European Medicines Agency

London, 1 October 2007
EMEA/CHMP/432352/2007

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 31 REFERRAL FOR

Agreal and associated names (see annex I)

International Non-Proprietary Name (INN): Veralipride

BACKGROUND INFORMATION*

Veralipride was approved since 1979 for the indication of treatment of vasomotor symptoms (hot flushes) associated with the menopause.

Veralipride was authorised in 6 European Member States: Belgium, France, Italy, Luxembourg and Portugal. Until June 2005, veralipride was also marketed in Spain.

On 7 September 2006, following the withdrawal of veralipride from the Spanish market due to reports of serious side effects affecting the nervous system, the European Commission referred the matter to the EMEA under Article 31 of Directive 2001/83/EC.

The referral procedure started on 21 September 2006. The Rapporteur and Co-Rapporteur appointed were: Eric Abadie and Barbara van Zwieten-Boot, respectively. Written explanations were provided by the Marketing Authorisation Holder on 4 January 2007. Oral explanations were given on 20 June 2007.

On 19 July 2007, based on evaluation of the currently available data and the Rapporteurs' assessment reports, the CHMP considered that the benefit/risk profile of veralipride-containing medicinal products is negative and therefore adopted an opinion recommending the withdrawal of the Marketing Authorisation for all medicinal products containing veralipride.

The list of product names concerned is given in Annex I.

The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 1 October 2007.

* **Note**:
The information given in this document and Annexes reflects the CHMP Opinion dated 19 July 2007.

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