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Judgment of the Court in Case C-291/22 P | D & A Pharma v Commission and EMA

Marketing authorisations for medicinal products: the European Medicines Agency (EMA) must ensure that the experts it consults do not have a conflict of interest

The EMA cannot avoid this obligation of objective impartiality by requiring the applicant to prove the bias of the committee member concerned

The laboratory D & A Pharma filed an application with the European Medicines Agency (EMA) for marketing authorisation for Hopveus, a medicinal product derived from sodium oxybate. That active substance is indicated to combat alcohol dependence in the medium and long term.

Following a negative opinion from the Committee for Medicinal Products for Human Use (CHMP - which is part of the EMA), D & A Pharma requested re-examination of its application, proposing in particular that the therapeutic indications of the medicinal product be revised and that a scientific advisory group on psychiatry (the SAG on Psychiatry) be convened. That request for re-examination also resulted in a negative opinion, which led the European Commission to refuse, in July 2020, the marketing authorisation for Hopveus.

Criticising, among other things, the lack of impartiality of the experts consulted (who allegedly had a conflict of interest) as well as a breach of the principle of adversarial examination, D & A Pharma requested the General Court of the European Union to annul the decision of the Commission. That action having been dismissed ¹, the laboratory then turned to the Court of Justice.

The Court sets aside the judgment of the General Court and annuls the decision of the Commission refusing the application for marketing authorisation for Hopveus.

In its judgment, the Court first pointed out that a member of the expert group consulted by the CHMP had a **conflict of interest**, substantially vitiating the procedure. It then found that the judgment of the General Court was vitiated by an **error of law**, in that the General Court's interpretation of the policy on competing interests is **incompatible with the principle of objective impartiality**.

Finally, taking the view that the state of the proceedings permits final judgment to be given, the Court added that the decision to convene an *ad hoc* expert group instead of the SAG on Psychiatry constitutes a **defect vitiating the procedure for adopting the opinion of the EMA**, which in turn affects the procedure undertaken by the Commission to adopt that decision. The EMA is required to undertake that the CHMP will systematically consult a SAG when the applicant for re-examination requests such consultation in good time and in a duly reasoned way.

NOTE: An appeal, on a point or points of law only, may be brought before the Court of Justice against a judgment or order of the General Court. In principle, the appeal does not have suspensive effect. If the appeal is admissible and

well founded, the Court of Justice sets aside the judgment of the General Court. Where the state of the proceedings so permits, the Court of Justice may itself give final judgment in the case. Otherwise, it refers the case back to the General Court, which is bound by the decision given by the Court of Justice on the appeal.

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The [full text and, as the case may be, the abstract](#) of the judgment is published on the CURIA website on the day of delivery.

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Pictures of the delivery of the judgment are available from [‘Europe by Satellite’](#) ☎ (+32) 2 2964106.

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¹ Judgment of 2 March 2022, *D & A Pharma v Commission and EMA*, [T-556/20](#).