EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2010
EMA/CHMP/344109/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

PecFent

fentanyl

On 24 June 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product PecFent, 100 µg / 100 µl ; 400 µg / 100 µl nasal spray solution intended for the management of breakthrough pain (BTP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain. The applicant for this medicinal product is Archimedes Development Ltd.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of PecFent is fentanyl, a Phenylpiperidine derivative (ATC code: N02AB03) - pure opioid agonist, which acts primarily through interaction with µ receptors located in the brain, spinal cord, and smooth muscle to produce its analgesic effect.

The benefits with PecFent are its ability to provide rapid pain relief in breakthrough cancer pain. The most common side effects are gastrointestinal disorders (vomiting, nausea, constipation); dizziness, headache and somnolence.

A pharmacovigilance plan for PecFent will be implemented as part of the marketing authorisation.

The approved indication is: management of breakthrough pain (BTP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.

Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

It is proposed that PecFent is prescribed by physicians experienced in the treatment of cancer pain.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), 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 there to be a favourable benefit to risk balance for PecFent and therefore recommends the granting of the marketing authorisation.