EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

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REGULATION
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
LAYING DOWN TRANSITIONAL RULES FOR THE PACKAGING AND LABELLING OF VETERINARY MEDICINAL PRODUCTS AUTHORISED OR REGISTERED IN ACCORDANCE WITH DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004

REGULATION (EU) 2022/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 May 2022

laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (b), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[2],

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1 Opinion of 23 March 2022 (not yet published in the Official Journal).
2 Position of the European Parliament of 5 May 2022 (not yet published in the Official Journal) and decision of the Council of 16 May 2022.

Whereas:

(1) Regulation (EU) 2019/6 of the European Parliament and of the Council[1] began to apply on 28 January 2022.

(2) Marketing authorisation holders and registration holders of veterinary medicinal products authorised or registered under Directive 2001/82/EC of the European Parliament and of the Council[2] or under Regulation (EC) No 726/2004 of the European Parliament and of the Council[3] are not able to comply, by 28 January 2022, with the requirements set out in Articles 10 to 16 of Regulation (EU) 2019/6. Furthermore, competent authorities are not in a position to process all the necessary variations, as defined in Article 4, point (39), of Regulation (EU) 2019/6, of marketing authorisations granted in accordance with either Directive 2001/82/EC or Regulation (EC) No 726/2004, and thereby to ensure compliance with Articles 10 to 16 of Regulation (EU) 2019/6 in a timely manner.

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1 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p.43).

2 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

3 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 L 136, 30.4.2004, p. 1).

(3) Therefore, it is necessary to provide for transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with either Directive 2001/82/EC or Regulation (EC) No 726/2004 to ensure the continued availability of those veterinary medicinal products in the Union and to establish legal certainty. The transitional rules should be limited to veterinary medicinal products that do not comply with the packaging and labelling requirements of Regulation (EU) 2019/6 but comply with all other provisions of Regulation (EU) 2019/6.

(4) Regulation (EC) No 726/2004 does not lay down specific requirements for labelling and packaging. However, it follows from Article 31(1), Article 34(1), point (c), Article 34(4), point (e), and Article 37(1), second subparagraph, of Regulation (EC) No 726/2004, in the version applicable on 27 January 2022, that products authorised under that Regulation are to comply with Articles 58 to 64 of Directive 2001/82/EC.

(5) This Regulation lays down transitional rules, which should apply from the date of application of Regulation (EU) 2019/6, that is from 28 January 2022. Therefore, this Regulation should apply from that date.

(6) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(7) This Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘veterinary medicinal product’ means a veterinary medicinal product as defined in Article 4, point (1), of Regulation (EU) 2019/6;

(2) ‘labelling’ means labelling as defined in Article 4, point (24), of Regulation (EU) 2019/6;

(3) ‘package leaflet’ means a package leaflet as defined in Article 4, point (27), of Regulation (EU) 2019/6;

(4) ‘placing on the market’ means placing on the market as defined in Article 4, point (35), of Regulation (EU) 2019/6.

Article 2

Transitional rules

Veterinary medicinal products which were authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 and which comply with Articles 58 to 64 of Directive 2001/82/EC, in the version applicable on 27 January 2022, may be placed on the market until 29 January 2027, even if their labelling and, where applicable, package leaflet are not in compliance with Articles 10 to 16 of Regulation (EU) 2019/6.

Article 3

Entry into force and application

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 28 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*