European Medicines Agency

London, 10 April 2006
EMEA/85997/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION

PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

Prograf and associated names (See Annex I)

International Non-Proprietary Name (INN): Tacrolimus

BACKGROUND INFORMATION

Tacrolimus is a macrolide immunosuppressant belonging to the pharmacological class of the calcineurin inhibitors.

Different Summaries of Product Characteristics (SPC) had been authorised, based on national, divergent decisions from the authorisations in the EU Member States. On 23 march 2005, Fujisawa GmbH on behalf of all the Marketing Authorisation Holders (see Annex 1 of Opinion) presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the national SPCs of the medicinal product Prograf and associated names.

The referral procedure started on 29 April 2005. The CHMP having considered the Rapporteur and the Co-Rapporteur assessment reports, the scientific discussion within the Committee and the comments from the Marketing Authorisation Holders (MAH), was of the opinion that the benefit/risk ratio of Prograf and associated names is considered to be positive in the following indications:

Prophylaxis of transplant rejection in liver, kidney or heart allograft recipients.

Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products.

The CHMP gave a positive opinion on 26 January 2006 recommending the harmonisation of the SPC for Prograf and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC in Annex III.

A Decision was issued by the European Commission on 10/04/06.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int