GENERAL COURT

Action brought on 4 August 2022 — Genzyme Europe v Commission

(Case T-483/22)

(2022/C 408/48)

Language of the case: English

Parties

Applicant: Genzyme Europe BV (Amsterdam, Netherlands) (represented by: P. Bogaert, B. Van Vooren and M. Oyarzabal Arigita, lawyers)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should:

— annul the decision that avalglucosidase alfa does not qualify as a 'new active substance', as contained in, or at least implied by, Commission Decision C(2022) 4531 final of 24 June 2022;

— annul Article 5 of that Commission Decision, providing that the medicinal product Nexviadyme — avalglucosidase alfa shall not be classified as an orphan medicinal product; and

— order the European Commission to pay the costs of these proceedings.

Pleas in law and main arguments

In support of the action, the applicant relies on three pleas in law.

1. First plea in law, alleging a breach of Article 10(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 ([1]) and of Article 14(11) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 ([2]) and a manifest error of assessment, combined with inadequate statement of reasons (against the first part of the contested decision, refusing the status of 'new active substance').

2. Second plea in law, alleging breach of the principle of good administration, as enshrined in Article 41 of the Charter of Fundamental Rights of the European Union (against the first part of the contested decision, refusing the status of 'new active substance').

3. Third plea in law, alleging breach of Article 5(12)(b) of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, ([3]) manifest error of assessment and inadequate statement of reasons (against the second part of the contested decision — withdrawal of orphan designation).

([1]) 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 use (OJ 2001 L 311, p. 67), as amended.

([2]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended.

([3]) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1), as amended.