



Bruxelles, 28.4.2014
C(2014)2916 (final)

COMMISSION IMPLEMENTING DECISION

of 28.4.2014

granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Delyba - delamanid", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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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 Agency¹, and in particular Article 10(2) and 14(7) thereof,

Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council²,

Having regard to the application submitted by Otsuka Novel Products GmbH, on 21 December 2011, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 5 December 2013 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) Commission Decision C(2008)488 of 1 February 2008, adopted in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products³ designated "(R)-2-Methyl-6-nitro-2-{4-[4-(4-trifluoromethoxyphenoxy)piperidin-1-yl]phenoxy-methyl}-2,3-dihydroimidazo[2,1-b]oxazole" as an orphan medicinal product.
- (2) "Delyba - delamanid" falls within the scope of Regulation (EC) No 507/2006, in particular Article 2(1) and 2(3). In addition, as set out in Annex IV, the medicinal product meets the requirements of Article 4 of this Regulation for the granting of a conditional marketing authorisation.
- (3) Authorisation for the placing on the market of "Delyba - delamanid" should therefore be granted subject to certain requirements, in accordance with Article 14(7) of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 92, 30.3.2006, p. 6.

³ OJ L 18, 22.1.2000, p. 1.

- (4) The Committee for Medicinal Products for Human Use considered that delamanid is a new active substance.
- (5) 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 conditional marketing authorisation provided for in Article 3 and 14(7) of Regulation (EC) No 726/2004 is granted for the orphan medicinal product "Delyba - delamanid", the characteristics of which are summarised in Annex I to this Decision. "Delyba - delamanid" shall be registered in the Community register of medicinal products under number EU/1/13/875.

Article 2

The marketing authorisation concerning the orphan medicinal product referred to in Article 1 shall be subject to compliance with the requirements set out in Annex II. Those requirements shall be reviewed annually.

Article 3

The labelling and package leaflet concerning the orphan medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorisation shall be one year from the date of notification of this Decision.

Article 5

This Decision is addressed to Otsuka Novel Products GmbH, Erika-Mann-Straße 21, D-80636 München, Deutschland.

Done at Brussels, 28.4.2014

For the Commission
Paola TESTORI COGGI
Director-General