21 June 2012
EMEA/CHMP/423444/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Volibris

ambrisentan

On 21 June 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 Volibris. The marketing authorisation holder for this medicinal product is Glaxo Group Ltd. 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 a new contraindication as follows:
"Idiopathic pulmonary fibrosis (IPF), with or without secondary pulmonary hypertension (see section 5.1)."

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.

For information, the full contraindications for Volibris will be as follows[2]:

4.3 Contraindications

- Hypersensitivity to the active substance, to soya, or to any of the excipients (see sections 4.4 and 6.1).
- Pregnancy (see section 4.6).
- Women of child-bearing potential who are not using reliable contraception (see sections 4.4 and 4.6).
- Lactation (see section 4.6).
- Severe hepatic impairment (with or without cirrhosis) (see section 4.2).

[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.
[2] The text in bold represents the new or the amended contraindication.

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
An agency of the European Union

- Baseline values of hepatic aminotransferases (aspartate aminotransferases (AST) and/or alanine aminotransferases (ALT))>3xULN (see sections 4.2 and 4.4).
- **Idiopathic pulmonary fibrosis (IPF), with or without secondary pulmonary hypertension (see section 5.1).**