EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market

POLICY no 0075
Status: Public
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Supersedes: EMA/429080/2009-Rev.1

1. Introduction and purpose

The main responsibility of the European Medicines Agency is the protection and promotion of public and animal health through the evaluation and supervision of medicines for human and veterinary use. A policy for classification and incentives for veterinary medicinal products indicated for Minor Use Minor Species (MUMS)/limited market (EMA/429080/2009-Rev.1) has been in place since September 2009. The policy is intended to stimulate the development of new veterinary medicines for minor species and for rare diseases in major species that would otherwise not be developed in the current market conditions. The availability of safe and effective veterinary medicinal products for MUMS/limited market will improve both animal welfare, animal health and, in some cases, public health. Article 79 of Regulation (EC) No 726/2004 requires the Agency to adopt measures to assist applicants at the time of submitting applications for products for MUMS/limited market. This sets out the basis for implementing a policy on MUMS. Sufficient experience in the operation of a MUMS/limited market policy has now been gained by the Agency and its Committee for Medicinal Products for Veterinary Use (CVMP) to require that the policy be updated to reflect the current approach.

2. Scope

This policy applies to the staff of the veterinary medicines division and to the CVMP.

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3. Definitions

Minor species:

There is no legislative definition in the EU for major or minor species. However, major species were defined by the CVMP. All animal species which are not considered major, are as a consequence, classed as minor species.

Major species have been defined for the purposes of this policy as follows:

Major food-producing animal species:

- cattle (dairy and meat animals)
- sheep (meat animals)
- pigs
- chickens (including laying hens)
- salmon[1]

Major companion animal species:

- cats
- dogs

All other animal species, which are not considered major, are as a consequence, classed as minor species.

Minor use: Minor use in a major species is generally considered as the use of veterinary medicinal products for the treatment of diseases that occur infrequently or occur in limited geographical areas and thus are indicated for a smaller market sector.

Experience has shown that there is insufficient data in the veterinary domain with respect to the incidence and prevalence of diseases to enable objective cut off values to be established below which a disease is considered minor. Therefore a case by case approach will continued to be used in classifying a product as MUMS/limited market.

Limited market: A market for a veterinary medicinal product that is limited in size due to the product being indicated for a disease or condition that represents a minor use in a major species or that occurs in a minor species; this term is retained as it is the term used in Article 79 of Regulation (EC) No 726/2004 but is interchangeable with the term MUMS in the context of this document.

4. Policy statement

Article 79 of Regulation (EC) No. 726/2004 states:

> *The Management Board shall, in the case of veterinary medicinal products which have limited markets, or in the case of veterinary medicinal products intended for diseases with a regional distribution, adopt the necessary measures to provide assistance to companies at the time of submission of their applications."*

[1] Salmon should be considered a major species, however other species of the *Salmonidae* family such as rainbow trout should be considered minor species.

The Agency, recognising the lack of availability of veterinary medicinal products and implications arising from this for animal welfare and for public health, has developed this policy which is intended to stimulate development of veterinary medicinal products for MUMS/limited markets.

The policy is intended to provide greater clarity and predictability to potential applicants with regard to the general framework under which the assistance referred to in Article 79 of Regulation (EC) No 726/2004 may be provided. The policy presents the principles for classification of a product intended for MUMS/limited market together with the incentives that are available to assist with bringing to market medicines for MUMS/limited markets that represent a considerable benefit for animal health and welfare and public health.

