19 May 2011
EMA/CHMP/398312/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Erbitux

(cetuximab)

On 19 May 2011 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 Erbitux. The marketing authorisation holder for this medicinal product is Merck KGAA. 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 recommended that the indication in metastatic colorectal cancer in combination with chemo-therapy should be restricted to use in combination with irinotecan-based chemotherapy or FOLFOX4.

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 indication(s) for Erbitux will be as follows[2]:

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

- ***in combination with irinotecan-based chemotherapy or FOLFOX4 (for details, see section 5.1),***
- *as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.*

Erbitux is indicated for the treatment of patients with squamous cell cancer of the head and neck

- *in combination with radiation therapy for locally advanced disease,*
- *in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.*

[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 indication.

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