European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 July 2008
EMEA/CHMP/428671/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Oracea

International Non-Proprietary Name (INN): doxycycline monohydrate

BACKGROUND INFORMATION

Oracea**,** 40 mg, modified release capsules is an antibiotic (doxycycline), indicated for the reduction of papulopustular lesions in adult patients with facial rosacea.

The applicant FGK Representative Service GmbH submitted an application for Marketing Authorisation Application of Oracea, 40 mg, modified release capsule on the basis of the marketing application to the UK on 28 February 2006. The Decentralised Procedure UK/H/0892/01/DC started on 12 April 2006. The Reference Member State was United Kingdom and the Concerned Member States were Austria, Germany, Finland, Ireland, Italy, Luxembourg, Netherlands and Sweden.

These Member States were not able to reach an agreement and therefore the United Kingdom referred the reasons for disagreement to the CHMP on 27 July 2007.

Significant difference had been identified with regard to the lack of sufficient safety and efficacy evidence, the emergence of bacterial resistance caused by the use of Oracea and the insufficient demonstration of a positive benefit: risk ratio. These issues were considered to be of serious public health concern.

The arbitration procedure started on 20 September 2007 with the adoption of a List of Questions. The Rapporteur was Dr Tomas Salmonson (SE) and Co-Rapporteur was Dr Ian Hudson (UK). The Applicant provided written explanations on 30 November 2007 and on 3 March 2008.

During their April 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 objections that triggered the Article 29 Referral should not prevent the granting of a Marketing Authorisation for Oracea and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. A positive opinion was therefore adopted by consensus on 24 April 2008 and the grounds for opinion, the conditions of the Marketing Authorisation and the amended SPC, labelling and package leaflet of the relevant Member State were annexed.

The list of the medicinal 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 conditions of the Marketing Authorisation are provided in Annex IV.

The final opinion was converted into a Decision by the European Commission on 22 July 2008.

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

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