of major cardiovascular events (stroke or myocardial infarction) or hospitalisations due to cardiovascular events, or death. It found a higher rate of events and hospitalisations with Multaq when compared with placebo.

The Agency's Committee for Medicinal Products for Human Use (CHMP) started a review in January 2011 of the overall benefit-risk balance of Multaq following reports of severe liver injury. The scope of this review has now been extended to also assess new information from the PALLAS study and the CHMP will determine the need for any further action at its next meeting of 18 - 21 July 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Multaq has been authorised in the EU since November 2009. More information about Multaq can be found in its European Public Assessment Report (EPAR) on the Agency's website.
3. The review of Multaq is being conducted in the context of a formal review under Article 20 of Regulation (EC) No 726/2004, initiated by the European Commission on 21 January 2011.

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4. On 8 July 2011 the European Commission asked the Agency to broaden this review to include also data from the Pallas study.

5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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