DD Month YYYY

Request to the CVMP for classification of a veterinary medicinal product <name> as intended for a limited market according to Article 4(29) and for eligibility for authorisation according to Article 23 (Applications for limited markets)

\* Request submitted by <Company Name, full address>

\* Customer account number[[1]](#footnote-2): <number>

\* Customer purchase order or Reference Number[[2]](#footnote-3): <number, if not applicable please state: n/a>

\* Does the Applicant have Small and Medium Enterprises (SME) status:

Yes, SME designation number: <number e.g. EMA/SME/123>

Not yet

N/A

\* Request in relation to <product name> containing the active substance <active substance[[3]](#footnote-4)>

\* Proposed indication: <indication>

\* Target species: <please specify>

(\* all above fields are mandatory)

Introduction

This document provides data to assist the Committee for Veterinary Medicinal Products (CVMP) in considering if the veterinary medicinal product <product name> meets the criteria for a limited market in accordance Article 4(29) of Regulation (EU) 2019/19 and is eligible for submission as an application for marketing authorisation in accordance with Article 23(1) of Regulation (EU) 2019/6.

According to Article 4(29) of Regulation (EU) 2019/6 ‘limited market’ “*means a market for one of the following medicinal product types:*

*(a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;*

*(b) veterinary medicinal products for animal species other than cattle, sheep for meat production, pigs, chickens, dogs and cats.*”

Article 23(1) states*: “By way of derogation from point (b) of Article 8(1), the applicant shall not be required to provide the comprehensive safety or efficacy documentation required in accordance with Annex II, if all of the following conditions are met:*

*(a) the benefit of the availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;*

*(b)* *the applicant provides* *the evidence that the veterinary medicinal product is intended for a limited market.”*

‘Limited market product eligible for Article 23’ (LM-Art.23) – a product that meets the definition of limited market according to Article 4(29) and, in addition, it is accepted that the benefit of the availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided (satisfies Article 23(1)(a) of Regulation (EU) 2019/6).

‘Limited market product not eligible for Article 23’ (LM-Art.8) – a product that meets the definition of limited market according to Article 4(29), but it is not accepted that the benefit of the availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided (does not satisfy Article 23(1)(a) of Regulation (EU) 2019/6).

Further information on the approach to implementing the Article 23 provision can be found in the ‘Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and eligibility for authorisation according to Article 23 (Applications for limited markets).’

1) Evidence that the veterinary medicinal product is intended for a limited market (according to Article 4(29) of Regulation (EU) 2019/6)

a) Is the product <product name> indicated for animal species other than cattle, sheep for meat production, pigs, chickens, dogs and cats;

b) Provide information on the target species and indication (disease, condition or syndrome) for which the product <product name> is indicated in the proposed or intended SPC3;

c) Is the product <product name> indicated for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;

[Provide information on the potential market size: the total number of animals that could potentially be administered the product annually. This value should be expressed as a percentage of the EU (EEA) target species population:

|  |  |  |
| --- | --- | --- |
| Estimated potential size of the market % = | total annual number of animals potentially treated | X 100 |
| EU (EEA) target species population |

*Provide any relevant additional data to support this argument:*

* *intended target population (sub-category of target species, e.g. type of production, age;*
* *whether the product is intended for prevention or treatment;*
* *the frequency of the disease/condition in the EU relevant to the indication sought;*
* *the precise wording of the indication depending on the disease/condition;*
* *the geographical area in which the disease/condition is present.*

*An indication/product will be considered as limited market when the potential market size is estimated to be less than 0.5% of the EU target species population or, in the case of vaccines only, is estimated to be less than 5.0% of the EU target species population]*

e) Is the product <product name> indicated for a disease that is subject to Community control measures?

[Indicate how this affects the market for the product within the EU]

2) Evidence that the veterinary medicinal product is eligible for authorisation for limited market under Article 23(1)(a) of Regulation (EU) 2019/6

Benefit of the availability of the product: provide justification of the benefit of the availability on the market of the veterinary medicinal product <product name> to the animal or public health.

*Provide any relevant data to support this argument:*

* *are products already authorised for this disease/condition in the EU? If so, please list names of products and countries in which they are authorised.*
* *are there alternative approaches to treat or prevent the disease/condition?*

[Include alternative approaches to therapy other than medicinal if appropriate; include reference to unauthorised products (indicating where they are authorised) either for the same target species or another target species, including man, via the cascade, and if these are established (widely used) treatments]

For further guidance on data requirements for applications for specific veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6, refer to published relevant CVMP guidelines.

Authorisation status

Provide information on any marketing authorisation or other official permission for use that the product may have in any country/region.

Provide information if classification for limited market in accordance with Article 23(1) has already been requested for the same product.

Provide information on the intended route of submission of the marketing authorisation (centralised, national/MRP or decentralised).

A CVMP confirmation on classification of a product as intended for a limited market and a confirmation on eligibility for consideration in accordance with Article 23 will be considered valid for a period of five years from the date of the decision. The period of validity will be renewable, subject to confirmation that the requirements in sections 1 and 2 above are still met.

The request should be submitted via Eudralink[[4]](#footnote-5) to: [vetlimitedmarkets@ema.europa.eu](mailto:vetlimitedmarkets@ema.europa.eu) at least 30 calendar days prior to the CVMP meeting you wish your request to be considered at.

1. The customer account number is a unique reference number with the Agency for financial matters. It is quoted on the invoice and all the related financial correspondence received from the Agency. It normally starts with 00005 for parallel distributors and 00006 for other organisations. Pease make sure this is provided with this submission. If you don't have a customer account number, click [here](https://www.ema.europa.eu/en/human-regulatory/overview/fees/how-pay) to request one. [↑](#footnote-ref-2)
2. Applicants and marketing authorisation holders requiring a purchase order number or similar references on their invoice are encouraged to issue a standing (blanket) purchase order covering all marketing authorisation and/or pharmacovigilance fees levied by the Agency for a given period and to provide such reference to the Agency’s accounts receivable service at [accountsreceivable@ema.europa.eu](mailto:accountsreceivable@ema.europa.eu). Alternatively, such reference can be provided here. In case PO is not applicable please enter ‘N/A’ in a field. [↑](#footnote-ref-3)
3. A preliminary draft SPC should be annexed if at all possible [↑](#footnote-ref-4)
4. Eudralink account can be requested via: <https://servicedesk.ema.europa.eu> [↑](#footnote-ref-5)