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Press Office

Press release

European Medicines Agency updates on ongoing benefit-risk review of Multaq

Prescribers reminded to follow current recommendations; further advice expected in September

The European Medicines Agency is currently reviewing benefits and risks of the anti-arrhythmic medicine Multaq (dronedarone), since preliminary data from a clinical study (PALLAS) have shown an increased risk of cardiovascular side effects such as cardiovascular death, stroke and cardiovascular hospitalisation in patients with permanent atrial fibrillation. These new data could have an impact on the use of the medicine in its approved indication, "adult clinically stable patients with a history of, or current, non-permanent atrial fibrillation, to prevent recurrence or to lower ventricular rate".

Awaiting the finalisation of the current review, prescribers in the European Union are reminded to follow the recommendations in the product information with respect to the indication, contraindications and warnings. Specifically, prescribers are advised to monitor patients regularly in order to ensure that they remain within the authorised indication and do not progress to permanent atrial fibrillation.

In January 2011, the Committee for Medicinal Products for Human Use (CHMP) started the review of the overall benefit-risk balance of Multaq following reports of severe liver injury. The scope of this review was extended to include new information from the PALLAS clinical study earlier this month. In the PALLAS study, Multaq was being investigated in patients with permanent atrial fibrillation and cardiovascular risk factors. At the time the study was stopped, 3,149 patients were enrolled.

Patients who wish to have more information on the potential risks and benefits associated with their treatment may contact their doctor. Patients are advised not to stop their medication without consulting their doctor.

The CHMP noted during the meeting that data for the PALLAS study have become available very recently. It will continue to assess these data in depth, together with all other available data on the benefits and risks of Multaq in order to finalise the current review in September 2011. Further advice will be issued at the time of the final assessment in September.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Multaq (dronedarone) from Sanofi Aventis is used in adults who have had an abnormal heart rhythm (atrial fibrillation) in the past or who currently have non-permanent fibrillation. Abnormal heart rhythm happens when the atria (the upper chambers of the heart) contract irregularly and rapidly. Multaq is used to prevent the fibrillation coming back or to lower the heart rate.
3. The following contraindications and warnings in the summary of product characteristics in relation to cardiovascular risk are particularly relevant:
    - Multaq is contraindicated in patients with bradycardia <50 beats per minute and in patients in unstable haemodynamic conditions, including patients with symptoms of heart failure at rest or with minimal exertion (corresponding with NYHA class IV and unstable class III patients).
    - Multaq is not recommended in stable patients with NYHA III or LVEF <35%.
    - If heart failure develops or worsens, consider the suspension or discontinuation of Multaq.
    - INR should be closely monitored after initiating dronedarone in patients taking vitamin K antagonist as per their label. (This recommendation is in the process of being added to the summary of product characteristics.)
4. Multaq has been authorised in the European Union since November 2009.
5. Multaq is marketed in the following European Union Member States: Austria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Lithuania, Malta, Poland, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. In addition, it is marketed in Iceland and Norway.
6. 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
7. On 8 July 2011 the European Commission asked the Agency to broaden this review to also include data from the PALLAS study
8. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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