Brussels, 05 May 2022

Minutes of the eighth 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

05 May 2022, Brussels (Webex)

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 Webex with the representatives of the competent veterinary authorities of Member States and EEA countries attending. The Chair noted the presence of the Council (represented by the Council Secretariat) and the absence of the European Parliament.

3. List of points discussed

3.1. Introduction

The Chair recalled that the purpose of the meeting was to inform the MS about the latest amendments of 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).

A short presentation was delivered after the introduction, by the Commission, to present any major changes in relation to the previous version of the draft and explain the rationale behind each one of them. The presentation concluded with a provisional timeline of the expected next steps in the progress of this legal text, until its eventual adoption and publication in the Official Journal of the EU.

The Commission circulated a revised version of the draft, prior to the meeting.

3.2. Discussion on the draft-Delegated act

Explanatory Memorandum – Recitals

The Commission explained the redrafting of the Explanatory Memorandum that has been refined and became more specific regarding the content and rationale of the draft. New recitals have been added to clarify that:

- This draft does not interfere with Reg. (EU) 2019/6 on the placing on the market, manufacturing, import , export use etc. of veterinary medicinal products.
- Vaccines against Rinderpest and *Mycobacterium Tuberculosis complex* (in certain animal species) should be prohibited

- Regular precautionary use of Newcastle Disease vaccines are out of the scope of this draft
- The modalities of the vaccination against Category A diseases (official vaccination plan, role of the competent authorities, preliminary information that must be provided, types of vaccination strategies, the need for disease specific conditions etc.).

Comments: One MS suggested that the draft should be aligned with the EMA reflection paper on AMR, hence the term preventive vaccination should be replaced by prophylactic vaccination (COM : acknowledged, will examine, although priority is to align the relevant terminology with the AHL).

Part I of the draft

The Commission presented minor additions in Articles 1, 3 and 4 that were necessary to include prohibitions in the vaccination against certain cat. B diseases (M. tuberculosis complex) explained. Some additional wording was also introduced in par. 3 of Article 3 to clarify the uses of Newcastle Disease vaccines that fall outside the scope of this draft.

Comments:
Art 9: One MS requested specific surveillance rules for preventive vaccination (COM: this is only for HPAI and is described in Annex XVIII)
Art 7: One MS requested more elaborate rules /criteria in the text as to when a MS resorts to emergency protective or preventive vaccination. (COM: The choice between the 2 strategies relies on the MS competent authorities since they know best the epidemiological situation and can best assess the relevant risk for their territories. More specific wording in the text would limit flexibility).
Art 8: One MS argued that it might not be possible to implement immediately emergency suppressive vaccination upon animals subject to the derogation of art 12(4) (b) of Reg (EU) 2020/687 (COM : take note, will examine bearing in mind the aforementioned article in relation to the derogation).

Part II of the draft

Title I

The Commission presented the changes introduced in Article 9 and explained that the various vaccination strategies will henceforth be described in this article rather that art. 2 (Definitions). Some additional wording was also added in Art. 12 in relation to restricted zones and compulsory killing after vaccination (correction of clerical error). It was also explained that all references to an "official vaccination plan" are now uniform across the entire draft.

Comments:
Art 12:One MS asked about the actual meaning of the recovery period (COM: The recovery period signals the end of the specific measures related to vaccination. These measures are meant to be separate from the relevant control measures for the same disease(s)).

Title II

The Commission explained that in par 1 of Art 15 additional wording was included to describe in detail the disease –specific requirements laid down in the Annexes

ANNEXES

The Commission presented the changes introduced in the Annexes as follows:

Annex I: A new Part II has been introduced to accommodate the prohibition for the *Myc. Tuberculosis complex* vaccines

Annex II: In Part 1, point 13 on kept animals was simplified. In the wild animals section, 2 points were added (knowledge of the population and ecological dynamics and risk of spread of disease in additional species/areas).

Comments: One MS proposed to add the zoonotic potential of diseases in the criteria for vaccination

Annex III: Part 1 has been split in 2 separate sections for kept and wild animals respectively. Point 1(i) was rephrased to improve clarity while point 1(l) was simplified (kept animals). Under point 2 (wild animals) 2 the peri-vaccination zone and vaccination seasons were added)

Annex IV: In the introductory sentence it was made clear that the preliminary info is provided before vaccination has begun and in point (f) reference to Art 110(3) of Reg. EU 2019/6 was removed as redundant (same approach throughout the annexes).

Annex V: No change

Annex VI: Substantial redrafting was carried out with replacement or amendments of many information points to ensure feasibility and promote simplification. The rationale is to describe the minimum information required to follow the evolution of the vaccination zones(s) and calculate the percentage of vaccinated animals /establishments and the percentage of vaccinated animals killed (if applicable). This information also includes some key dates (expected or actual) for the completion of important parts of the official vaccination campaign. This information, when provided with successive reports, allows to follow the progress of vaccination in a straightforward manner.

Comments : One MS proposed to review the information requested on the vaccination and peri-vaccination zones as these may not be applicable to all vaccination strategies (COM : take note). One MS requested clarifications on the rationale behind the higher frequency of reports in case of wild animals vaccination (COM : this is connected with seasonality of diseases and animal populations , in relation to wildlife).

