



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

International Nonproprietary Name (INN): *temsirolimus*

On 23 July 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 Torisel. The Marketing Authorisation Holder for this medicinal product is Wyeth Europa Ltd.

The CHMP adopted a new indication as follows:

''Torisel is indicated for the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma [MCL]''.
''

The opinion on this type II variation also includes a recommendation from the CHMP that one additional year of marketing protection be granted***, because the Committee concluded that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies, based on improved efficacy.

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.

For information, the full indications for Torisel will be as follows****:

Renal cell carcinoma

Torisel is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC) who have at least three of six prognostic risk factors (see section 5.1).

Mantle cell lymphoma

Torisel is indicated for the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma [MCL], (see section 5.1).

* 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.

** 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.

*** In accordance with the provisions of Article 14(11) of Regulation (EC) No 726/2004.

**** The text in bold represents the new or the amended indication.