14 January 2026
EMA/CVMP/IWP/54533/2006–Rev.1*
Committee for Veterinary Medicinal Products (CVMP)

Guideline on user safety for immunological veterinary medicinal products

Adopted by Committee for Veterinary Medicinal Products (CVMP)	18 April 2007
Revised guideline (revision 1) agreed by Immunologicals Working Party (IWP)	22 October 2025
Adopted by CVMP	14 January 2026
Date for coming into effect	14 July 2026

* This guideline replaces the Guideline on user safety for immunological veterinary medicinal products (EMEA/CVMP/IWP/54533/2006).The current revision consists of administrative changes made in order to align the guideline to 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.

Keywords	***User safety, Hazard identification and characterisation, exposure assessment risk characterisation, risk management, risk communication***

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Executive summary

This guideline provides a structured approach for the assessment and management of user safety risks associated with immunological veterinary medicinal products (IVMPs**)** in the European Union, in line with Regulation (EU) 2019/6.

It applies to new applications and variations for marketing authorisation and supports the inclusion of appropriate warnings and precautions in the Summary of Product Characteristics (SPC) and package leaflet.

The user is defined as any person who may come into contact with the product during storage, preparation, administration, or disposal which includes veterinarians, farmers, and animal owners. Special populations (e.g. immunocompromised persons, pregnant women) must be specifically considered.

1. Introduction (background)

Applications for marketing authorisations of veterinary medicinal products (VMPs), including immunological veterinary medicinal products (IVMPs) in the European Union are issued in accordance with Regulation (EU) 2019/6 . This legislation requires that the applicant provides documentation on the reasons for any precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human and animal health and to plants. For VMPs that imply such risks, the legislation allows for the definition of special precautions to be taken by the person administering the VMP to animals, in order to reduce the risks to an acceptable level. Those precautions are to be stated in the summary of products characteristics (SPC) and package leaflet (Articles 14.1.(i).

Regulation 2019/6, Annex II, section III.3B(7) (User safety) states that appropriate user warnings and other risk management measures shall be formulated to mitigate any risk derived from human exposure to the product.

Guidance on remedial action to be taken following accidental contact should also be given, when necessary. It might be helpful to describe the expected outcome of a self-injection.

The legislation does not give specific guidance on exact data requirements and assessment methods to be used to identify the risks, or on the measures for risk reduction, but refers that user safety shall be addressed in accordance with relevant guidance published by the Agency. This guideline is presented to provide this guidance for user safety related to IVMPs.

2. Scope

This guideline applies to new applications and variations for marketing authorisation for IVMPs and does not require the generation of specific or additional data.

The assessment of the user safety of a product should address only the exposure situations resulting from the normal conditions of use and from the foreseeable accidents (including accidental self-injection, oral ingestion, inhalation). It does not include exposure situations resulting from deliberate misuse.

For the assessment of user safety, the user is regarded as any person administering the IVMP or that may come into contact with the IVMP or components of the product before its application to the animal (e.g. during storage or preparation of the product to be administered), during its application, and after its application (e.g. through contact with disposed of, unused or waste product, or with treated animals). This implies that the user can be for example a veterinarian, a farmer, a breeder, a pet-owner or any

person used to assist in restraining the animals during vaccination or living in the same environment. Consumers of products derived from vaccinated food producing animals (meat, milk etc.) are excluded from this definition. This guideline does not cover occupational safety during the production of IVMPs.

3. Legal basis

This guideline should be read in conjunction with the relevant principles and requirements of Regulation 2019/6 of the European Parliament and of the Council on veterinary medicinal products, relevant European Pharmacopoeia (Ph. Eur.) monographs and chapters as well as all other relevant EU and VICH guidelines.

4. Principles of assessment

The assessment of the user safety will comprise the following steps:

i. hazard identification and characterisation

ii. exposure assessment

iii. assessment of the consequence of a hazard occurring

iv. risk characterisation

v. risk management (selection and assignment of appropriate control measures)

vi. risk communication.

All relevant exposure scenarios should be considered. To allow the characterisation of risks for each scenario, the hazards should be identified and characterised, taking into account the route and frequency of anticipated exposure. When there is a predicted risk for the user, appropriate measures for risk management should be proposed and evaluated.

