International Alliance for
Biological Standardization

Avoiding Antimicrobial Resistance: Veterinary Use of Phages for Prevention, Therapy and Control of Bacterial Infections

November 19-20, 2024
Virtual Meeting

Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy

Currently, bacteriophages are reappearing in the therapeutic arsenal as a potential alternative to antibiotic therapy (or to complement the latter) as a salvage therapy in therapeutic dead end, due to increasing antibiotic resistance.

In the veterinary field, these products can be classified as medicines and require a marketing authorization before commercialisation, as stated in Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

Bacteriophages as therapies present certain peculiarities. Their action is linked to their lytic activity, generally restricted to specific bacterial strains. Additionally, the interaction bacteriophage-host bacteria is a dynamic process and host bacteria might develop resistance against bacteriophages with some frequency.

Consequently, VMP based on bacteriophages are expected to require frequent changes in composition for the bacteriophage strain(s) to maintain efficacy/circumvent resistance development in relation to the intended indication.

In order to avoid regulatory constraints due to the variable composition of bacteriophages as medicinal products, the EMA drafted the Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy.

The applicable regulatory/technical and scientific requirements for the marketing authorization of this type of medicines are described there.

The guideline establishes the basis for the authorization of phage products with flexible qualitative and quantitative composition as veterinary medicines.

In general, the requirements stated in Annex II of Regulation (EU) 2019/6 should be followed. Phage therapy products are classified as novel therapies (NT) and this allows the application of risk-based principles for determining the requirements for the marketing authorization.

The allowed adaptation implies a deep scientific knowledge of the product, the application of risk based approaches, and appropriate design of quality risk management system, and pharmaceutical quality systems.

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In the guideline, the concepts of parental bacteriophage products and representative preparations are explained. Both concepts allow the authorisation of medicines with variable composition on bacteriophages.

The guideline would benefit both industry and regulators due to provision of a relevant guidance on data requirements for bacteriophages medicinal products. It will facilitate and speed up the development and authorisation of veterinary medicinal products specifically designed for phage therapy, hence contributing to increase the availability of the veterinary medicinal products tackling with antibiotic resistance.

The development of the guideline involved experts of the OEG (operational expert group) on bacteriophages, the NTWP (Novel therapy Working Party), and the CVMP (Committee for Veterinary Medicinal Products). We would like to thank all the experts collaborating in this work.