

Pleas in law and main arguments

EMA submits two grounds of appeal.

- 1) The first ground of appeal comprises two limbs. Under the first limb of this first ground of appeal, EMA submits that the General Court erred in law when holding, at paragraph 50 of the judgment under appeal, that Article 5(1) of the Orphan Regulation ⁽¹⁾ should be read separately from Article 5(2). Such interpretation stands in violation of Article 5(1), as it undermines the effectiveness of the provision.

Under the second limb of the first ground of appeal, EMA submits that the General Court erred in law when holding, at paragraph 64 of the judgment under appeal, that the notion of medicinal product should be relied upon by the EMA when it establishes for the purpose of Article 5(1) whether an application for orphan designation and a previously submitted application for marketing authorisation overlap.

- 2) Under the second ground of appeal, EMA submits that the General Court relied on an incorrect reading of the notion of medicinal products as set out in Article 1(2) of Directive ⁽²⁾ 2001/83/EC, insofar as it held that a difference in excipients and routes of administration between two products would render them different for the purpose of Article 5(1) of the Orphan Regulation.

⁽¹⁾ 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)

⁽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)

Request for a preliminary ruling from the Tribunale Amministrativo Regionale per la Lombardia (Italy) lodged on 4 June 2018 — Eni SpA v Ministero dello Sviluppo Economico, Ministero dell’Economia e delle Finanze

(Case C-364/18)

(2018/C 294/32)

Language of the case: Italian

Referring court

Tribunale Amministrativo Regionale per la Lombardia

Parties to the main proceedings

Applicant: Eni SpA

Defendants: Ministero dello Sviluppo Economico, Ministero dell’Economia e delle Finanze

Question referred

Do Article 6(1) and the sixth recital of Directive 94/22/EC ⁽¹⁾ preclude national legislation, in particular Article 19(5-bis) of Legislative Decree No 625 of 1996, which, by reason of the interpretation provided by the Consiglio di Stato in judgment No 290/2018, allows the imposition, in the context of the payment of royalties, of the QE (energy share) parameter, based on the listed prices of oil and other fuels, rather than on the basis of the PFOR index, which is pegged to the price of gas on the short-term market?

⁽¹⁾ Directive 94/22/EC of the European Parliament and of the Council of 30 May 1994 on the conditions for granting and using authorisations for the prospecting, exploration and production of hydrocarbons (OJ 1994 L 164, p. 3).