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Public statement

Dimethyl fumarate Teva (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 Teva (dimethyl fumarate) in the European Union (EU). Dimethyl fumarate Teva was a generic medicine of Tecfidera. The marketing authorisation holder for the medicine was TEVA GmbH.

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 Teva 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 Teva 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 Teva was granted marketing authorisation in the EU on 12 December 2022 for treatment of relapsing remitting multiple sclerosis (RRMS).

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Assessment Report (EPAR) for Dimethyl fumarate Teva will be updated to indicate that the marketing authorisation is no longer valid.

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