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SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the revision of the note for guidance on the use of adjuvanted veterinary vaccines

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 'Note for guidance on the use of adjuvanted veterinary vaccines' (EMA/CVMP/IWP/043/97).

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

Keywords	Adjuvant, immunological veterinary medicinal product, veterinary vaccine

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. Introduction

The 'Note for Guidance on the Use of Adjuvanted Veterinary Vaccines' (EMA/CVMP/IWP/043/97) was adopted in November 1998 and came into effect on 1st December 1998. This document was intended to provide advice to manufacturers seeking marketing authorisation for veterinary vaccines containing an adjuvant. In recent years, experience has been gained from pharmacovigilance and within the regulatory network on such vaccines and some legal provisions have changed, e.g. pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (Regulation 37/2010). Adjuvants as part of an immunological veterinary medicinal product are therefore subject to this Regulation. Some scientific aspects of the guidance are therefore now considered to be in need of updating.

2. Problem statement

The 'Note for Guidance on the Use of Adjuvanted Veterinary Vaccines' is now over eighteen years old, and was developed at a time when only a few adjuvants were available. Considering the scientific developments in the field of veterinary adjuvants and the potential for these novel adjuvants to be included in applications for marketing authorisations, the CVMP/IWP considers that this guidance should be updated in order to reflect current knowledge on classical and new adjuvants and ensure continued relevance for development of commercial vaccines and other immunological products for veterinary use.

3. Discussion (on the problem statement)

The use of adjuvants is common in immunological veterinary medicinal products, irrespective of the species (mammalian, avian, fish) to be vaccinated, the antigen(s) in the vaccine or the nature of the product (live, inactivated, subunit etc.). Although recent advances have resulted in the development of adjuvants which induce less local and/or general reactions in the treated animal, this has not necessarily resulted in the inclusion of these newer type adjuvants in vaccines and other immunological products for veterinary use. One reason for the lack of progress in products containing novel adjuvant systems is because manufacturers consider the regulatory guidance associated with establishing the safety for the animal and consumers inadequate for new substances. The revision of the note for guidance needs to reflect this item to allow the introduction of new adjuvants in veterinary immunological products. It is therefore an appropriate time to review the guidance with a view to updating it to take account of more recent scientific developments and experience gained. Some examples where revision may be particularly appropriate include, but are not limited to:

- The need to update the requirements for quality, safety and efficacy testing of products containing adjuvants and the type of data to be presented in the marketing authorisation application;
- The need for particular consideration of the use of adjuvants in various species;
- The need to address and clarify the requirements for food producing animals concerning maximum residue limits for adjuvants;
- The need to include requirements for adjuvants used as solvent for a range of immunological products;

- Extend the scope of the note for guidance to immunological veterinary products other than conventional veterinary vaccines e.g. to include novel products which have an impact on the immune response.

4. Recommendation

The Immunologicals Working Party recommends revisiting the contents and replacing the note for guidance on the use of adjuvanted veterinary vaccines with a new guideline, to take into account scientific developments and experience gained since the guidance came into effect. Based on this it is considered that the following areas in particular will require amendment: types of adjuvants, test procedures, assessment criteria for local and general reaction, the criteria for benefit-risk assessment, data requirements for marketing authorisation application.

5. Proposed timetable

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

6. Resource requirements for preparation

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

Discussion at 2 – 3 IWP meetings.

7. Impact assessment (anticipated)

It is anticipated that the revised guidance would benefit both industry and regulators due to provision of more up-to-date and relevant guidance on development and manufacture of adjuvants for use in the formulation of immunological veterinary medicinal products.

8. Interested parties

Veterinary pharmaceutical industry and consultants.

Regulatory authorities involved in assessment of Marketing Authorisation applications.