

Risk management plan for novel therapy VMPs

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Risk Management Plan (RMP) for novel therapy veterinary medicinal products

Background

Legal basis
and rationale

Benefits and
intended
outcomes

Guidance for
applicants

Background

- A risk management plan (RMP) is **required for the authorisation** of veterinary medicinal products classified as novel therapies.
- The RMP focuses on **risks linked to the specific characteristics of the novel therapy**, including rare, long-term, or highly specific risks beyond routine pharmacovigilance activities.
- It should **be provided by the applicant** in the initial marketing authorisation dossier submission (Part 1a).
- The proposed RMP will be assessed by the CVMP as part of the overall **evaluation of the marketing authorisation application**, and a summary will be published as part of the product's EPAR.

**Risk management plan
for novel therapy
veterinary medicinal
products**

Legal basis and rationale

►B 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
(Text with EEA relevance)
(OJ L 4, 7.1.2019, p. 43)

SECTION V

REQUIREMENTS FOR MARKETING AUTHORISATION APPLICATIONS FOR PARTICULAR VETERINARY MEDICINAL PRODUCTS

This Section lays down specific requirements for identified veterinary medicinal products related to the nature of the active substances contained therein.

V.1. Novel therapies veterinary medicinal products

V.1.1 General requirements

V.1.1.6. To address data gaps or uncertainties at the time of product authorisation, implementation of post-authorisation measures or studies may be considered on a case-by-case basis. In order to detect early or delayed signals of adverse reactions, to prevent clinical consequences of such reactions and to ensure timely treatment and to gain information on the long-term safety and efficacy of novel therapy veterinary medicinal products a risk management plan shall detail the measures envisaged to ensure such follow up.

[Commission Delegated Regulation \(EU\) 2021/805](#)

C/2024/1443

14.2.2024

COMMISSION NOTICE

Guidance to Applicants - Veterinary Medicinal Products

(Text with EEA relevance)

(C/2024/1443)

3. MARKETING AUTHORISATION APPLICATIONS

3.1. General principles and requirements

Marketing authorisations subject to obligations or conditions

Marketing authorisations for veterinary medicinal products can be subject to specific obligations and/or conditions where appropriate, including but not only in the case of marketing authorisations for antimicrobial veterinary medicinal products and marketing authorisations granted under Articles 23 (limited markets) and 25 (exceptional circumstances) of the Regulation.

In the case of marketing authorisations granted for novel therapy veterinary medicinal products, the imposition of post-marketing authorisation studies can be considered on a case-by-case basis. Regardless of whether post-authorisation studies are imposed, applicants for such products should submit a risk management plan detailing measures envisaged to ensure appropriate follow-up of treated animals with a view to detecting early and delayed adverse reactions and to gain information on the long-term efficacy and safety profile of the concerned novel therapy veterinary medicinal product ⁽³⁸⁾.

[Guidance to Applicants – Veterinary Medicinal Products](#)

Benefits and intended outcomes

- Detection of early or delayed signals of adverse reactions.
- Prevention of clinical consequences of adverse reactions and ensure timely treatment.
- Information gain on long-term safety and efficacy of novel therapy veterinary medicinal products.

The RMP focuses on risks linked to the specific characteristics of the novel therapy, addressing rare, long-term, or highly specific risks beyond routine pharmacovigilance.

CVMP developed guidance with a dedicated, fit-for-purpose template.

**Risk management plan
for novel therapy
veterinary medicinal
products**

Guidance for applicants



12 March 2026

Guidance and template on the risk management plan (RMP) for novel therapy veterinary medicinal products

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Risk management plan for novel therapy veterinary medicinal products: template



Guidance for applicants: RMP template

- **Identification of risks** associated with the specific novel therapy VMP, confirmed and potential, based on the available data and its intrinsic characteristics.
- Discuss **clinical consequences**, early signals of adverse events that may occur, delayed adverse events that may occur, and the monitoring of long-term safety and efficacy.
- Discuss the **methodology** used to capture these events and assess whether they are adequately monitored through standard pharmacovigilance (PhV) activities.
- If **additional PhV activities or risk minimisation measures are needed**, provide justification for their inclusion in the risk management plan.
- If **no additional measures** are to be applied, justification that the standard PhV and risk minimisation activities are sufficient to manage the concerns.

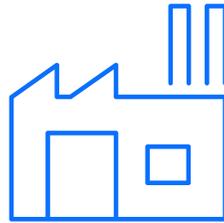
Risk identification for novel therapy VMPs



Preclinical and clinical data available for the product



Product composition, including the use of biological or other complex materials



Manufacturing process



Mode of action



Administration



Some points for considerations

- Have the correct classification for your veterinary medicinal product.
- Be concise when listing identified or potential risks.
- Ensure all information is scientific and non-promotional.
- Template is non-exhaustive and intended as flexible guidance.
- Requirements should be adapted to the specific product.
- Focus on risks that are rare, long-term, or highly specific to the category of novel therapy, as standard pharmacovigilance already covers continuous monitoring of the VMP.



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