Brussels, 11 March 2020

Minutes of the 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

11 March 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 COVID-19 situation and derived constrains only the Council representative and some Member States' and EEA countries representatives from the competent veterinary authorities could attend the meeting in person, however it could be followed by web streaming. 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 have a focused exchange of views, experiences, and get technical feedback in relation to the use of veterinary medicinal products to prevent and control certain listed animal diseases and in particular the use of vaccines as well as to identify policy choices for the future, within the framework of Regulation (EU) 2016/429 (the 'Animal Health Law') (AHL). In this sense, a presentation based on the distributed discussion paper was designed to establish the order of points for discussion.

The Commission acknowledged those Member States (Bulgaria and Spain) that had sent comments on the discussion paper ahead of the meeting and announced that, due to the absence of many of the Member States (MSs) and the impossibility to hear their opinions, no conclusions or agreements would be reached during the meeting. However, the MSs were given a possibility to react in writing after the meeting.

3.2. Exchange of views with Member States (MSs) on the use of veterinary medicinal products to prevent and control certain listed animal diseases

Legislative background

The Commission reminded of the list of legal acts currently containing provisions on the use of veterinary medicinal products for the prevention and control of diseases, and in particular the use of vaccines, and noted that all those legal acts will cease to apply as from 20 April 2021 and therefore it is necessary to develop new legislation in this field.

The Commission explained the legal basis to develop this new legislation within the framework of the Animal Health Law and its relation with other Delegated acts adopted under this Regulation and also its relation with Regulation (EU) 2019/6 (the 'VMP Regulation'). The Commission emphasised that the

scope of this new regulation will not interfere with the rules applicable for the authorisation of veterinary medicines under the VMP Regulation.

Implications

The Commission provided an overview of the implications of developing new legislation on the use of veterinary medicinal products for the prevention and control of diseases in relation to the OIE standards and the current policy on entry into the Union of animals, germinal products and products of animal origin. However, the Commission also presented the implications of not developing such new legislation in order to justify the necessity of harmonised rules and to raise the debate with the MSs experts.

Point for discussion 1: the scope

The first point under discussion was the scope of the future legislation. In this regard, the Commission launched three specific questions to MSs: which animal species should be covered (terrestrial/aquatic); which categories of listed diseases should be regulated and which veterinary medicinal products should be included.

For each of the questions, the Commission explained all the possible approaches and their implications.

Those MSs attending the meeting presented their preliminary reflections on whether or not measures concerning the use of VMPs in aquatic animals should be included in the scope. The exchange of views continued concerning the need to include Category B and C diseases or not. There was some discussion also on the issue whether the legislation should only cover the use of vaccines, or should also other VMPs be included. In the absence of many delegations, there were no conclusions drawn on this point.

Point for discussion 2: use of vaccines for the prevention and control of category A diseases

The Commission noted that, regardless of the outcome of the discussion on the scope, it is necessary that the new legislation on the use of VMPs for the prevention and control of listed diseases include harmonised rules for the use of vaccines for the prevention and control of category A diseases in terrestrial animals.

In this regard, the Commission presented a proposed approach on the content of the future legislation. This includes harmonized principles for the MSs to apply when determining whether to use or not, and how to frame the use of vaccines to prevent and control a category A disease. These principles would apply generally regardless of the disease, the type of vaccine or the type of vaccination. The Commission asked the MSs their opinion on the proposed basic principles that include a list of pre-conditions and a list of elements of the official vaccination campaign.

The approach proposed by the Commission also contained a first list of rules on the use of vaccines and on vaccination. In this sense, the Commission asked the MSs about the variables that should be taken into account when establishing such rules and the level of detail that they should cover.

The MSs that spoke have largely supported the basic principles set out in the Commission's proposed approach. On more detailed questions such as on variables, level of details to be covered by the

legislation, technical details including types of vaccines to be regulated, their views were rather preliminary and more dispersed.

4. Miscellaneous.

4.1. Conclusions

The Commission thanked MSs for their input and comments and committed to circulate a questionnaire with all the questions launched during meeting in order to give them time to reflect on them and to collect all the opinions, including of those MSs that could not attend to the meeting. The Commission invited the MSs to provide their written feedback not later than 27 March 2020.

5. Next steps

The outcome of the discussion and the opinions provided by participants during this expert group meeting and the requested written comments will be used by the Commission to develop a first draft of a Delegated Regulation on the use of veterinary medicinal products for prevention and control of listed diseases.

6. Next meeting

Is the intention of the Commission to organise a second Expert Group on this issue before the summer break.