EUROPEAN
COMMISSION

Brussels, 2.5.2023
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COMMISSION IMPLEMENTING DECISION

of 2.5.2023

amending the marketing authorisation granted by Decision C(2014)601(final) for "Tecfidera - Dimethyl fumarate", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, in particular Article 266 thereof,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human 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 Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Biogen Netherlands B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 13 January 2022, on 27 January 2022 and on 22 April 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) 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.

(2) The review of the data submitted by Biogen Netherlands B.V., on 19 June 2021 has shown that the new therapeutic indication proposed for the medicinal product "Tecfidera - Dimethyl fumarate", brings a significant clinical benefit in comparison with existing therapies.

(3) The marketing authorisation holder applied for an extension of the marketing protection of one additional year in accordance with Article 14(11) of Regulation (EC) No 726/2004.

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

(4) By its Judgment of 5 May 2021 in Case T-611/18, *Pharmaceutical Works Polpharma v EMA*[3], the General Court held that Commission Implementing Decision C(2014)601(final) is inapplicable in so far as, in that Commission Implementing decision, the Commission found that Tecfidera did not belong to the same global marketing authorisation as Fumaderm. as described in Article 6(1) of Directive 2001/83/EC. For the purpose of implementing that judgment the European Medicines Agency conducted an *ad hoc* assessment relating to the therapeutic effect of monoethyl fumarate salts (MEF) within Fumaderm. The scientific conclusions of the *ad hoc* European Medicines Agency's Opinion of 11 November 2021 underlines that the totality of the available data cannot establish that monoethyl fumarate salts (MEF) exerts a clinically relevant therapeutic contribution within Fumaderm. On this basis the Committee for Medicinal Products for Human Use (CHMP) concluded that, without prejudice to the outcome of the appellate proceedings against the judgment T-611/18, the granting of an additional one-year of marketing protection period for Tecfidera could not be recommended at this time.

(5) Following a request by the marketing authorisation holder for re-examination, the CHMP reviewed its initial opinion on the granting of an additional one-year of marketing protection period for Tecfidera. With its final opinion of 22 April 2022, the CHMP confirmed its initial opinion of 27 January 2022.

(6) On 16 March 2023, in its judgment in joined Cases C-438/21 P, C-439/21 P and C-440/21 P, the Court of Justice set aside the judgment of the General Court of 5 May 2021 in case T-611/18 and concluded that the Commission did not make a manifest error of assessment in concluding that Tecfidera did not belong to the same global marketing authorisation as Fumaderm. As a consequence, the Commission Implementing Decision C(2014)601 (final) of 30 January 2014 is valid in its entirety. It is apparent from paragraphs 86 to 89 of the judgment that, for the purpose of deciding whether or not two products belong to the same global marketing authorisation within the meaning of the second subparagraph of Article 6(1) of Directive 2001/83, the Commission was not required to verify the therapeutic contribution of MEF within Fumaderm or, a fortiori, the relevance of that contribution. Therefore, the *ad hoc* European Medicines Agency's Opinion of 11 November 2021 is no longer relevant.

(7) On the basis of the scientific elements of Annex IV of this Decision, which regulatory part is to be read in light of the outcome of the final judgment of the Court of Justice of 16 March 2023, an additional year of marketing protection can be granted in accordance with Article 14(11) of Regulation (EC) No 726/2004. Thus, the marketing protection period for the medicinal product Tecfidera ends on 2 February 2025.

(8) Decision C(2022)3251(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(9) In accordance with Article 266 of the Treaty on the Functioning of the European Union, the Commission takes the necessary measures to comply with the final judgment of the Court of Justice of the European Union. Consequently, this Decision shall apply retroactively from the date of the final judgment of the Court of Justice.

[3] OJ C 242, 21.6.2021, p. 20.

(10) 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(2022)3251(final) should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2022)3251(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 scientific elements contained 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. The marketing protection period expires 11 years after Commission Implementing Decision C(2014)601 (final) took effect on 3 February 2014.

Article 3

This Decision repeals and replaces Decision C(2022)3251(final) of 13 May 2022. It shall apply from 16 March 2023.

Article 4

This Decision is addressed to Biogen Netherlands B.V., Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland.

Done at Brussels, 2.5.2023

For the Commission

Sandra GALLINA
Director-General