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Guideline on duration of immunity achieved by veterinary vaccines

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This guideline replaces the Note for guidance: Duration of protection achieved by veterinary vaccines (EMEA/CVMP/682/99-FINAL).

Keywords	***Duration of immunity, veterinary vaccines***

*The current revision consists of administrative changes made in order to align the guideline to the new definitions and terminology provided by Article 4 of Regulation (EU) 2019/6. The references to the legislation applicable and other scientific guidelines have also been updated. As no changes were made to the scientific content, no concept paper and no public consultation were deemed necessary.

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Executive summary

This document provides information on the points to be considered in the design and conduct of studies in support of the duration of immunity of immunological veterinary medicinal products (IVMPs).

The guideline outlines the data requirements in support of duration of immunity of IVMPs after basic vaccination and after re-vaccination. Also, requirements for vaccines inducing active or passive immunity are indicated.

1. Introduction (background)

Concerning immunological veterinary medicinal products, Regulation (EU) 2019/6 states that unless justified, the onset and duration of immunity shall be established and supported by data from trials.

The European Pharmacopoeia states that any claim regarding the duration of immunity achieved by vaccines shall be supported by evidence of protection, without specifying the methods and requirements concerned.

The formulation of claims shall take into account the guidance contained in the Position paper on Indications and Specific Claims for immunological veterinary medicinal products.

In the case of vaccines, efficacy means induction of immunity to provide protection. The nature, degree, onset and duration are the main parameters of the protection.

The duration of immunity achieved by vaccines is influenced by a number of factors such as the characteristics of the causal agent(s) of the disease, the epizootiology of the infection, the immunogenicity of the active substances of the vaccines and the nature of the immune response of the target animals.

The duration of immunity may be different for each category of vaccines and for the products within a category of vaccines, as a consequence of the quality and properties of the products concerned.

In addition, it has to be realised that the duration of immunity achieved under field conditions can vary from time to time and can also vary from that achievable under laboratory conditions because of the influence of a number of factors, such as the field conditions of use, e.g. exposure to the infectious agent(s) and the health, condition and immunological status of the animals to be vaccinated.

The guidance in this paper is specifically aimed at vaccines against infectious diseases, although the same principles may be applicable to products which through immunological mechanisms affect the physiological functions of an animal.

In order to avoid frequent vaccinations, it is recommended to study the vaccines in a manner which demonstrate the actual duration of immunity provided and to develop products that provide as long a duration of immunity as possible.

2. Scope

The scope of this guidance is to define what data shall be generated from trials and how such data can then be used to support claims for the duration of immunity achieved by veterinary vaccines.

3. Legal basis

The legal basis for the authorisation of a veterinary medicinal product is laid down in Regulation (EU) 2019/6. This guideline should be read in conjunction with part 4, title II of Annex II to Regulation (EU) 2019/6, as amended.

In addition, Ph. Eur. chapter 5.2.7, monograph 0062 and relevant individual monographs should be taken into account, as well as all other relevant EU and VICH guidelines.

For vaccines within the scope of this guideline containing GMOs, the legal requirements as outlined in Article 8.5 of Regulation (EU) 2019/6 will apply.

4. Duration of immunity

For most infectious animal diseases, one administration of a vaccine does not provide protection which will last for the natural or economical life of the animals. Therefore, regimens of vaccination are in most cases necessary.

Where multiple administrations of a vaccine are recommended in the basic vaccination scheme and/or the re-vaccination scheme, the duration of immunity after completion of the basic vaccination or the re-vaccination has to be addressed.

Where there is no recommendation for re-vaccination, the claimed duration of immunity shall be specified and supported by sufficient data. In such cases, the duration of immunity is expected to be related to the natural or economical lifespan of the target species.

In cases of seasonal diseases, it will be sufficient to demonstrate the duration of immunity in the year after vaccination until the end of the natural occurrence of the disease. The protection in the seasonal period(s) in the next year(s), with or without re-vaccination, will have also to be addressed.

