COURT OF JUSTICE
OF THE EUROPEAN UNION

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Judgment of the Court in Joined Cases C-6/21 P and C-16/21 P | Germany and Estonia v Pharma Mar and Commission

The Court of Justice sets aside the assessment made by the General Court with regard to the impartiality of experts from the European Medicines Agency (EMA)

The General Court concluded that the procedure did not provide sufficient guarantees after having wrongly equated experts from a university hospital who participated in the evaluation with employees from a pharmaceutical company

Based on the negative opinion of the EMA's Committee for Medicinal Products for Human Use (EMA), the Commission rejected, by decision of 17 July 2018, the application by the company Pharma Mar for marketing authorisation of the orphan medicinal product Aplidin ('the decision at issue'). That medicinal product, the active substance of which is plitidepsin, was developed to treat a serious cancer of the bone marrow. Pharma Mar then brought an action before the General Court for annulment of the decision at issue.

By judgment of 28 October 2020, the General Court annulled the decision at issue[1]. It considered that the procedure which led to its adoption did not provide sufficient guarantees to exclude any legitimate doubt as to a possible bias on the part of the experts who participated in the evaluation of the medicinal product, two of whom having been employees of a university hospital.

Germany and Estonia brought an appeal before the Court of Justice seeking to set aside the judgment of the General Court.

By today's judgment, **the Court sets aside the judgment of the General Court and refers the case back to it**.

The Court notes first of all that, with a view to harmonising the internal market for new medicinal products, the centralised EU authorisation procedure should also apply to orphan medicinal products in order for patients with rare conditions to be entitled to medicinal products whose quality, safety and efficacy are the same as those of other patients.

Next, it points out that the EU legislature was conferred, by the treaties, a discretion as regards the most appropriate method of approximation, in particular in fields with complex technical features. In a context where the proposed approximation requires physical, chemical or biological analyses to be made and scientific developments in the field concerned to be taken into account, the EU legislature empowered the EMA with the task of reconciling, on the one hand, the twofold requirement of impartiality and independence of its experts, and, on the other hand the public interest of the best possible scientific advice on any question relating to the evaluation of the quality,

[1] Judgment of 28 October 2020, Pharma Mar v Commission, T-594/18.

safety and efficacy of medicinal products for human use.

Germany and Estonia complained in particular that the General Court erred in law in equating the university hospital with a 'pharmaceutical company' under the EMA rules, according to which a job in such a company is, in principle, incompatible with participation in activities of the EMA.

In that regard, the Court notes the proximity that the university hospitals have with a university, dedicating themselves to care, education and research and not being involved in the marketing of medicinal products. It concluded that the fact of excluding them from the concept of 'pharmaceutical company' helps to **strike a balance between the need to carry out, on the one hand, an impartial examination of marketing authorisation applications and, on the other hand, a careful and as precise scientific examination as possible**. To consider that all the staff of a university hospital are employed by a 'pharmaceutical company' would be contrary to EU law. Indeed, an overall exclusion of university hospital experts from participation in scientific opinions on the ground that that hospital has, within it, one or more entities capable of constituting pharmaceutical companies risks creating a shortage of experts with detailed medical knowledge in certain scientific fields, in particular in relation to orphan medicinal products and advanced medicinal products.

The Court concludes that the General Court **erred in law in taking the view that the university hospital in question was a 'pharmaceutical company' solely because it controlled a cell therapy centre which itself satisfied the criteria of the 'pharmaceutical company'**.

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.

The full text 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