



QSM/MC/IEA.116

23 July 2007

Information Exchange System

Alert No. 116

More risks than benefits with veralipride; marketing authorization withdrawn for all medicinal products containing veralipride

The European Medicines Agency (EMA) has issued a Press Release recommending the withdrawal of the marketing authorization for all medicinal products containing veralipride. The Agency made this recommendation under advice from the Committee for Medicinal Products for Human Use (CHMP) that the risks of veralipride in the treatment of hot flushes associated with menopause in women are greater than its benefits.

The CHMP has assessed all available information on the safety and efficacy of veralipride and has concluded that while veralipride shows limited efficacy, it is associated with side-effects, including depression, anxiety, and tardive dyskinesia (a movement disorder which may be long-lasting or irreversible), both during and after treatment. The CHMP undertook this assessment following a request from the European Commission in September 2006 when veralipride was withdrawn from the Spanish Market due to reports of serious nervous system disorders.

The EMA advises that patients who are taking veralipride for the treatment of hot flushes should consult their doctor to discuss other treatment options if necessary; veralipride treatment should not be stopped abruptly but the dose should be reduced gradually.

This WHO Alert is being released for wider communication of the EMA market decision for veralipride and to assist in any appropriate action by countries outside of Europe.

Reference:

Press Release, European Medicines Agency Press Office, 19 July 2007
(www.emea.europa.eu/whatsnew).