

- Infringement of Article 7(1)(c) of Regulation (EU) 2017/1001 of the European Parliament and of the Council;
- Infringement of Article 94(1) of Regulation (EU) 2017/1001 of the European Parliament and of the Council, of Article 41(2)(c) of the Charter of Fundamental Rights of the European Union and of Article 41(1) of the Charter of Fundamental Rights in conjunction with Article 20 and Article 21(1) thereof.

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**Action brought on 5 March 2021 — Amort and Others v Commission**

**(Case T-136/21)**

(2021/C 148/37)

*Language of the case: German*

**Parties**

*Applicants:* Heidi Amort (Jenesien, Italy) and 37 other applicants (represented by: R. Holzeisen, lawyer)

*Defendant:* European Commission

**Form of order sought**

The applicants claim that the Court should annul the contested implementing decision.

**Pleas in law and main arguments**

In support of the action against European Commission Implementing Decision C(2021) 94 (final) of 6 January 2021 granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'COVID-19 Vaccine Moderna — COVID-19 mRNA Vaccine (nucleoside modified)', a medicinal product for human use, the applicants rely on the following pleas in law.

1. First plea in law, alleging that the contested implementing decision infringes Article 2(1) and (2) of Regulation (EC) No 507/2006. (1) It has been scientifically proven that the worldwide panic on account of the high mortality rate supposedly connected with the SARS-CoV-2 infection is unfounded. Furthermore, the WHO and the EU have not duly recognised the crisis situation as a public health threat.
2. Second plea in law, alleging that the contested implementing decision infringes Article 4 of Regulation (EC) No 507/2006 due to:
  - the absence of a positive risk-benefit balance, as defined in Article 1(28a) of Directive 2001/83/EC; (2)
  - the failure to meet the requirement under Article 4(1)(b) of Regulation (EC) No 507/2006, since the applicant is not likely to be in a position to provide the comprehensive clinical data;
  - the failure to meet the requirement under Article 4(1)(c) of Regulation (EC) No 507/2006, since there are no unmet medical needs that will be fulfilled by the authorised medicinal product;
  - the failure to meet the requirement under Article 4(1)(d) of Regulation (EC) No 507/2006.

3. Third plea in law, alleging infringement of Regulation (EC) No 1394/2007, <sup>(3)</sup> Directive 2001/83/EC and Regulation (EC) No 726/2004. <sup>(4)</sup>
4. Fourth plea in law, alleging serious infringement of Articles 168 and 169 TFEU and Articles 3, 35 and 38 of the EU Charter.

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- <sup>(1)</sup> Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6).
- <sup>(2)</sup> 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).
- <sup>(3)</sup> Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2007 L 324, p. 121).
- <sup>(4)</sup> 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).

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**Action brought on 7 March 2021 — WIZZ Air Hungary v Commission**

**(Case T-142/21)**

(2021/C 148/38)

*Language of the case: English*

**Parties**

*Applicant:* WIZZ Air Hungary Légiközlekedési Zrt. (Budapest, Hungary) (represented by: E. Vahida, S. Rating, and I. Metaxas-Maranghidis, lawyers)

*Defendant:* European Commission

**Form of order sought**

The applicant claims that the Court should:

- annul the defendant's decision (EU) of 20 August 2020 in State aid Case SA.57026 (2020/N) — *Romania COVID-19: Aid to Blue Air* <sup>(1)</sup>; and
- order the defendant to pay the costs.

**Pleas in law and main arguments**

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

1. First plea in law, alleging that the defendant misapplied Article 107(2)(b) TFEU and committed a manifest error of assessment in its review of the proportionality of the aid to the damage caused by the COVID-19 crisis.
2. Second plea in law, alleging that the defendant's review of the eligibility and compatibility conditions for the rescue aid is flawed.
3. Third plea in law, alleging that the defendant violated specific provisions of the TFEU and the general principles of European law regarding the prohibition of discrimination, free provision of services and free establishment that have underpinned the liberalisation of air transport in the EU since the late 1980s <sup>(2)</sup>.