Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2022/0053(COD)
Packaging and labelling of veterinary medicinal products: transitional rules Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20 Public health	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		
Council of the European Union			
European Commission	Commission DG	Commissioner	
	Health and Food Safety	KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events

02/03/2022	Legislative proposal published	COM(2022)0076	Summary
07/03/2022	Committee referral announced in Parliament, 1st reading		
25/04/2022	Decision by committee, without report		
05/05/2022	Results of vote in Parliament		
05/05/2022	Decision by Parliament, 1st reading	T9-0198/2022	Summary
16/05/2022	Act adopted by Council after Parliament's 1st reading		
30/05/2022	Final act signed		
31/05/2022	Final act published in Official Journal		

Technical information

Procedure reference	2022/0053(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)

Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 163; Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/08473

Documentation gateway

Legislative proposal		COM(2022)0076	02/03/2022	EC	Summary
Economic and Social Committee: opinion, report		CES1391/2022	23/03/2022	ESC	
Text adopted by Parliament, 1st reading/single reading		T9-0198/2022	05/05/2022	EP	Summary
Draft final act		00019/2022/LEX	30/05/2022	CSL	
Commission response to text adopted in plenary		SP(2022)324	08/06/2022	EC	

Final act

Regulation 2022/839
OJ L 148 31.05.2022, p. 0006

Packaging and labelling of veterinary medicinal products: transitional rules

PURPOSE: to avoid the risk of shortages of veterinary medicine products which would have led to a serious impact on animal health and welfare, both in farm and companion animals.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EU) 2019/6 on veterinary medicinal products entered into force on 28 January 2022. Holders of marketing authorisations for veterinary medicinal products authorised under Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products or Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use, are not in a position to comply with the requirements set out in Articles 10 to 16 of Regulation (EU) 2019/6 with effect from 28 January 2022.

Therefore, it is necessary to take urgent measures to address the concerns raised by Member States' competent authorities and stakeholders about the practical application of Regulation (EU) 2019/6 in order to remove any legal uncertainty and to avoid possible disruptions in the supply of veterinary medicines.

CONTENT: the proposal provides for transitional rules in the proposal allow marketing authorisation holders to continue to place veterinary medicinal products 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.

Packaging and labelling of veterinary medicinal products: transitional rules

The European Parliament adopted by 589 votes to 5, with 2 abstentions, a legislative resolution 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 726/200.

Parliament adopted its position at first reading under the ordinary legislative procedure.

The proposed regulation responds to the need to provide for 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 in order to ensure the continued availability of these veterinary medicinal products in the Union and to create legal certainty.

The transitional rules are 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.

The Regulation provides that veterinary medicinal products which have been 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 appropriate, package leaflets do not comply with Articles 10 to 16 of Regulation (EU) 2019/6.

The regulation will apply from 28 January 2022.