EUROPEAN
COMMISSION

Brussels, 17.4.2020
C(2020)2574 (final)

COMMISSION IMPLEMENTING DECISION

of 17.4.2020

amending the marketing authorisation granted by Decision C(2015)234(final) for "Ofev - Nintedanib", 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 Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Articles 17(2) and 20(7)(a) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Boehringer Ingelheim International GmbH in accordance with Regulation (EC) No 1234/2008,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[3],

Having regard to the opinion of the European Medicines Agency, formulated on 12 December 2019 by the Committee for Medicinal Products for Human Use,

Having regard to the opinions of the European Medicines Agency, formulated on 27 February 2020 by the Committee for Medicinal Products for Human Use and on 19 March 2020 by the Committee for Orphan Medicinal Products,

Whereas:

(1) Commission Decision C(2016)5631(final), adopted in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products designated "Nintedanib" as an orphan medicinal product.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 334, 12.12.2008, p. 7.
[3] OJ L 18, 22.1.2000, p. 1.

(2) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(3) Decision C(2015)234(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(4) The review of the data submitted by Boehringer Ingelheim International GmbH on 30 March 2019 has shown that the new therapeutic indication proposed for the medicinal product "Ofev - Nintedanib" brings significant clinical benefit in comparison with existing therapies. Therefore, an additional year of marketing protection in accordance with Article 14(11) of Regulation (EC) No 726/2004 should be granted.

(5) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2015)234(final) should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2015)234(final) is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

Based on the conclusions set out in Annex IV to this Decision, the additional year of marketing protection is granted in accordance with Article 14(11) of Regulation (EC) No 726/2004.

Article 3

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 17.4.2020

For the Commission

Anne BUCHER
Director-General