Annex VII (FMD): In Part 1 the minimum vaccination coverage (point 3) has been aligned to the OIE guidelines. In Part 2 a derogation has been introduced to allow derogation from the clinical examination of all listed species while laboratory examination has been reduced to a sample that can detect 5% minimum prevalence with 95% level of confidence in all establishments. Classification of establishments was also removed, being not relevant for FMD. As a result in Part 3 all references to establishments' classification were removed and derogations or non-vaccinated offspring of vaccinated dams has been limited to cattle, following a consultation with the EURL. Finally the derogations provided for special types of animals, at the end of Part 3 were removed and replaced by additional wording in Part 4 (*Recovery Period)* with direct reference to Reg. 2020/687.

Annex VIII (RVF): Part 1 has been amended to prohibit the use of live attenuated vaccines, considering the possibility of circulation and re-assortment of vaccine strains. Minor rephrasing in Parts 3 and 4 to improve clarity. The rephrasing in Part 4 is now used through the "empty" annexes or empty parts thereof *("No additional disease specific requirements").*

Comments : One MS proposed to allow live attenuated vaccines for overseas territories where RVF may be endemic (COM : take note).

Annex IX (LSD): In Part 1 prioritisation of vaccines has focused on homologous ones, without further reference to live attenuated or inactivated , in vase the latter become available sometime in the future. Throughout Parts 2 and 3 reference to the competent authority was replaced by a "neutral" implementation of measures and derogations thereof while the entire channelling procedure described at the end of Part 3 was removed since this is already described in Reg. 2020/687 (articles 7 , 22 and 24). The title of Part 4 was also rephrased for clarity reasons and in order to align it with Part 4 of the other annexes (same/similar phrasing introduced throughout).

Annex XII (PPR) : In Part 2 some disease symptoms were removed from passive surveillance, being not PPR relevant/specific. The "competent authority" was removed throughout while the title of Part 4 was rephrased to improve clarity.

Annex XIV (AHS): In Part 1 prioritisation of live attenuated vaccines was removed in view of the risk of possible circulation /re-assortment of Orbivirus live vaccine strains. In Part 2 [par. (b)] more specific rules have been drafted, regarding surveillance in the vaccination zone , particularly if a DIVA vaccine is used, taking into account OIE rules too. The epidemiological survey at the end of this part was removed as redundant and to reduce administrative burden. In Part 3 two additional points 2 (b) (iv) and (v) were added, introducing additional requirements for the derogations from movements prohibitions in equine animals. These additional requirements enhance safety and align the current rules with the requirements for imports from third countries. Finally the title of Part 4 was rephrased for reasons of clarity (alignment with the titles of Parts 4 of other annexes).

Annex XVI (CSF) : In this Annex references to the competent authority have been replaced by "neutral" implementation of measures, as elsewhere in the annexes. In Part 4 , apart from the rephrased title (in line with Part 4 of other Annexes) additional wording has been added to exclude specific types of vaccinated animals from the obligation to be slaughtered / killed after vaccination when it is possible to distinguish vaccinated from naturally infected individuals.

Comments: Clarifications were requested by one MS on whether vaccination in wild boar alone will result in measures implemented domestic pigs as well. (COM: not the intention, will check the text again).

Annex XVIII (HPAI) : In Part 1 there was some redrafting to clarify that live attenuated vaccines shall not be used. References to the competent authority have been replaced by "neutral" implementation of measures, throughout this Annex, as elsewhere in the other annexes and the title of Part 4 was rephrased for reasons of clarity (alignment with the titles of Parts 4 of other annexes). In Part 5 (preventive vaccination, available only for HPAI) there was the addition of serology in par. 2.2(b) as an alternative to virological testing , when it allows distinction between vaccinated and naturally infected bird (active surveillance after preventive

vaccination). Finally in par. 6 and 7 of Part 5 explicit references were included to passive and active surveillance, to improve clarity. The COM explained that DIVA vaccines are not mentioned explicitly to avoid limiting the range of vaccines that may be used, although the "DIVA" concept per se is favoured by the current text.

Comments: One MS proposed to include a direct reference to DIVA vaccines , in the hope to make HPAI more acceptable by third countries (COM: explicit reference to DIVA vaccines might better be avoided for reasons already mentioned, however some wording may be added to clarify the "DIVA concept" of post vaccination surveillance.) A couple of MS suggested to improve the wording on the type of vaccine (COM : take note) while another MS suggested to re-examine the replacement of "flock" by epidemiological unit in Part 5 (2) b (COM : take note). One MS also propose to reduce the time in Part 4 , par. 4 (5) b from 72 to 48 hours to increase sensitivity of pre-movement clinical examination and testing. (COM : take note, would welcome additional scientific information supporting this change). Finally one MS asked on whether there is or should be a recovery period in the case of preventive vaccination otherwise preventive vaccination may need o be removed from the definition of recovery period (COM : take note, to examine).

Annex XIV (Newcastle Disease): No major changes, apart from the replacement of the "competent authority", as elsewhere in the Annexes.

<u>REMAINING ANNEXES</u> : [Annex X (CBPP), Annex XI (Sheep – Goat Pox), Annex XIII (CCPP) , Annex XV (Glanders), Annex XVII (ASF)]: In these annexes only the main title was preserved and "standard wording" was added *("No additional disease specific requirements")*. Otherwise no essential changes.

4. Conclusions/recommendations/opinions

The Commission thanked Member States for their input and invited them to provide their written feedback by 12 May 2022. The current text appears to be "solid" with MS requesting relatively few amendments with little effect on the overall structure and content.

5. Next steps

The final version of the text, with some redrafting, in view of the MS comments and the outcome of the inter-service consultation, will be shared with the experts and submitted for public feedback.

6. Next meeting

No next meeting is planned, unless there are specific reasons to hold one.

END