Brussels, 24 June 2020

Minutes of the second 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 June 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 general approach and the structure of a draft Commission Delegated Regulation supplementing Regulation (EU) 2016/429 (the 'Animal Health Law') (AHL) as regards the use of veterinary medicinal products to prevent and control certain listed animal diseases and in particular the use of vaccines ('the draft-Delegated act'). In this sense, a first draft of the Delegated act was circulated prior to the meeting and a presentation based on it was designed to establish the order of points for discussion.

3.2. Summary of the feedback obtained from MSs as a follow up of the expert group meeting of 11 March 2020

The Commission presented a summary of MSs replies to the questionnaire circulated after the expert group meeting of 11 March 2020. Based on the discussion held in that meeting, the questionnaire included questions on the scope of and the rules to be provided by the draft-Delegated act.

The Commission explained that, in general, MSs supported the approach proposed by the Commission and that this feedback enabled the Commission to develop general principles included in the circulated draft.

There were no comments from MSs as regards this presentation.

3.3. Presentation and discussion on the draft-Delegated act

Approach

Before entering into details on the content, the Commission provided an overview of the proposed structure of the draft-Delegated act to facilitate the discussion.

Part I

The Commission explained that Part I of the draft-Delegated act provides for the general rules on the use of VMPs for the prevention and control of listed diseases. This includes the following: 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.

Whether listed diseases of aquatic animals should be covered by the draft-Delegated act or not was part of the discussion with MSs as well as the categories of diseases (A, B, C and/or D) that should be covered by this part. In general, MSs were in favour to include listed diseases of aquatic animals. As regards the categories of listed diseases, there were certain concerns about the particularities of some category C and D diseases, such as rabies.

The Commission pointed out that some definitions are needed in the draft-Delegated act, especially for those veterinary medicinal products included in the group of the immunological VMPs (as defined in Regulation (EU) 2019/6) that will be regulated in the draft-Delegated act. In this regard, the Commission clarified that the definitions included in the circulated draft are just preliminary proposals for discussion, also with other Units within the Commission, and will be further developed. Some MSs proposed certain amendments and other requested to include other definitions not reflected in the draft.

The Commission noted 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. MSs that intervened largely supported the prohibition of the use of antimicrobials and autogenous vaccines for the control of category A, B and C diseases. Some MSs expressed their positive opinion about allowing the use of antivirals for listed diseases. However, the table needs further reflection and discussion. The Commission invited the MSs to send written comments.

Part II

The Commission explained that Part II of the draft-Delegated act, at this stage, focuses on the use of vaccines for the prevention and control of category A diseases in terrestrial animals. It provides for common rules on the use of vaccines such as the preconditions for, and the development of, an official vaccination plan. The Commission clarified that those preconditions would apply in addition to those already provided for in other legal acts, i.e. the marketing authorisation of the vaccine and the development of a contingency plan.

The Commission presented a proposed classification and definition of the different vaccination strategies in kept and wild terrestrial animals. Some MSs had comments on the proposed classification, in particular one MS was against the concept of suppressive vaccination and another MS had concerns on the division of protective vaccination into two categories.

The Commission raised a question on whether a time limit to implement each one of the proposed strategies is needed or not. Similarly, the Commission asked for MSs views about detailed rules on the size of the vaccination and peri-vaccination zone, the prioritisation of animals to be vaccinated and

destination of the vaccinated animals. In general, MSs asked for flexibility in relation to these questions.

The Commission noted that Part II could also cover rules for the use of VMPs other than vaccines, such as antivirals. The Commission asked MSs to reflect on this point and invited them to share their views or to send written comments on it.

Part III

The Commission explained that Part III of the draft-Delegated act covers disease-specific and product specific rules on vaccination against category A diseases and noted that at a first stage the draft only includes a Title covering specific rules for infection with lumpy skin disease virus. This presents an example (a case study) on what would include and how could look like different Titles for various category A diseases.

In this regard, the Commission presented a proposed approach on the content of this Title that includes rules on the implementation of vaccination; measures and surveillance to be applied in the vaccination and peri-vaccination zones; the recovery periods (based on the OIE standards) and the surveillance to be applied after vaccination.

The Commission noted again that Part III could also cover specific rules for the use of VMPs other than vaccines and asked MSs for their views.

4. Miscellaneous.

4.1. Conclusions

The Commission thanked MSs for their input and invited them to provide their written feedback by 10 August 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 third meeting of the Expert Group in early October 2020.