



EUROPEAN
COMMISSION

Brussels, 13.5.2022
C(2022)3253 (final)

COMMISSION IMPLEMENTING DECISION

of 13.5.2022

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

(Text with EEA relevance)

(ONLY THE POLISH 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency¹, and in particular Article 10(2) thereof,

Having regard to the application submitted by Zakłady Farmaceutyczne POLPHARMA S.A., on 17 June 2021, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 24 February 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) The medicinal product "Dimethyl fumerate Polpharma - 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 use².
- (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,

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 "Dimethyl fumerate Polpharma - dimethyl fumarate", the characteristics of which are summarised in Annex I to this Decision. "Dimethyl fumerate Polpharma - dimethyl fumarate" shall be registered in the Union Register of Medicinal Products under number EU/1/22/1635.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 311, 28.11.2001, p. 67.

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 Zakłady Farmaceutyczne POLPHARMA S.A., ul. Pelplińska 19, 83-200 Starogard Gdański, Polska.

Done at Brussels, 13.5.2022

For the Commission

Sandra GALLINA

Director-General