EUROPEAN
COMMISSION

Brussels, 30.1.2014
C(2014)601 (final)

COMMISSION IMPLEMENTING DECISION

of 30.1.2014

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

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 30.1.2014

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

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Biogen Idec Limited, on 21 March 2012, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 21 November 2013 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Tecfidera - Dimethyl fumarate" 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) Dimethyl fumarate (DMF), the active substance of "Tecfidera - Dimethyl fumarate", is part of the composition of the authorised medicinal product Fumaderm which consist of DMF and calcium salt of ethyl fumarate, magnesium salt of ethyl hydrogen fumarate and zinc salt of ethyl hydrogen fumarate (MEF salts), belonging to the same marketing authorisation holder. The Committee for Medicinal Products for Human Use concluded that MEF and DMF are both active and are not the same active substance since they do not share the same therapeutic moiety. Therefore it is considered that Tecfidera containing DMF is different from Fumaderm the other already authorised medicinal product composed of DMF and MEF salts. Therefore "Tecfidera - Dimethyl fumarate", the application of which was based on Article 8(3) of Directive 2001/83/EC, and the already

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.

authorised medicinal product Fumaderm do not belong to the same global marketing authorisation as described in Article 6(1) of Directive 2001/83/EC.

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

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 "Tecfidera - Dimethyl fumarate", the characteristics of which are summarised in Annex I to this Decision. "Tecfidera - Dimethyl fumarate" shall be registered in the Community register of medicinal products under number EU/1/13/837.

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 Biogen Idec Limited, Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom.

Done at Brussels, 30.1.2014

For the Commission
Paola TESTORI COGGI
Director-General