EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD)

Agreed by Immunologicals Working Party (IWP)	June 2016
Adopted by CVMP for release for consultation	08 September 2016
Start of public consultation	28 September 2016
End of consultation (deadline for comments)	31 December 2016

The proposed guideline will replace the 'Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)' (EMA/CVMP/IWP/105506/2007).

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

Keywords	Multi-strain, veterinary vaccines, avian influenza, blue tongue, foot and mouth disease, AI, BT, FMD

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1. Introduction

The concept of a multi-strain dossier was included in the revised Technical Annex I to Directive 2001/82/EC, Directive 9/2009/EC and in the revised Variation Regulation (EC) 1234/2008 in order to provide regulatory incentives for marketing authorisation applications for vaccines against Avian Influenza (AI), Blue tongue (BT) and Foot-and-Mouth Disease (FMD).

The multi-strain dossier concept is seen as an opportunity to address some of the priorities around veterinary vaccine availability and is a key deliverable as part of the Network action plan on availability of veterinary vaccines.

2. Problem statement

The development of the CVMP "Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)" was based on sound scientific and regulatory principles in advance of any practical experience from actual assessment of CAP applications.

The first product application, against foot-and-mouth disease virus, appeared to fit the model developed in the guideline with a fixed formulation and dose-volume for the target species with the only variables the qualitative and quantitative composition of the antigen(s) established with the appropriate safety and efficacy studies.

Conversely, the complexity of Bluetongue disease virus vaccines for cattle and sheep has prompted the need to reconsider the applicability of the existing guideline in order to take into account the differences in the development of a multi-strain dossier for this disease.

3. Discussion (on the problem statement)

From the outcome of some discussions with industry concerning the interpretation of the existing guideline and from the challenges posed by some on-going applications, it is clear that there is a need to clarify the terms of applicability of the guideline in order to facilitate the development of multi-strain dossiers.

The following points have been identified by some applicants relevant for submitted dossier and on prospective applications:

- Variable payloads for the same vaccine strain/serotype for one target species;
- Different dose-volumes for different target species;
- Different dose-volumes for the same target species;
- Variable adjuvant content for a fixed dose-volume depending on strain and species;
- Efficacy data absent for one or more target species for a new serotype;
- Restricted number of fixed combination products for a multi-strain dossier.

The list of issues mentioned above could be expanded if more stakeholders are consulted.

Although the existing guideline was aimed to provide sufficient details on the quality, safety and efficacy parts of a multi-strain dossier, it appears that specific issues are not covered by the current text.

4. Recommendation

The Immunologicals Working Party recommends to review, and possibly revise, the CVMP guideline on data requirements for multi-strain dossiers for inactivated vaccines against AI, BT and FMD, in order to take into account some additional issues identified since the guideline came into effect and the experience gained during assessment of recent applications for marketing authorisations. To ensure that all potential issues are covered, the IWP is relying on industry's cooperation during the consultation period of this concept paper. To this aim, it is important to identify any remaining issues not covered by the existing guideline or listed in this concept paper and the corresponding level of clarification needed.

The most appropriate way to deliver the answers to the different questions with regard to the interpretation of the guideline needs to be agreed. The current guideline is a comprehensive document that presents an overall outline of a multi-strain dossier. The inclusion of specific points to the current layout of the guideline might complicate the understanding of the whole document. As an alternative, a questions/answer annex to the guideline could clarify the content of the guideline.

5. Proposed timetable

September 2016	Concept paper released for consultation
December 2016	Deadline for comments
February 2017	Discussion in IWP
Q3 of 2017	Proposed date for release of draft guideline for consultation
Q2 of 2018	Deadline for comments
Q4 of 2018	Expected date for adoption by CVMP

6. Resource requirements for preparation

Revising the guideline will involve one rapporteur and one co-rapporteur.

Preparation of the draft guideline will require discussion at 2 – 3 IWP meetings.

7. Impact assessment (anticipated)

It is anticipated that the guidance would benefit both industry and regulators due to clarification regarding the applicability of the existing guideline. It will result in a more consistent assessment of products by regulators. This will contribute to the veterinary vaccine availability for major diseases, and thereby benefit animal health.

8. Interested parties

Regulatory authorities for medicinal products for veterinary use, the veterinary pharmaceuticals industry.