European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 October 2007
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(4)[1] REFERRAL FOR

Fentanyl-ratiopharm 25/50/75/100 µg/h TTS and associated names

International Non-Proprietary Name (INN): fentanyl

BACKGROUND INFORMATION

Fentanyl-ratiopharm 25/50/75/100 µg/h TTS and associated names, is an opioid analgesic which is indicated in severe chronic pain which can be adequately managed only with opioid analgesics.

Ratiopharm GmbH submitted applications for mutual recognition of Fentanyl-ratiopharm 25/50/75/100 µg/h TTS and associated names, transdermal patch on the basis of the marketing authorisation granted by Germany 04 April 2006. The Mutual Recognition Procedure started on 06 July 2006. The Reference Member State was Germany and the Concerned Member States were Austria, France, the Netherlands, Spain and the United Kingdom. These Member States were not able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. Germany referred the reasons for disagreement to the EMEA on 20 December 2006.

Significant difference has been identified with regard to the proposed indication, posology and contraindications in the product information and the demonstration of bioequivalence and this was considered to be of serious public health concern. This refers to the extension of the indication to non-cancer patients, the choice of conversion tables, whether contraindication for breastfeeding and for interactions with partial agonist opioids should be given inn the product information and the studies needed to demonstrate bioequivalence with the reference medicinal product.

The arbitration procedure started on 24 January 2007 with the adoption of a list of questions. The Rapporteur was Dr Karl Broich and Co-Rapporteur was Dr Eric Abadie. The Marketing Authorisation Holder provided written explanations on 13 April 2007.

During their July 2007 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Fentanyl-ratiopharm 25/50/75/100 µg/h TTS and associated names, that the objections raised by France should not prevent the granting of a Marketing Authorisation and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. A positive opinion was adopted by consensus 19 July 2007.

The list of the product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the Summary of Product Characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 23 October 2007.

[1] Article 29(4) of Directive 2001/83/EC, as amended.

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