Council of the European Union

Brussels, 17 March 2021
(OR. en)

6878/21
ADD 1

AGRILEG 40
VETER 11
PHARM 37
MI 151
DELACT 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*

Statement of the Czech Republic

Declaration of the Czech Republic to the 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

The Czech Republic is fully aware of the seriousness of the risks associated with the resistance of microorganisms to antimicrobial medicaments in veterinary and human medicine. We have long been actively involved in international activities aimed at eliminating this phenomenon.

In this context, we fully appreciate the importance of data collection on sales and use of antimicrobials for the use rationalization and the use reduction at this category of medicines. Therefore, reducing the risk of microbe resistance to available medicines. In conformity with this approach, the Czech Republic welcomes any progress reached in the system of the data collection on sales and use of antimicrobials in the veterinary medicine both at the national and international level. We appreciate the contribution of Regulation (EU) 2019/6 and its delegated and implementing acts to harmonization of collection practices in different Member States. This includes the **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**, which the Czech Republic can finally support.

However, at the same time, we are aware that the process of unifying data collection systems is not without its pitfalls, it affects a wide range of stakeholders with different backgrounds in terms of time-tested practice and strategic interests. Our long-term aim is to shape a data collection system geared towards effective achievement of the goal to enable in particular the direct or indirect evaluation of the use of such products in food-producing animals at farm level (as envisaged in the Regulation 2019/6, Article 57) with really necessary administrative burden and financial costs only. In this context, it has caused concerns on provision of Article 11, Par. 2, where sufficient space for discussion was not given to the experts during preparation of delegated act. We expressed our reservations in a note WK 2860/2021 REV 1.

We would like to thank hereby to the Presidency for providing opportunity to discuss on the delegated regulation in question during the CVO WP meeting held on 10 March 2021. The Commission explanation of the wording of the mentioned Article, as well as its application in practice, given at this meeting allayed our concerns and the Czech Republic can support the above-mentioned delegated act. We consider the declared flexibility in method of data collection retained to the MS to be essential element of the provision. The Czech Republic will certainly make use of declared flexibility at data retrieval and collection and will also make use in the future of the current functional system of the retrieval and collection of data on the consumption of veterinary antimicrobials, in particular via distributors. This will enable us to retain the continuity of the system and the retrieval and collection of data in the required quality without any extra burdens, which we find essential.