C/2025/5820

10.11.2025

Judgment of the General Court of 24 September 2025 – Zakłady Farmaceutyczne Polpharma v Commission

(Case T-258/23) ([1])

(Medicinal products for human use – Variation of the marketing authorisation for Tecfidera – Dimethyl fumarate, a medicinal product for human use – Directive 2001/83/EC – Article 14(11) of Regulation (EC) No 726/2004 – Article 266 TFEU)

(C/2025/5820)

Language of the case: English

Parties

Applicant: Zakłady Farmaceutyczne Polpharma S.A. (Starogard Gdański, Poland) (represented by: K. Roox, T. De Meese, J. Stuyck and C. Dumont, lawyers)

Defendant: European Commission (represented by: L. Haasbeek, E. Mathieu and A. Spina, acting as Agents)

Intervener in support of the applicant: Biogaran (Colombes, France) (represented by: C. Mereu and S. Englebert, lawyers)

Intervener in support of the defendant: Biogen Netherlands BV (Amsterdam, Netherlands) (represented by: C. Schoonderbeek and B. Jong, lawyers)

Re:

By its action under Article 263 TFEU, the applicant seeks the annulment of Commission Implementing Decision C(2023) 3067 (final) of 2 May 2023 amending the marketing authorisation granted by Decision C(2014) 601 (final) for 'Tecfidera – Dimethyl fumarate', a medicinal product for human use.

Operative part of the judgment

The Court:

1. Annuls Commission Implementing Decision C(2023) 3067 (final) of 2 May 2023 amending the marketing authorisation granted by Decision C(2014) 601 (final) for 'Tecfidera – Dimethyl fumarate', a medicinal product for human use;

2. Dismisses the action as to the remainder;

3. Orders the European Commission, in addition to bearing its own costs, to pay the costs incurred by Zakłady Farmaceutyczne Polpharma S.A., including those relating to the interim proceedings before the Court;

4. Declares that Biogen Netherlands BV and Biogaran are to bear their own costs.

([1]) OJ C 252, 17.7.2023.