European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 September 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
MULTAQ

International Non-proprietary Name (INN): ***dronedarone***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending granting a marketing authorisation for the medicinal product Multaq 400 mg film-coated tablet indicated in adult clinically stable patients with history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate (see section 5.1).

The active substance of Multaq is dronedarone an antiarrhythmic medicinal product (ATC code: not yet assigned). Dronedarone has electrophysiological properties belonging to all four Vaughan-Williams classes. Dronedarone is a multi-channel blocker inhibiting the potassium currents (including IK (Ach), IKur, IKr, IKs) and thus prolonging cardiac action potential and refractory periods (Class III). It also inhibits the sodium currents (Class Ib) and the calcium currents (Class IV). It non-competitively antagonises adrenergic activities (Class II).

The benefit with dronedarone is its antiarrhythmic (rhythm and rate control) properties in patients with atrial fibrillation. It has been shown to decrease the risk of atrial fibrillation-related hospitalisations. The most common adverse reactions are diarrhoea, nausea and vomiting, fatigue and asthenia.
A pharmacovigilance plan for Multaq, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: MULTAQ is indicated in adult clinically stable patients with history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate (see section 5.1).

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.
The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Multaq and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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