European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends withdrawal of medicinal products containing veralipride

The European Medicines Agency (EMEA) has recommended the withdrawal of the marketing authorisation for medicinal products containing veralipride. The EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded that the risks of veralipride in the treatment of hot flushes associated with the menopause in women are greater than its benefits and therefore recommended that the medicine should be taken off the market.

Patients who are taking medicinal products containing veralipride for the treatment of hot flushes should consult their doctor to discuss other treatment options if necessary. Treatment should not be stopped abruptly but the dose of veralipride should be reduced gradually.

Following the assessment of all available information on the safety and efficacy of veralipride, the CHMP 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.

This assessment was carried out under an 'Article 31' procedure, following a request from the European Commission in September 2006. This was triggered by the withdrawal of veralipride from the Spanish market because of reports of serious side effects affecting the nervous system, and by a number of regulatory actions in other European Union Member States where veralipride is authorised.

The CHMP opinion will now be forwarded to the European Commission for the adoption of a Decision.

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Notes:

1. For more information, see the accompanying question-and-answer document.
2. Veralipride is authorised in Europe under the trade names Agreal or Agradil in Belgium, France, Italy, Luxembourg and Portugal.
3. The procedure was carried out under Article 31 of the Community code on human medicinal products (Directive 2001/83/EC as amended).
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu.

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