Brussels, 24 November 2020

Minutes of the third 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

24 November 2020, Brussels

1. Approval of the agenda

A preliminary 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 COVID-19 situation the meeting was attended via WebEx by the representatives of the Council and the competent veterinary authorities of Member States (MSs) and EEA countries. The Chair noted the absence of the European Parliament.

3. List of points discussed

3.1. Introduction

The Commission recalled that the purpose of the meeting was to discuss 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 ('the draft-Delegated act'). In this sense, a revised version of the draft was circulated prior to the meeting.

3.2. Presentation and discussion on the draft-Delegated act

Presentation

Before entering into details on the content, the Commission provided a presentation with an overview of the main changes introduced in the text after the meeting held on 24 June, with the corresponding justifications.

Part I

The Commission explained that aquatic animals as well as category D diseases have been finally included in the scope of the draft-Delegated act. As regards category D diseases, the Commission clarified that they have been included mainly to facilitate the discussion with MSs about the necessity to establish restrictions to the use of VMPs for their prevention and eradication. In this respect, a MS proposed that, if at the end of the discussion process it is clear that there are no restrictions to be imposed to such use, they should be removed from the scope and left for decision of MS for their use and related requirements.

The Commission also informed about the amendments introduced in Article 3, which cover the circumstances under which VMPs can be used for the control and prevention of listed diseases; who is

responsible to decide on the use of VMPs for those purposes and which VMPs can be used in such situations, for each category of diseases. In this regard, one MS expressed concerns about the particularities of rabies and how the current use of vaccines against this disease in the Union matches with the rules proposed in the draft-Delegated act. The Commission committed to reflect on this point.

The Commission reaffirmed that one of the key elements of Part I of the draft-Delegated act is the table in Annex I, where the authorised and non-authorised uses of VMPs for the prevention and control of listed diseases are established. The Commission explained changes introduced in that table. The Commission invited the MSs to send written comments on the reviewed table and their views in relation to the restrictions that should be laid down for category C and D diseases.

Part II

The Commission explained that Part II of the draft-Delegated act, which focuses on the use of vaccines for the prevention and control of category A diseases in terrestrial animals, has been simplified. In particular, as regards the classification of the vaccination strategies and the requirements for their implementation. The Commission also highlighted the newly introduced solution as regards the requirements on the implementation of clinical and laboratory surveillance in the vaccination and peri-vaccination zones, which have been simplified by referring to Annex I to Commission Delegated Regulation (EU) 2020/687.

As regards the preconditions to implement vaccination, a MS warned about an obligation to strictly follow the instructions of the manufacturer when using vaccines and proposed to amend that wording in a way that does not limit all the circumstances covered by Regulation (EU) 2019/6.

The Commission stressed the need to reflect carefully on the pending issues related to Part I and Part II and invited MSs to send written comments and suggestions.

Part III

The Commission reminded that Part III of the draft-Delegated act covers disease-specific rules on vaccination against category A diseases and that at this stage it only includes specific rules for the use of vaccines against infection with lumpy skin disease virus (LSD). Those rules will mainly take over the rules provided for in the current implementing legislation that have proven to be effective and will therefore be quite detailed. However, the Commission noted that it would not be possible to reach the same level of detail for all category A diseases as there is not such available scientific knowledge nor experience in the Union for some of them.

The Commission presented the proposed rules on the implementation of vaccination against LSD.. The Commission highlighted that the previous classification of vaccines has been simplified into two categories: live attenuated vaccines and vaccines other than live attenuated vaccines. This classification will affect the prohibitions related to the use of such vaccines. Finally, the Commission explained that the surveillance requirements during the recovery periods, which were presented in the previous meeting, have been simplified because of the proposed surveillance system for the vaccination and peri-vaccination zones proposed in Part II.

4. Miscellaneous.

4.1. Conclusions

The Commission thanked MSs for their input and invited them to provide their written feedback by 10 December 2020.

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

6. Next meeting

The Commission plans to organise a fourth meeting of the Expert Group at the end of January 2021.