European Medicines Agency

London, 6 October 2009
Doc. Ref. EMA/CHMP/393579/2009 rev1
EMEA/H/A-29/1168

Questions and answers on the referral for Fentrix and associated names 25, 50, 70 and 100 microgram/hour fentanyl transdermal patch

The European Medicines Agency (EMEA) has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of Fentrix transdermal patch and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Fentrix outweigh its risks, and the marketing authorisation can be granted in Germany and in the following Member States of the EU, Austria, Belgium, Italy, the Netherlands, Portugal, Slovenia and Spain.
The review was carried out under an 'Article 29' referral[1].

What is Fentrix?
Fentrix is a transdermal patch (device that delivers the drug across the skin) that contains the active substance fentanyl. It is used to treat severe long-term (chronic) pain which can only be adequately treated with opioid painkillers (medicines that are related to morphine).
The active substance in Fentrix, fentanyl, is an opioid that acts on receptors in the brain and spinal cord to prevent pain.
Fentrix is a 'generic medicine'. This means that Fentrix is similar to a 'reference medicine' already authorised in the European Union (EU) called Durogesic.

Why was Fentrix reviewed?
Helm Pharmaceuticals GmbH submitted Fentrix transdermal patch to Germany for a decentralised procedure. This is a procedure when one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view of granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Belgium, Italy, the Netherlands, Portugal, Slovenia and Spain).

However, the Member States were not able to reach an agreement and the Spanish medicines regulatory agency referred the matter to the CHMP for arbitration on 4 May 2009.

The grounds for the referral were that:

- that Fentrix did not show a comparable local skin tolerability to the reference medicine, Durogesic;
- the non-clinical local irritation and how sensitive the skin was to Fentrix were not investigated in accordance with current CHMP guidelines.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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What are the conclusions of the CHMP?
Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Fentrix outweigh its risks, and therefore the marketing authorisation for Fentrix should be granted in all concerned Member States.

The European Commission issued a decision on 6 October 2009.

Rapporteur:	Dr. Karl Broich (Germany)
Co-rapporteur(s):	Dr. Concha Prieto Yerro (Spain)
Referral start date:	29 May 2009
Opinion date:	25 June 2009