C/2026/3669

20.7.2026

Action brought on 7 May 2026 – AstraZeneca v Commission

(Case T-289/26)

(C/2026/3669)

Language of the case: English

Parties

Applicant: AstraZeneca AB (Södertälje, Sweden) (represented by: B. Jong, lawyer)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should:

— annul the decision of the European Commission, the defendant, of 12 February 2026 (C(2026) 1035 final) granting marketing authorisation under Regulation (EC) No 726/2004 for 'Aumseqa – aumolertinib', a medicinal product for human use; and

— order the European Commission to pay the costs.

Pleas in law and main arguments

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

1. First plea in law, alleging a violation of Article 12(1) of the Regulation (EC) No 726/2004 ([1]), read in conjunction with Article 8(3) of the Directive 2001/83/EC ([2]) and its Annex and regulatory guidelines, in that the Commission made a manifest error of assessment by failing to recognise that the marketing authorisation applicant has not adequately demonstrated the quality, safety, or efficacy of the medicinal product in accordance with the applicable requirements.

2. Second plea in law, alleging a violation of Article 14(11) of the Regulation (EC) No 726/2004 by reliance on clinical data contained in the dossier of a medicinal product still covered by data protection.

([1]) 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.

([2]) 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.