Two types of assistance may be provided with respect to products classified by CVMP as indicated for MUMS/limited market: reduced data requirements, and financial incentives for applications. In addition, a greater level of advice and assistance is provided for MUMS/limited market products in terms of pre-submission meetings for potential centralised applications and for advice in relation to putting an application together for scientific advice or to establish a Maximum Residue Limit (MRL). The rules relating to the Agency's fees are governed by the fee Regulation (Council Regulation (EC) No 297/95) and its implementing rules. The Agency publishes an explanatory note for guidance on the fees due and details of the full or partial exemption from payment of fees relating to applications for products classified by the CVMP as indicated for minor use and/or minor species and for which eligibility for fee incentives under Article 9 paragraph 2 of Council Regulation (EC) No 297/95 is confirmed, are given in that document. Regulation (EC) No 2049/2005 concerning micro, small and medium-sized enterprises (SMEs) foresees the adoption of specific provisions allowing a reduction of fees, deferring the payment of fees, and providing administrative assistance for SME registered applicants. Fee incentives are not cumulative and where an applicant could, in respect of the same fee, benefit from more than one category of fee reduction or incentive (e.g. MUMS/limited market and/or micro, small or medium sized enterprises) the provisions which are the most favourable to the applicant would apply.
For incentives to apply, there always has to be the CVMP recommendation on classification of the medicinal product as MUMS/ limited market. An applicant does not have to request classification as a MUMS/limited market product unless they wish to avail of the incentives provided under these initiatives, which are valid for five years once classification is confirmed.

MUMS data requirements are applicable to any product that has been classified by CVMP as indicated for a MUMS/limited market. MUMS data requirements are specified in the relevant CVMP guidelines and generally reduce the amount of data required for authorisation. The extent of reduction depends on the nature of the product and the indication. Applicants are advised to request scientific advice on their individual data package to confirm the precise requirements for their specific product application.

Only products indicated for food producing species are considered eligible for fee incentives where no alternative product is authorised as it is considered that the availability of medicines is most restricted in food producing species. Furthermore, products intended for food producing species have the greatest potential for improving animal and public health.

These financial incentives include free scientific advice and fee reductions for applications for establishing MRLs for minor species, fee waivers for applications for extensions of existing MRLs to include minor species and also fee reductions for submission of marketing authorisation applications under the centralised procedure. Only sponsor/applicant (owner) established in the EU may benefit from the financial incentives that are available from the EMA under this policy. The fees applicable to MUMS/limited market applications for national authorisations (including decentralised and mutual recognition applications) are decided by the National Competent Authority to which the application is

made. As for data requirements, the financial incentives awarded to products under development for food producing animals are valid for five years from the date of classification and can then be renewed upon request, if the classification criteria are still applicable.

More details on the application of the policy can be found in the guidance document on the classification of veterinary medicinal products indicated for minor use minor species (MUMS)/limited market (EMA/CVMP/388694/2014) published on the Agency website.

5. Related documents

1. European Parliament and Council (2004). Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. *Off. J. Eur. Comm.* L136: 30.4.2004, 1–33.
2. Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) /limited market (EMA/CVMP/388694/2014). Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001763.jsp&mid=WC0b01ac0580b2d858
3. Template for a request for classification of a veterinary medicinal products indicated for minor use minor species (MUMS) /limited market. Available at: https://www.ema.europa.eu/documents/template-form/template-request-cvmp-reclassify-veterinary-medicinal-product-minor-use-minor-species-mums/intended-use-limited-market_en.doc
4. EMEA - CVMP Position Paper regarding availability of products for Minor Uses and Minor Species (MUMS). (EMEA/CVMP/477/03-Final). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Position_statement/2009/10/WC500005163.pdf
5. Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/IWP/123243/2006). Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001641.jsp&mid=WC0b01ac058002ddc8
6. Guideline on quality data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/QWP/128710/2004). Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001469.jsp&mid=WC0b01ac058002dd35
7. Guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/SWP/66781/2005-Rev.1). Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001536.jsp&mid=WC0b01ac058002dd38
8. Guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/EWP/117899/2004). Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001579.jsp&mid=WC0b01ac058002ddc3
9. Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises
10. Explanatory note on fees payable to the European Medicines Agency. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp&mid=WC0b01ac0580024596

6. Changes since last revision

The previously published policy has been separated out in line with the Agency working practice into this policy document and a separate guidance document (EMA/CVMP/388694/2014) for applicants.

The scientific guidelines describing the data requirements for MUMS/limited market products will be reviewed and periodically updated in line with scientific developments.

Amsterdam, 16 December 2021

[Signature on file]

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Executive Director