European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 January 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
EFFENTORA

International Nonproprietary Name (INN): ***fentanyl citrate***

On 24 January 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant marketing authorisation for the medicinal product Effentora buccal tablet 100 µg, 200 µg, 400 µg, 600 µg and 800 µg intended for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. The applicant for this medicinal product is Cephalon Europe.

The active substance of Effentora is fentanyl citrate, a Phenylpiperidine derivatives medicinal product (N02AB03), an opioid analgesic, interacting predominantly with the opioid µ-receptor. Its primary therapeutic actions are analgesia and sedation.
The benefits with Effentora are its efficacy in the treatment of breakthrough pain (BTP) in cancer patients under maintenance opioid therapy, due to a rapid trans-mucosal absorption of fentanyl after buccal disintegration. The most common side effects are nausea, dizziness, vomiting, fatigue, headache, constipation, somnolence, anemia and peripheral edema.

A pharmacovigilance plan for Effentora, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Effentora is indicated for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. It is proposed that Effentora is prescribed by physicians experienced in the management of opioid therapy in cancer patients.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Effentora and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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.

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