European Medicines Agency
Evaluation of Medicines for Human Use

London, 12 September 2008
EMEA/CHMP/495857/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Rapinyl and associated names

International Non-Proprietary Name (INN): fentanyl citrate

BACKGROUND INFORMATION

Rapinyl and associated names, 50µg, 100µg, 200µg, 300µg, 400µg, 600µg, 800µg, sublingual tablets is indicated for the management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain.

ProStrakan Ltd submitted applications for Rapinyl and associated names, 50µg, 100µg, 200µg, 300µg, 400µg, 600µg, 800µg, sublingual tablets. The Decentralised Procedure, SE/H/575/07/DC, started on 1 September 2006.

The Reference Member State was Sweden and the Concerned Member States were Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain and United Kingdom.

These Member States were not able to reach an agreement and Sweden referred the reasons for disagreement to the EMEA on 27 September 2007.

Significant difference has been identified with regard to the need for further clinical efficacy and safety data for the evaluation of the benefit/risk and the lack of PK data under normal conditions of use of the product. This refers to the bridging strategy of the Applicant and was considered to be a serious public health concern.

The arbitration procedure started on 18 October 2007 with the adoption of a list of questions. The Rapporteur was Dr Tomas Salmonson (SE) and Dr Pierre Demolis (FR) was Co-Rapporteur. The Applicant provided written explanations on 7 April 2008.

During their June 2008 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 **Rapinyl** and associated names, that the objections raised by Germany, France, Norway and United Kingdom 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 on 26 June 2008

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 11 September 2008.

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

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