EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DD, Month YYYY

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

Request submitted by <Company Name>

In relation to <product name> containing the active substance<active substance[1]>

Proposed indication: <indication>

Target species: <major or minor>

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.

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

a) Is the product indicated for a minor species?

b) Prevalence of the 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]

c) Current and/or alternative approaches to therapy and available treatments

[To include alternative approaches to therapy other than medicinal if appropriate; Include reference to authorised or 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]A preliminary draft SPC should be annexed if at all possible

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d) Severity of the condition and the need for this medicinal product

[Comment on the extent to which availability of medicinal products will prevent unnecessary suffering and thereby promote animal health]

e) Potential zoonosis, if applicable

[Include information on the potential impact on human health]

f) Is the product for use in food producing animals?

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

g) 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]

Authorisation status

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

CVMP recommendation

A. MUMS – for data requirements

B. MUMS/limited market financial incentives - for food producing animals only