DD Month YYYY

Request to the CVMP to <re>classify <a veterinary medicinal product><indication of the veterinary medicinal product> as minor use minor species (MUMS)/ intended for use in a limited market

Request submitted by <Company Name, address>

In relation to <product name> containing the active substance <active substance[[1]](#footnote-2)>

Proposed indication[[2]](#footnote-3): <indication>

Target species: <please specify>

Introduction

This document provides data to assist the CVMP in considering if the veterinary medicinal product <product name> meets the criteria of a product intended for use in a limited market in the context of Art 79 of Regulation 726/2004 and, in particular, if the intended use can be classified as minor use in a major species or use in a minor species.

The holder of a MUMS / limited market classification can still apply before 28 January 2022 for an initial [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation)/variation/extension and have this application validated according to Directive 2001/82/EC, as amended. However, for applications holding a MUMS / limited market classification that are validated after 28 January 2022, the MUMS / limited market classification will cease to be valid. The applicant might want to submit a new eligibility request for limited markets applications under Article 23 of Regulation (EU) 2019/6 to the responsible regulatory body to benefit from the limited markets scheme provided by the Regulation.

CVMP will continue providing MUMS/ limited market classifications/re-classifications until December 2021. However, considering the timeframe between classification and application, applicants are encouraged to request MUMS/limited market classifications or re-classifications only for those products or indications for which an initial marketing authorisation application, variation or extension is planned to be submitted and validated before 28 January 2022.

EMA aims to provide guidance on the new legal and procedural framework in 2021 to help potential applicants and holders of MUMS / limited market classifications decide on any actions to take.

Information on the indication (disease, condition or syndrome), <indication>, for which the product <product name> is indicated in the proposed or intended SPC

1. Is the product indicated for a minor species?
2. Prevalence of the disease/condition in the EU, including geographical distribution

*[Indicate if prevalence is similar across Member States or not, and the source of the data used to estimate prevalence/incidence]*

*[Reclassification*

*Summarise any changes over 5 years in the epidemiological/ disease/disorder status relevant for the product indication]*

1. 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.
2. Are there alternative approaches to treat or prevent the disease/condition?

[To 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]

1. Is the product for use in food producing animals?

[Indicate if an MRL is established or will be needed]

1. Is the product indicated for a disease that is subject to Community control measures?

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

Potential market size and return on investment

[Expressed in number of individual animal treatments estimated per year; number of dose units estimated per year and estimated cost of production; an estimated time on the market for return on investment may be submitted; details of the methodology used for both cost and return should be provided]

*[Reclassification*

*For authorised products: summarise sales volume data/number of treated animals as reported in PSURs. Provide information on return on investment to date and how this is expected to progress over the next 5 years]*

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 MUMS classification has already been requested for the same products (also for other species)]

*[Reclassification*

*For unauthorised products: provide a report on a current state of development of the product (i.e. what studies have been done, planned submission time and route).*

*Provide also date of the initial MUMS classification and the reference number of the outcome letter.]*

Applicant has Small and Medium Enterprises (SME) status:

YES

NOT YET

N/A

**Applicant is requesting:**

MUMS/limited market reduced data requirements

MUMS/limited market financial incentives (for food producing animals only)

Submit to: [VetMUMSapplications@ema.europa.eu](mailto:VetMUMSapplications@ema.europa.eu) at least 20 days prior to the CVMP meeting you wish your request to be considered at.

1. A preliminary draft SPC should be annexed if at all possible [↑](#footnote-ref-2)
2. Confirm whether MUMS request is submitted for the whole product or indication of product [↑](#footnote-ref-3)