EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Concept paper on the development of a guideline for using owner assessment as efficacy parameter

Agreed by Efficacy Working Party (EWP-V)	November 2025
Adopted by CVMP for release for consultation	14 January 2026
Start of public consultation	23 January 2026
End of consultation (deadline for comments)	30 April 2026

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

Keywords	Owner assessment, efficacy, endpoints, target animal species

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1. Introduction

In recent years, owner assessment has been employed as either a primary or secondary endpoint for demonstrating clinical efficacy in a number of application procedures for authorisation of veterinary medicinal products. Historically there has been discussion on the relevance of owner-assessed endpoints with regard to their reliability and validity[1]. Consequently, the CVMP has identified the need to develop guidance on owner assessed parameters used to support the demonstration of efficacy for veterinary medicinal products.

Problem statement

Both primary and secondary efficacy endpoints are generally used to support demonstrating efficacy of a veterinary medicinal product. Objective endpoints are preferred given that they are considered to be more standardised, reproducible, and based on 'hard' facts that are not subject to dispute. However, measurement of objective endpoints may have practical limitations in a clinical setting (e.g. it may not always be possible to perform laboratory tests, etc.). In such cases, consideration needs to be given to the use of different endpoints such as owner assessment of response to treatment. However, it is acknowledged that there is likely to be some degree of subjectivity in the measurement of any endpoint (e.g. assessment of gait). Regardless of the type of endpoint employed, it is essential that it has reliability and validity.

In certain cases, animal owners may be able to provide a well-informed assessment of response to treatment in their animal(s), and which may, on occasion and depending upon the parameters being measured, be more representative than in a clinical setting. For example, for some animal species (e.g. cats), assessment of certain endpoints, such as pain, may be more difficult when presented to a veterinarian, since the animals may not display their natural behaviour and often have a stress response making it more difficult to meaningfully assess clinical signs or response to treatment.

It is therefore proposed that guidance is developed to provide clarification on what might be considered an acceptable and appropriate approach to the use of owner assessment as an efficacy parameter for the purpose of demonstrating efficacy of a veterinary medicinal product.

Discussion (on the problem statement)

Based on previous experience of applications for marketing authorisation of veterinary medicinal products, owner assessment has been used to varying extent and with varying acceptance (depending upon the methods used and the data generated). Different assessment tools have been used to assess pain in animals using various scales and clinical signs. However, reliability and validity of the various approaches differ substantially as does the degree of subjectivity. Differences have also been noted in respect of the suitability of the assessment tools for the intended indication(s) and the approach to ensuring consistent application and interpretation of those tools (e.g. explanation to and training of animal owners).

It is therefore proposed that the guidance to be developed will address at least the following:

- General approach to the use of animal owner assessment;
- Guidance on the approach to selection of tools to be used by owners;

[1] validation refers to the process of testing whether a tool/method is appropriate for purpose, i.e. testing its reliability (whether it measures something consistently) and validity (whether it actually measures what is says it measures). A tool/method is therefore valid when it has proven validity in test-theoretical sense.

- Measures to be taken to ensure that the methods of assessment performed by owners are reliable and appropriately validated;
- Suggestions for approaches to ensuring reliability in owner assessment and therefore validity of the findings;
- Recommendations on the selection of clinical parameters that are suited to owner assessment;
- Examples of situations where owner assessment might be used as the primary efficacy endpoint and where owner assessment may be better suited to being used as a secondary efficacy endpoint.
- Considerations on use of questionnaires such as 'quality of life' questionnaires and their relevance for supporting efficacy.

Considering the above, the need to develop guidance was identified by CVMP in order to provide a clear framework for inclusion of owner assessment as an efficacy endpoint. The objective of the guidance would be to provide a framework for veterinary pharmaceutical industry and regulatory authorities involved in the assessment of marketing authorisation applications, in order to identify acceptable approaches to owner assessment, which could then be used appropriately and yield meaningful results.

Recommendation

The CVMP recommends the development of a guideline on the use of owner assessment as an efficacy parameter, in order to provide clear guidance on the topic, taking into account the issues identified above, current scientific knowledge, and regulatory requirements.

Proposed timetable

January 2026	Concept paper adopted by CVMP and released for public consultation
April 2026	Deadline for comments from interested parties
January 2027	Expected date for adoption of the draft guideline by CVMP for release for consultation
July 2027	Expected end of consultation on the draft guideline
December 2027	Expected date for adoption by CVMP and publication of the final guideline

Resource requirements for preparation

Development of the guideline will involve a rapporteur and co-rapporteurs from EWP-V, as appropriate.

The preparation of the draft guideline will require discussion at several EWP-V plenary meetings. Drafting group meetings (virtual) will be organised, as needed.

Impact assessment (anticipated)

The development of the guideline is expected to improve the guidance available to applicants as well as to regulatory authorities. It is not intended to increase the requirements for marketing authorisation applications for veterinary medicinal products.

Interested parties

- Veterinary pharmaceutical industry and consultants.
- EU regulatory authorities involved in the assessment of marketing authorisation applications for veterinary medicinal products.
- Veterinary organisations and professional bodies.
- Scientific veterinary associations.