European Medicines Agency
Evaluation of Medicines for Human Use

London, 22 November 2007
EMEA/433691/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Bicaluplex and associated names

International Non-Proprietary Name (INN): bicalutamide

BACKGROUND INFORMATION

Bicaluplex and associated names, 150 mg, film-coated tablet, is an oral anti-androgen used in the management of prostate cancer.

Ingers Industrials Solutions s.r.o submitted applications for mutual recognition of Bicaluplex and associated names, 150 mg, film-coated tablet on the basis of the marketing authorisation granted by Czech Republic on 30 November 2005. The Mutual Recognition Procedure started on 21 September 2006. The Reference Member State was Czech Republic and the Concerned Member States were Austria, Denmark, Germany, Estonia, Greece, France, Hungary, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Slovak Republic 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. Czech Republic referred the reasons for disagreement to the EMEA on 30 March 2007.

Significant differences have been identified with regard to the benefit/risk ratio of the product. This refers to two indications (treatment of locally advanced prostatic carcinoma without metastases, for which surgical castration or other type of medical intervention is not indicated or unacceptable; and as monotherapy in early treatment or as an adjunct to treatment with radiotherapy or radical prostatectomy in patients with prostatic carcinoma (T3-T4, any Stage N, M0) and this was considered to be of serious public health concern.

The arbitration procedure started on 26 April 2007 with the adoption of a list of questions. The Rapporteur was Dr Ondrej Slanar and Co-Rapporteur was Dr Matthew Thatcher. The Marketing Authorisation Holder provided written explanations on 20 July 2007.

During their September 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 Bicaluplex and associated names, that the objections raised by Germany 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 20 September 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 22 November 2007.

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

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu