Conseil de
l'Union européenne

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LIMITE

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NOTE POINT "I"

Origine:	Secrétariat général du Conseil
Destinataire:	Comité des représentants permanents
Objet:	Proposition de RÈGLEMENT DU PARLEMENT EUROPÉEN ET DU CONSEIL établissant des règles transitoires pour l'emballage et l'étiquetage des médicaments vétérinaires autorisés conformément à la directive 2001/82/CE et au règlement (CE) n°726/2004 *- Mandat de négociation avec le Parlement européen*

Les délégations trouveront en annexe le texte amendé à la suite de l'examen effectué par le groupe « Conseillers/Attachés (Agri – Animaux et questions vétérinaires / Produits et systèmes alimentaires) », qui servira de base aux négociations avec le Parlement européen sur la proposition visée en objet.

Les modifications apportées à la proposition de la Commission sont indiquées en **caractères gras et soulignés**.

ANNEXE

2022/0053 (COD)

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 or registered in accordance with Directive 2001/82/EC and 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 Articles 114 and 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,

After consulting the European Economic and Social Committee[1],

After consulting the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulation (EU) 2019/6 of the European Parliament and of the Council[3] started applying on 28 January 2022.

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1 OJ C , , p. .

2 OJ C , , p. .

3 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) Marketing authorisation holders of veterinary medicinal products authorised **or registered** under Directive 2001/82/EC of the European Parliament and of the Council[4] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[5] 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 to ensure compliance with Articles 10 to 16 of Regulation (EU) 2019/6 in a timely manner.

(3) Therefore, it is necessary to provide for transitional rules in relation to packaging and labelling of 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 which comply with all other provisions of that Regulation.

(4) Regulation (EC) No 726/2004 does not lay down specific requirement for labelling and packaging. However, it follows from Articles 31(1), 34(1)(c), 34(4)(e) and 37 of Regulation (EC) No 726/2004, as 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 same 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,

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4 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).

5 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).

HAVE ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the definitions in Article 4(1), (24), (27) and (35) of Regulation (EU) 2019/6 shall apply.

Article 2

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, as applicable on 27 January 2022, can 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

This Regulation shall enter into force on the twentieth day following that 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*