European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 13 December 2007
Doc.Ref. EMEA/CHMP/562878/2007, corr.[+]

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION[*]
for
MYFENAX

International Nonproprietary Name (INN): ***mycophenolate mofetil***

On 13 December 2007 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,[**] recommending to grant a marketing authorisation for the medicinal product Myfenax, 250 mg hard capsules and 500 mg film coated tablets intended for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants in combination with ciclosporin and corticosteroids. The applicant for this medicinal product is Teva Pharma B.V.

The active substance of Myfenax is mycophenolate mofetil, a selective immunosuppressive agent medicinal product *(*L04AA06*).*
Myfenax is a generic of CellCept which has been authorised in the EU since 14 February 1996. Studies have demonstrated the satisfactory quality of Myfenax, and its bioequivalence with CellCept. A question-and-answer document on generic medicines can be found here.

The approved indication is: "in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants". It is proposed that treatment with Myfenax should be initiated and maintained by appropriately qualified transplant specialists.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Myfenax and therefore recommends the granting of the marketing authorisation.

[+] Correction: Strength of the product has been corrected from 5000 mg to 500 mg

[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

[**] Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu