COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21-II-2008
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NOT FOR PUBLICATION

COMMISSION DECISION

of 21-II-2008

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Mycophenolate mofetil Teva - Mycophenolate mofetil", a medicinal product for human use

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Teva Pharma B.V., on 22 July 2007, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 13 December 2007,

Whereas:

(1) The medicinal product "Mycophenolate mofetil Teva - Mycophenolate mofetil" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

[2] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Mycophenolate mofetil Teva - Mycophenolate mofetil", the characteristics of which are summarised in Annex I to this Decision. "Mycophenolate mofetil Teva - Mycophenolate mofetil" shall be registered in the Community register of medicinal products under number(s)

EU/1/07/439/001	Mycophenolate mofetil Teva-250 mg-Capsule, hard-Oral use-blister (PVC/PVDC/alu)- 100 capsules
EU/1/07/439/002	Mycophenolate mofetil Teva-250 mg-Capsule, hard-Oral use-blister (PVC/PVDC/alu)- 300 capsules
EU/1/07/439/003	Mycophenolate mofetil Teva-500 mg-Film-coated tablet-Oral use-blister (PVC/PVDC/alu)- 50 tablets
EU/1/07/439/004	Mycophenolate mofetil Teva-500 mg-Film-coated tablet-Oral use-blister (PVC/PVDC/alu)- 150 tablets

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Teva Pharma B.V., Computerweg 10, DR Utrecht 3542, Nederland.

Done at Brussels, 21-II-2008

For the Commission
Heinz ZOUREK
Director-General