Special attention should be paid to categories of potential users, such as immunocompromised persons (due to disease or immunosuppressive treatment) and pregnant women who may be more susceptible and should therefore avoid exposure to infectious challenges.

Following the risk assessment, and on a case-by-case basis, the appropriate warnings, if any, are incorporated in the SPC.

5. Hazard identification and characterisation

From data collected during the research and development phases of a specific IVMP and without requiring extra experimental workload, it is important to know if and what specific hazard exists for the user of that product.

Effects predominantly have to be assessed for the active substances of the IVMPs. If a potential risk is identified, it may in addition be necessary to assess the effects of one or more excipients, especially adjuvants.

For live vaccines, the pathogenicity of the vaccine strain for humans is the main concern (zoonotic agents, such as brucella, rabies virus, salmonella or Newcastle disease virus).

Pathogenicity for humans should be assessed based on published cases of human exposure to the same strain (e.g. for *Brucella melitensis* Rev.1), or on published information on related modified or field strains (e.g. rabies). Some agents, that are not pathogenic for humans as such, may become a concern in the case of immunocompromised individuals or pregnant women (e.g. toxoplasma, chlamydia). Added

adjuvants (e.g. oily adjuvants), or other components (e.g. preservatives) may cause local or systemic reactions following accidental self-injection.

6. Exposure assessment

The assessment of any risk deriving from an IVMP should consider the way of preparation (e.g. recovery from liquid nitrogen, resuspension or dilution of the ingredients, the filling into application systems as well as the route of administration (e.g. injection by syringe or mechanical device, coarse spray, oral application). The absolute amount or concentration of the active substances or the excipients of the IVMP, the duration and the frequency of exposure to the vaccine (e.g. single dose, repeated dose, booster or seasonal/occasional vaccination) should be considered as well as the number, the species and category of animals to be vaccinated (e.g. individual or mass vaccination, companion or food producing animals, young or pregnant animals). The time period, during that the IVMP may be excreted by vaccinated animals, should be considered in case of potential pathogenicity for humans.

The risk of exposure to the IVMP may affect the person who administers the vaccine as well as persons assisting in restraining the animal(s). When the vaccine strain is excreted by the vaccinated animal(s), the animal owners or caretakers may be affected after vaccination in addition (in case of potential pathogenicity for humans).

7. Risk characterisation

Risk characterisation integrates the results of the hazard identification and the release assessment into a risk statement that includes a likelihood rating (low, medium, high) and a consequence rating (low, medium, high).

If the risk correlates with the amount of IVMP a person was exposed to or the time of exposure, the effects can be quantified to some extent. However, the quantitative assessment of effects after exposure to live vaccines in case of pathogenicity of the vaccine strain(s) for humans may be limited.

8. Risk management and communication

Risk management includes the design and implementation of mitigative procedures to reduce or eliminate potential safety risks.

When the outcome of the assessment identified a specific risk for persons being in contact with the vaccine (or vaccinated animals), recommendations for the use of the IVMP should be proposed and, according to regulation (EU) 2019/6 (articles 35 and 14), appropriate warnings incorporated in the SPC and the package leaflet, such as:

- Prevention or minimising exposure to the product during administration and, where relevant, during preparation and/or following administration. Corresponding recommendations may include the use of personal protective equipment according to the route of administration (e.g. gloves, masks).
- Identification of highly susceptible categories of users (e.g. immunocompromised persons, pregnant women) and their exclusion from contact with the product.
- Remedial action to be taken following accidental contact, when necessary. The expected outcome of any exposure, including self-injection, should be described. This is particularly applicable in case of exposure to live zoonotic agents and oily adjuvants. If it is deemed necessary to include some advice to consult a physician after exposure to the IVMP, clear instructions should be given on the treatment after exposure, if required measurements exceed common medical practice. In any case, statements like "seek medical advice immediately and show the package insert or the label to the

physician", should be included only when a relevant risk (e.g. after self-injection with a vaccine containing mineral oil) has been identified.

If the risk assessment is inconclusive regarding an effect, for example due to absence of clear correlation between an effect and the exposure to an IVMP, a statement could be included on a case-by-case basis, depending on the severity and probability of the possible reaction.