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Committee on Sanitary and Phytosanitary Measures

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EUROPEAN UNION REVIEW OF LEGISLATION ON VETERINARY MEDICINAL PRODUCTS – SPECIFIC TRADE CONCERN 446

SUBMISSION BY THE UNITED STATES OF AMERICA

The following submission, received on 28 March 2022, is the statement made by the United States of America at the 23-25 March 2022 WTO SPS Committee, and is being circulated at the request of the Delegation of the United States of America.

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1. The United States would like to once again call attention to previous statements made at the SPS Committee, most recently during the November 2021 meetings and documented in the summary reports, that lay out our concerns regarding the implementation of Article 118 of EU Regulation 2019/6.

2. We appreciate that the EU Commission met with third countries to provide information about the developments of the legislation in 2019 and 2020, and note that in July 2021 DG SANTE offered to meet and provide updates to third countries. However, that meeting has not taken place. We encourage the European Union to prioritize this meeting as soon as possible in 2022 to share the outstanding details of the legislation, including how the proposed measures will consider the competence of third country's regulatory systems.

3. The United States notes that the European Medicine Agency, or EMA, published the recommended list of antimicrobials that will be reserved for human use. We ask that the EU Commission follow the scientific recommendations of the EMA in the delegated acts that will formalize the implementation of Article 118.

4. The United States will also note that the delays in implementation of the veterinary medicine legislation are causing significant uncertainty for producers in third countries, including the United States.

5. Further, animal species, specific pathogens causing diseases, health management practices, antimicrobial access, availability of alternative treatments, and antimicrobial susceptibility profiles vary by region, country, and even regions within particular countries. The United States requests that any EU measure allows flexibility to trading partners to meet the EU level of protection by imposing requirements in their own jurisdictions that are appropriate for the circumstances in the Member.

6. The restricted use of antimicrobial drugs may result in unintended negative animal health consequences through the spread of disease and negatively impact livelihoods of livestock producers in the European Union and beyond, ultimately preventing countries from achieving food security and sustainable development goals.

7. The United States requests that the EU Commission provide a new timeline, taking into consideration the lifespan of different animal species, for a pragmatic implementation process that considers the shelf and storage life of products already in the supply chain. For example, US cattle would need at least five years to implement any potential changes to animal health requirements.

8. Regardless of when the measures are implemented, our concerns remain that the legislation may unjustifiably limit access to the medicines needed in modern animal husbandry, particularly in developing countries where alternative treatments are not available.

9. The United States requests for clarification on the European Union's scientific justification for the restrictions on the use of antimicrobial drugs that are not medically important for humans. Such a provision may divert countries' resources away from more meaningful interventions around antimicrobial resistance with direct human health impacts.

10. Therefore, we reiterate our request to the EU Commission to provide details on how the list of antimicrobials will be maintained to ensure a fair, transparent, and science- and risk-based approach.

11. The United States again urges the European Union to base its regulations on science and risk, and to consider the impact of its SPS measures on global animal health, food security, trade, and agricultural sustainability.