C/2025/6183

24.11.2025

Action brought on 8 September 2025 – Mylan Healthcare v EMA

(Case T-610/25)

(C/2025/6183)

Language of the case: English

Parties

Applicant: Mylan Healthcare BV (Amstelveen, Netherlands) (represented by: J. Tingen, S. de Jong and A. Collignon, lawyers)

Defendant: European Medicines Agency

Form of order sought

The applicant claims that the Court should:

— annul, in full or in part, the decision of the European Medicines Agency of 27 June 2025 with reference number EMA/208014/2025, granting partial access to a Periodic Safety Update Report for the medicinal product Dymista (azelastine/fluticasone) to a third party, pursuant to Regulation (EC) No 1049/2001 of the European Parliament and of the Council ([1]); and

— order the European Medicines Agency to pay the applicant's costs or, in the alternative, an appropriate proportion of the costs pursuant to Article 134 of the Rules of Procedure of the General Court.

Pleas in law and main arguments

In support of the action, the applicant relies on the following plea in law.

Plea in law, alleging that the Agency erred in law in finding that the exception to the right of access to documents laid down in the first indent of Article 4(2) of Regulation No 1049/2001 does not justify the non-disclosure of certain information in a Periodic Safety Update Report for the medicinal product Dymista (azelastine/fluticasone). In particular:

— disclosure of the names of business partners together with details of their contractual arrangements, would undermine Mylan's commercial interests;

— disclosure of patient and sales data would undermine Mylan's commercial interests;

— disclosure of information concerning a specific clinical trial would undermine Mylan's commercial interests.

([1]) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43).