



European Medicines Agency
Evaluation of Medicines for Human Use

London, 19 November 2009
Doc.Ref. EMEA/CHMP/752754/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
DOCETAXEL WINTHROP

International Nonproprietary Name (INN): *docetaxel*

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Docetaxel Winthrop. The Marketing Authorisation Holder for this medicinal product is Aventis Pharma S.A.

The CHMP adopted the removal of a contraindication as follows:
“Docetaxel must not be used in pregnant or breast-feeding women.”

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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.

* 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.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.