



C/2025/6512

15.12.2025

**Action brought on 9 June 2025 – Holzeisen v Commission**

(Case T-375/25)

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*Language of the case: German*

**Parties**

*Applicant:* Renate Holzeisen (Bolzano, Italy) (represented by: A. Fusillo, lawyer)

*Defendant:* European Commission

**Form of order sought**

The applicant seeks the annulment of Commission Implementing Decision C(2025)1094 (final) of 12 February 2025 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Kostaive – Zapomeran', a medicinal product for human use.

**Pleas in law and main arguments**

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

1. First plea in law, alleging serious infringement of Articles 168 and 169 TFEU, Articles 1, 3, 35 and 38 of the Charter of Fundamental Rights of the European Union, Articles 8, 11, 26, 54, 58, 59, 86 et seq., 101 et seq., Part I, Part III, and Part IV of Annex I to Directive 2001/83/EC, <sup>(1)</sup> Articles 3 to 7, 10a, 12, 14-a of Regulation (EC) No 726/2004 <sup>(2)</sup> and the Universal Declaration on the Human Genome and Human Rights <sup>(3)</sup> by circumventing the high testing standards laid down for gene-based medicinal products – and the need for an incidental review of the legality of Directive 2009/120/EC <sup>(4)</sup> pursuant to Article 277 TFEU.
2. Second plea in law, alleging infringement of Regulation (EU) No 536/2014, <sup>(5)</sup> in that an unlawful pharmacological and genetic-engineering experiment with criminal implications is being carried out on the entire EU population using a substance that is illegally administered and capable of being spread.
3. Third plea in law, alleging serious infringement of Articles 168 and 169 TFEU and Articles 1, 3, 35 and 38 of the Charter of Fundamental Rights of the European Union.

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<sup>(1)</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>(2)</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).

<sup>(3)</sup> That declaration was adopted by the Member States at the 29th UNESCO General Conference in November 1997.

<sup>(4)</sup> Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (OJ 2009 L 242, p. 3).

<sup>(5)</sup> Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ 2014 L 158, p. 1).