It is not possible to generalise about the minimum period for which a vaccine shall be expected to provide protection. However, in all cases, the duration of immunity demonstrated shall be justified in relation to the length of time for which an animal is likely to be at risk.

5. Data requirements

The duration of immunity that can be claimed is the longest interval between the administration of a vaccine to target animals and the observed protection.

The studies required to generate this data shall be conducted under well-controlled conditions. Where laboratory trials cannot be supportive of the duration of immunity, the performance of clinical trials alone may be acceptable. While the duration of immunity is investigated in the studies, it shall be ensured that the vaccinated target animals are not exposed to intercurrent field infection which could confound the results. It is usually necessary, therefore, to maintain unvaccinated target animals to act as sentinels in pre-clinical or clinical studies to provide the assurances needed on this point.

5.1. Duration of immunity from the basic vaccination scheme

5.1.1. For active immunity

The duration of immunity provided by the basic vaccination scheme shall usually be demonstrated by a challenge of vaccinated animals just before the recommended time point for re-vaccination (if applicable).

5.1.2. For passive immunity

The duration of immunity of the progeny by passively acquired antibodies shall usually be demonstrated by a challenge at the time of natural susceptibility of the offspring of female animals which have been vaccinated at the maximum interval recommended between the basic vaccination scheme and parturition or lay.

In addition, data shall be presented to support the duration that is claimed for the protection of the offspring.

The nature of the disease concerned, including the age of the animals at which the onset of the disease usually occurs, as well as the onset of age resistance needs to be taken into account.

5.2. Duration of immunity from the re-vaccination scheme

The re-vaccination shall result in protection that is quantitatively and qualitatively at least equivalent to the response to the basic vaccination scheme. This is best demonstrated by challenge trials at suitable times between the end of the scheme and the end of the claimed period of protection thereafter.

Vaccination-challenge trials, in particular those to study the duration of immunity, are expensive and time-consuming as well as having animal welfare issues involved. In order to limit the need for frequent challenges in studies on the duration of immunity, it may be considered:

- to challenge of a lower number of immunised animals
- to measure the protection using a suitable indicator other than challenge.

Antibodies against the causal agent(s) of the infectious disease may be an example of such indicators.

For such an indicator to be acceptable, evidence shall be provided to show that the indicator plays a substantial role in the protection of the target species and that there is a sufficient qualitative and quantitative relationship between the indicator and the protection of the target species against the disease concerned.

It must be demonstrated (via serological studies or other markers of protection) that the level of response before revaccination or at the end of the protection period can be considered as equal to the one observed at the time of challenge used to demonstrate the efficacy.

In order to avoid unnecessary challenge studies, efficacy data from a vaccine of a larger combination of active substances may be used to support the duration of immunity of the smaller combination. Similarly, the results from challenge studies with a vaccine containing fewer active substances may be used to support the duration of immunity of the larger combination. In both cases certain provisions apply, these are detailed in the Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (EMA/CVMP/IWP/594618/2010).

Since the immune systems of -even related- species are different, the use of data from trials in a species other than the target species will normally not be acceptable.

In view of the diversities of species and diseases, each case has to be considered on an individual basis.

Definitions

For the purpose of this guidance the following definitions apply:

Basic vaccination scheme: one or more administrations of a vaccine with the second and any recommended subsequent doses given a short time after the first dose. This is the vaccination scheme which is necessary to obtain and maintain the level of protection claimed by the applicant.

Re-vaccination scheme: one or more administrations of a vaccine used to maintain its initial protective effects, induced by the basic vaccination scheme. The first (or only) dose of the re-vaccination is given a relatively long time (e.g. 3 months or more, depending on the species and the disease) after the basic vaccination scheme.

Regimen of vaccination: the basic vaccination scheme and re-vaccination scheme altogether.