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Public statement

Dimethyl fumarate Neuraxpharm (dimethyl fumarate)

Revocation of the marketing authorisation in the European Union

On 13 December 2023, the European Commission revoked the marketing authorisation for Dimethyl fumarate Neuraxpharm (dimethyl fumarate) in the European Union (EU). Dimethyl fumarate Neuraxpharm was a generic medicine of Tecfidera. The marketing authorisation holder for the medicine was Laboratorios Lesvi S.L.

The revocation of the marketing authorisation was necessary in order to implement the judgment of the Court of Justice of 16 March 2023 in Commission and Others v Pharmaceutical Works Polpharma, Cases C-438/21 P to C-440/21 P. It follows from that judgment that the marketing authorisation for Dimethyl fumarate Neuraxpharm was submitted at a point in time when the regulatory data protection period of the reference product (Tecfidera) had not expired. Further information in relation to the revocation of Dimethyl fumarate Neuraxpharm may be found in the Commission Implementing Decision revoking the marketing authorisation, which is available on the Union Register of medicinal products for human use.

Dimethyl fumarate Neuraxpharm was granted marketing authorisation in the EU on 13 May 2022 for treatment of relapsing remitting multiple sclerosis (RRMS).

The European Public Assessment Report (EPAR) for Dimethyl fumarate Neuraxpharm will be updated to indicate that the marketing authorisation is no longer valid.

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