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AGRILEG 40
VETER 11
PHARM 37
MI 151
DELECT 49

'I/A' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee (Part 1)/Council

No. Cion doc.: 5850/21 + ADD 1

Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 29.1.2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals
- Intention not to raise objections

1. On 29 January 2021, the Commission submitted the above delegated act to the Council in accordance with the procedure set out in Article 290 TFEU and with Article 57(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products¹ ('Regulation'). The Council may object to it until 30 March 2021.
2. During a silence consultation, one delegation indicated its intention to object to this delegated act².

¹ 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 4/43 (7.1.2019).

² WK 2860/2020 REV 1.

3. Consequently, the Presidency included the item on the agenda of the informal VTC of the members of the Chief Veterinary Officers on 10 March 2021. During the discussion, the delegation which had indicated its intention to object to the delegated act explained its concerns which were related to Article 11 on methods for collecting data on the volume of sales of veterinary antimicrobial medicinal products. Its intervention was followed by interventions by some other delegations which also expressed concerns on the wording of the same Article, which they considered unnecessarily restrictive for the competent authorities.
4. The Commission representative gave a thorough explanation on the aim and the structure of that Article, stressing that it would allow the competent authorities the flexibility they needed.
5. At the end of the discussion, the Presidency noted that there was no qualified majority in favor of objecting to the act and invited delegations to inform it by 12 March 2021 of any additional objections.
6. By the given deadline, no additional delegation indicated an intention to object to the delegated act. In addition, the delegation which had indicated its objection during the silence consultation informed the Presidency that the exchange of the views with other delegations and the clarifications provided by the Commission representative were sufficient for it to be able to support the delegated act.
7. It is therefore suggested that the Coreper recommend that the Council, as an "A" item on the agenda of one of its forthcoming meetings, confirm that it has no intention to object to the delegated act and that the Commission and the European Parliament are to be informed thereof. This implies that, unless the European Parliament objects to it, the delegated act shall be published and enter into force in accordance with Article 147(7) of the Regulation.