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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 in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

This proposal addresses the serious concerns raised by Member State competent authorities and stakeholders in relation to the practical application of Article 152(2) of Regulation (EU) 2019/6 on veterinary medicinal products and the need to ensure continued supply of veterinary medicinal products (VMPs) authorised under the preceding legislation on the EU market. It is necessary to take urgent steps to address the interpretation problems raised, to remove any legal uncertainty and avoid any disruption in the supply of VMPs, as Regulation (EU) 2019/6 entered into application on 28 January 2022. The proposal aims to avoid the risk of shortages of VMPs, which would have led to a serious impact on animal health and welfare, both in farm and companion animals. It therefore provides for transitional rules allowing marketing authorisation holders to place VMPs complying with the packaging and labelling requirements of Directive 2001/82/EC or Regulation (EC) No 726/2004 on the market until 29 January 2027, even if they do not comply with the relevant requirements of Regulation (EU) 2019/6.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The legal bases of this proposal are, Articles 114 and 168(4), point (b) of the Treaty on the Functioning of the European Union.

• Subsidiarity (for non-exclusive competence)

The authorisation of veterinary medicinal products, including requirements concerning packaging and labelling, have been comprehensively regulated at Union level. Therefore, it would not be possible to address the issue at national level.

• Proportionality

Laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 is indispensable in order to ensure the continued availability of veterinary medicinal products and to establish legal certainty.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

From a Better Regulation perspective, a roadmap, stakeholder consultation or impact assessment are not necessary, as the proposal sets out transitional rules that are necessary for the entry into application of Regulation (EU) 2019/6, which already started to apply on 28 January 2022. It is therefore required as a matter of urgency. The proposal does not introduce any burden on economic operators or on Member States. DG SANTE's statement issued on 28 January 2022, indicating its intention to prepare this proposal, responded to concerns raised by both industry and Member State competent authorities.

4. BUDGETARY IMPLICATIONS

The proposal has no implications on the Union budget.

5. OTHER ELEMENTS

- **Detailed explanation of the specific provisions of the proposal**

The transitional rules in the proposal allow marketing authorisation holders to continue to place VMPs complying with the packaging and labelling requirements of Directive 2001/82/EC or Regulation (EC) No 726/2004 on the market until 29 January 2027, even if they do not comply with the relevant requirements of Regulation 2019/6.

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(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.

(2) Marketing authorisation holders of veterinary medicinal products authorised 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 in accordance with either Directive 2001/82/EC or Regulation (EC) No 726/2004 to ensure the continued availability of those veterinary

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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).

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).

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,

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 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*