

EMA Veterinary Medicines Info Day 2026

Regulatory and procedural developments

Kristina Paterson
Head of Veterinary Regulatory Affairs and Referrals





Table of contents

Data
protection

Limited
markets

Article 25
applications

Novel
therapy VMP
classification

Clock-stop
extension

Invented
names

Contacting
the Agency

QRD v9.1

Transparency on periods of data protection

- Increased complexity of data protection framework under Regulation (EU) 2019/6.
- **Responsibility of the applicant** to ensure that the period of protection has expired. ⁽¹⁾
- Competent authorities to **reject applications** in breach of the period of protection (based on information provided by applicants).
- No responsibility for competent authorities to **define or publish the date** of expiry of the period of protection.
- Increased transparency in EPARs on the applicability of legal provisions.

⁽¹⁾ Article 18(1)(c) of Regulation (EU) 2019/6; [EC Guidance to Applicants](#)

“With regard to Article 40(5), this variation meets the scientific criterion, because the applicant has demonstrated an improvement of the benefit-risk balance of the veterinary medicinal product (criterion (b) of Article 40(5)).”



Limited markets (LM): updated guidance

New Q&A document

Supersedes the reflection paper on the classification of a product as intended for a limited market.

LM classification is provisional: the validity will be checked at all stages of the procedure up to issuing the marketing authorisation decision. The same criteria used for the initial classification will be reviewed.

Scientific guidelines adopted in 2024 **remain unchanged.**

What falls under 'exceptional circumstances' and what doesn't?

- No legal definition of *exceptional circumstances*.
- Art. 25 is a derogation of Art. 8(1) and should be interpreted **narrowly**.
- Article is product-agnostic, i.e. all categories of products could be eligible.
- 'Unmet medical need' in and by itself **does not constitute exceptional circumstances**.

Article 25

Applications in exceptional circumstances

By way of derogation from point (b) of Article 8(1), in exceptional circumstances related to animal or public health, an applicant may submit an application which does not meet all requirements of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided. In such a case, the applicant shall be required to demonstrate that for objective and verifiable reasons certain in accordance with Annex II cannot be provided.

Source: Regulation (EU) 2019/6

Novel therapy veterinary medicines classification



Confirmation of novel therapy category will help **define dossier requirements** and regulatory aspects, including the need for a risk management plan (RMP).



Voluntary request⁽¹⁾ for classification of novel therapy VMPs at any stage of the development.

Free of charge



If no classification has been provided, the Agency will address it with the applicant at the stage of confirming **eligibility**.

⁽¹⁾ Using the [form for classification of veterinary medicinal products](#) (non-biological, biological non-immunological, or biological immunological).

Requests for clock-stop extension



- Recent requests to CVMP for initial MAA and variations:
 - Multiple requests for the same application;
 - Requests for long extensions.
- In many cases, the underlying reason seems to be a **prematurely submitted** dossier and hence the need to finalise/carry out further studies during the clock-stop.
- EMA/CVMP planning on working on a procedural guidance document on clock-stops, similar to CHMP - **stricter approach envisaged.**

Applicants are advised to submit their requests in a timely manner and provide sufficient justification.

Invented names check

- In particular, the (invented) name of a veterinary medicinal product:
 - should not convey misleading therapeutic or pharmaceutical connotations;
 - should not be misleading with respect to the composition of the product.
- Multiple requests for the same application, but **two** invented names can be proposed per procedure.
- Applicants advised to ensure the names are in line with the guideline to avoid the need for additional checks.
- Past precedents of non-compliant names not taken into account.



16 May 2013
EMA/248010/2007
Committee for Veterinary Medicinal Products (CVMP)
EMA/328/1998-Rev.3¹

Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure

Adopted by CVMP for release for consultation	June 2007 ²
End of consultation (deadline for comments)	30 September 2007 ³
Adopted by CVMP	16 January 2008

The objective of the guideline is to provide applicants/Marketing Authorisation Holders (MAHs) guidance on the criteria applied by CVMP when reviewing the acceptability of the proposed names for medicinal products processed through the centralised procedure.

It provides details on the procedure for checking the acceptability of the proposed names.

[Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure](#) – **under revision**

Channels for contacting the Agency

① Ask EMA

- General questions on veterinary medicines, website content, reporting missing documents, or general regulatory clarifications (not for ongoing procedures).
- Single interaction. The query will be responded by EMA expert.
- Does not require an EMA account.

② Service Now

- Technical support and reporting bugs or accessibility issues with EMA IT systems.
- Start administrative, pre-submission and certain post-authorisation veterinary regulatory procedures.
- Multiple interactions possible within the same query.
- Requires an EMA account.



Alignment with QRD v9.1

Legal deadline: 29 January 2027

- The product information of VMPs needs to be aligned with the requirements of Regulation (EU) 2019/6 by 29 January 2027 to allow for batches to be released on the market.
- No exceptions from this legal requirement are expected to be accepted after the deadline.
- MAHs are reminded to submit a VRA G.I.18 in a timely manner.



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Thank you

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