European Medicines Agency
Evaluation of Medicines for Human Use

London, 30 May 2008
Doc.Ref. EMEA/CHMP/280402/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
ERBITUX

International Nonproprietary Name (INN): ***cetuximab***

On 30 May 2008 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 Erbitux. The Marketing Authorisation Holder for this medicinal product is Merck KGaA.

The CHMP adopted a new indication as follows:

Erbitux is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer

- as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.

The CHMP adopted a change to an indication as follows:

Erbitux is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer

- in combination with chemotherapy

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 Erbitux will be as follows[***]:

Erbitux is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, **KRAS wild-type** metastatic colorectal cancer

- **in combination with chemotherapy**
- **as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.**

Erbitux in combination with radiation therapy is indicated for the treatment of patients with locally advanced squamous cell cancer of the head and neck.

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[*] 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.

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

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