Packaging and labelling of veterinary medicinal products: transitional rules

2022/0053(COD) - 02/03/2022 - Legislative proposal

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.