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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004 - Outcome of the European Parliament's first reading (Strasbourg, 2-5 May 2022)

I. INTRODUCTION

A number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

After the plenary approved the request of the Committee on the Environment, Public Health and Food Safety to proceed according to the Rule 163 (urgent procedure) on 3 May 2022, the EPP, S&D, Renew, Greens/EFA and ID groups jointly presented a compromise amendment (amendment number 2) to the abovementioned proposal for a Regulation. This amendment had been agreed during the informal contacts referred to above. In addition, The Left group tabled one amendment (amendment number 1).

II. VOTE

When it voted on 5 May 2022, the plenary adopted the compromise amendment (amendment number 2) to the abovementioned proposal for a Regulation. No other amendments were adopted. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto[1].

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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[1] The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics.*** The symbol " ▌ " indicates deleted text.

P9_TA(2022)0198

Transitional rules for the packaging and labelling of veterinary medicinal products ***I

European Parliament legislative resolution of 5 May 2022 on the proposal for a regulation of the European Parliament and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004 (COM(2022)0076 – C9-0054/2022 – 2022/0053(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2022)0076),

– having regard to Article 294(2) and Article 114 and Article 168(4), point (b), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0054/2022),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 23 March 2022[2],

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 27 April 2022 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[2] Not yet published in the Official Journal.

P9_TC1-COD(2022)0053

Position of the European Parliament adopted at first reading on 5 May 2022 with a view to the adoption of Regulation (EU) 2022/… 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

(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[3],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[4],

[3] Opinion of 23 March 2022 (not yet published in the Official Journal).
[4] Position of the European Parliament of 5 May 2022.

Whereas:

(1) Regulation (EU) 2019/6 of the European Parliament and of the Council[5] 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[6] or under Regulation (EC) No 726/2004 of the European Parliament and of the Council[7] 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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5 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).

6 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).

7 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 ..., ...

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