15 March 2012
EMA/CHMP/191421/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ventavis

iloprost

On 15 March 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Ventavis. The marketing authorisation holder for this medicinal product is Bayer Pharma AG. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted the removal of a contraindication as follows:

"4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- ~~Pregnancy and lactation (see section 4.6).~~
- Conditions where the effects of Ventavis on platelets might increase the risk of haemorrhage (e.g. active peptic ulcers, trauma, intracranial haemorrhage).
- Severe coronary heart disease or unstable angina;
- Myocardial infarction within the last six months;
- Decompensated cardiac failure if not under close medical supervision;
- Severe arrhythmias;
- Cerebrovascular events (e.g. transient ischaemic attack, stroke) within the last 3 months.
- Pulmonary hypertension due to venous occlusive disease.
- Congenital or acquired valvular defects with clinically relevant myocardial function disorders not related to pulmonary hypertension."

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.