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SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Concept paper for the revision of the Guideline on live recombinant vector vaccines for veterinary use (EMEA/CVMP/004/04-FINAL)

Agreed by Immunologicals Working Party (IWP)	25 April 2023
Adopted by CVMP for release for consultation	15 June 2023
Start of public consultation	23 June 2023
End of consultation (deadline for comments)	22 September 2023

The proposed guideline will replace the Guideline on live recombinant vector vaccines for veterinary use (EMEA/CVMP/004/04-FINAL)

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

Keywords	Live, recombinant vector vaccine, veterinary

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1. Introduction

The "Guideline on live recombinant vector vaccines for veterinary use" (EMEA/CVMP/004/04-FINAL) was adopted in December 2004 and came into effect on 8 June 2005. This document was intended to provide advice to manufacturers seeking marketing authorisation for a live recombinant vector vaccine for use in animals. The objective of this guideline is to define what should be presented in the analytical, safety and efficacy part of the application considering the particular properties of live recombinant vector vaccines in the target and non-target species, including the natural host of the parental organism (where relevant).

In recent years, experience has been gained within the regulatory network on such vaccines, and aspects of the guideline are now considered to be out-of-date.

2. Problem statement

The "Guideline on live recombinant vector vaccines for veterinary use" is now over 15 years old, and was developed at a time when only a few vector vaccines were available.

Considering the scientific and regulatory developments since then and experiences gained, the CVMP/IWP considers that this guideline should be updated in order to reflect current knowledge and ensure continued relevance for development of commercial vaccines.

3. Discussion (on the problem statement)

Recombinant live vector vaccines are preparations of one or more types of live bacteria, viruses or fungi that are non-pathogenic or have a low pathogenicity for the target species. They contain one or more foreign genes encoding antigens inserted and stimulate an immune response. The heterologous antigen gene included in the vector may be of viral, bacterial or parasitic origin. The heterologous gene may comprise sequences coding for an entire antigen, a fragment of an antigen or more than one antigen.

The use of recombinant live vector vaccines has progressed considerably over the past decades and a substantial number of marketing authorisations are available of this type of vaccines.

In the guideline, the scope is defined as: 'Vaccines where a live micro-organism (bacteria or virus) has been modified to express entire genomes or a portion of foreign RNA or DNA sequences or proteins and where the replicative competent vector acts as a carrier and may itself act as a protective immunogen fall within the scope of this guideline.' It should be considered for which types of recombinant vector vaccines the guideline provides advice.

The concept of a vaccine platform technology master file is introduced in the European Union (EU) legislation in Annex II of the Regulation (EU) 2019/6 (Commission Delegated Regulation (EU) 2021/805 of March 2021 amending Annex II to Regulation (EC) No 2019/6 of the European Parliament and of the Council). This is a new concept in EU legislation for the authorisation of immunological veterinary medicinal products (IVMPs) that aims to avoid the unnecessary re-submission and re-evaluation of data relating to a vaccine platform technology used in an already authorised IVMP for subsequent vaccines based on this platform. This possibility should be reflected in the revised guideline.

The existing guideline should be reviewed taken into consideration the requirements of Annex II of Regulation (EU) 2019/6.

4. Recommendation

The Immunologicals Working Party recommends revising the "Guideline on live recombinant vector vaccines for veterinary use" to consider scientific and regulatory developments since the guideline came into effect and experiences gained. Based on this, it is considered that the following areas in particular will require amendment: definitions, scope, description of the starting materials, safety and efficacy testing. Furthermore, the possibility of using the concept of the vaccine platform technology master file should be addressed.

5. Proposed timetable

April 2023	Concept paper endorsed by IWP
June 2023	Concept paper released for consultation
September 2023	Deadline for comments
Q4 2023	Discussion in IWP
Q2 2024	Proposed date for release of draft guideline for consultation
Q3 2024	Deadline for comments
Q4 2024	Expected adoption by CVMP

6. Resource requirements for preparation

The revision of the guideline will involve the IWP (including a drafting group composed of rapporteur, co-rapporteur and 1-2 IWP members).

The IWP drafting group will meet virtually as required (e.g. 3-4 virtual meetings). Discussion is foreseen at 1-2 IWP plenary meetings.

7. Impact assessment (anticipated)

It is anticipated that the revised guideline would benefit both industry and regulators due to provision of more up-to-date and relevant guidance on development and manufacture of recombinant live vector vaccines for veterinary use.

8. Interested parties

Veterinary pharmaceutical industry and consultants.

Regulatory authorities involved in assessment of marketing authorisation applications.