Brussels, 28 October 2021

Minutes of the sixth meeting of the expert group to discuss a draft delegated act on rules for the use of veterinary medicinal products for prevention and control of certain listed diseases under Regulation (EU) 2016/429

28 October 2021, Brussels

1. Approval of the agenda

An annotated agenda was circulated prior to the meeting and approved at the beginning of the meeting.

2. Nature of the meeting

The meeting was non-public. Because of the constraints related to the COVID-19 situation, the meeting was held via Skype for business with the representatives of the competent veterinary authorities of Member States and EEA countries attending. The Chair noted the absence of the European Parliament and the Council.

3. List of points discussed

3.1. Introduction

The Chair recalled that the purpose of the meeting was to continue discussing the draft Commission Delegated Regulation supplementing Regulation (EU) 2016/429 (the 'Animal Health Law' (AHL)) as regards the use of veterinary medicinal products (VMPs) to prevent and control certain listed animal diseases and in particular the use of vaccines (SANTE/7144/2020) (the draft).

The Commission circulated a revised version of the draft, in track-changes, prior to the meeting.

3.2. Discussion on the draft-Delegated act

Part I of the draft

The Commission explained small changes introduced in Article 2 with a new reference to the definitions for veterinary medicinal products provided for in Regulation (EU) 2019/6.

As regards the rules for the use of vaccines against Newcastle disease, the Commission explained the changes made in Article 3 to reflect written comments received from some Member States. The new text seems to provide the necessary flexibility for the use of vaccines against that disease out of the disease control context, in accordance with the reactions of some Member States.

Part II of the draft

Title I

The Commission presented the changes introduced in relation to the general rules provided for in Title I of Part II of the draft-Delegated act. It explained that after the comments received (all of them in favour), this Title now covers both terrestrial and aquatic animals, regardless of the fact that there are currently no available vaccines for category A diseases in fish.

The draft provides for a simplified approach as regards the assessment and the official vaccination plan for emergency suppressive vaccination.

As regards the vaccination strategies provided for in Article 7, some Member States requested for more clarity and specific definitions to explain the situations covered in each case. In addition, Member States raised some inconsistencies between that Article and Delegated Regulation (EU) 2020/687. The Commission committed to reflect on those and to correct them where necessary.

Title II

- **Annexes on foot and mouth disease, infection with lumpy skin disease, infection with Rift valley fever virus, infection with Mycoplasma mycoides subsp. Mycoides SC, Infection with peste des petits ruminants virus, African horse sickness, Classical swine fever and African swine fever**

The Commission explained that the specific rules for the use of vaccines for prevention and control of foot and mouth disease and infection with lumpy skin disease would not be discussed in this meeting because they need further internal reflections.

One Member State commented on some of those chapters, and in particular on foot and mouth disease, asking the Commission to reflect about the level of clinical and laboratory surveillance after applying vaccination. The surveillance should be useful, but also realistic and adjusted to the OIE standards. However, the Commission presented the proposal as regards the specific rules for infection with Rift valley fever virus, which are based on the latest opinion published by EFSA on 2020, and infection with peste des petits ruminants virus, which follow a more prescriptive approach considering the disease-free status granted by the OIE.

The Commission also presented the proposal for African horse sickness and classical swine fever, both based on the rules provided for in the old Directives, which have been updated and aligned with the OIE standards. In relation to African horse sickness, one Member State asked for clarification as regards the possibility to vaccinate infected establishments, since this possibility seems to be provided by the draft Annex but not by Article 7.

For infections with Mycoplasmas and African swine fever, the intention of the Commission is not to provide specific rules in the relevant Annexes.

- **Highly pathogenic avian influenza and Newcastle disease**

The Commission presented the first draft of the Annexes providing for specific rules for highly pathogenic avian influenza and Newcastle disease following the approach presented in the Expert Group meeting hold in September 2021 and already including certain changes based on the preliminary feedback from Members States. These changes were related to the type of vaccines to be used for HPAI (not only vaccines compatible with DIVA strategies), simplified rules for clinical and laboratory surveillance and certain restrictions for HPAI. One Member State asked about the proposed level of surveillance, which was in their view too demanding and not realistic in all situations, in particular for the captive birds from zoos, and asked for some further clarifications. A few Member States commented favourable on the changes in

Article 3 of the draft that would leave the specific rules for preventive vaccination for Newcastle disease to be decided at national level

4. Conclusions/recommendations/opinions

The Commission thanked Member States for their input and invited them to provide their written feedback by 10 November 2021.

5. Next steps

The Commission will use the outcomes of the discussion and the opinions obtained during this expert group meeting and the requested written comments to develop a revised version of the draft-Delegated act, which will include disease-specific rules for all category A diseases.

6. Next meeting

The Commission plans to organise a sixth meeting of the Expert Group at the end of November 2021.

END