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Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market

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This guideline is based on the Revised Policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market (EMA/308411/2014).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market

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Introduction

For some time there has been considerable concern amongst all parties concerned with animal health in the EU about the lack of veterinary medicines for minor uses and for minor species. The European Medicines Agency (the Agency) at the behest of its Management Board began its discussions and consultations on this in 1998. The revision of the pharmaceutical legislation in 2004 recognized the need to address the availability issue for veterinary medicines. Among the provisions introduced, Article 79 of Regulation (EC) No 726/2004 [1] requires the Agency to introduce measures to assist applicants at the time of submitting applications for products for limited markets.

The Agency developed a policy on minor use and minor species (MUMS)/limited market (EMA/429080/2009-Rev.1) [2], which has been in effect since September 2009 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 measures made available range from administrative assistance through to fee reductions, and cover all aspects of applications from scientific advice, through maximum residue limits (MRLs), to marketing authorisation applications.

The previous policy document also described the procedural details and guidance for the implementation of the policy. Following a review of the MUMS/limited market policy in 2013/2014 in light of experience gained over five years in operation, the policy was updated. The updated policy was separated out, in line with the Agency working practice, into a policy document (EMA/308411/2014) [3] and this separate guidance document for applicants. This document gives guidance for implementing the updated policy, describes the procedure and the steps to be followed by the applicant and the Agency when dealing with a request for classification.

In 2017 this guidance was revised to introduce administrative changes to ensure that the document corresponds with the revised guidelines on data requirements for veterinary medicinal products intended for MUMS/limited market that were adopted by CVMP in 2016-2017. The opportunity was also taken to introduce a simplification to the request process for applicants and to improve the clarity of the document without changing the meaning or intention.

The current revision introduces clarity on the limitation of financial incentives under the policy to sponsor/applicant (owner) established in the EU.

1. Scope

This guidance document relates to requests from applicants seeking to access incentives for MUMS/limited market products where a request for classification is made to the Committee for Medicinal Products for Veterinary Use (CVMP). Classification of products by CVMP is not necessary in the case of products intended for submission to national competent authorities where the recommendation on whether or not a product is indicated for a limited market lies with the authority concerned. However, potential applicants should note that the measures detailed in section 6, including scientific advice and MRL incentives, may be provided to products classified by CVMP as MUMS/limited market irrespective of the final authorisation route. Furthermore, it is expected that this procedure and the other related documents will assist authorities in terms of classifying indications at a national level as MUMS/limited market and a classification by the CVMP can be useful as guidance in particular for authorisations under decentralised or mutual recognition procedures.

Applicants may apply for classification in relation to products for minor species either when seeking authorisation of a new product indicated only for one or more minor species or when extending an existing authorisation to a new, minor species, for products intended for minor use in a major species or in respect to the establishment for maximum residue limits (MRLs) for (a) minor species.

This document has been prepared for guidance only and applicants must comply with Union legislative provisions, currently in force and relating to veterinary medicinal products.

2. Definitions

Minor species

There is no legislative definition in the EU for major or minor species. However, major species were defined by the CVMP according to animal population data and total consumption figures, using global numbers across the European Union for the purpose of CVMP guidelines in its position paper regarding availability of products for minor uses and minor species (MUMS) (EMEA/CVMP/477/03-Final) [4].

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

Major food-producing species:

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

Major companion animal species:

- cats;
- dogs.

Minor use

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

Limited market

A 'limited market' for a veterinary medicinal product is a market 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

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

that occurs in a minor species.

While in the majority of cases the term 'limited market' is interchangeable with the term MUMS in the context of this document, there are situations where products may be indicated for MUMS but the market is not considered limited (such as most anthelmintics for horses, see section 4) and, conversely, there may be diseases which do not inherently have a low incidence or prevalence but the market in the EU is limited. Treatments of indications with low prevalence/incidence would be expected to have a low return on investment and thus represent a limited market. The term limited market is therefore retained both because it is the term used in Article 79 of Regulation (EC) No 726/2004 and to ensure that the scope of the policy fully encompasses all types of products for which the market in the EU is limited.

Products concerning epizootic diseases which are subject to community control (e.g. Classical Swine Fever, Foot-and-Mouth Disease, Bluetongue, avian influenza) represent a specific scenario, where the limited nature of the market is the result of a combination of legal, market and technical factors. Appropriate measures to assist applicants to develop vaccines against these diseases are developed on a case-by-case basis (e.g. data requirements, authorisation under exceptional circumstances, fee incentives, multistrain dossier approach) and they are therefore excluded from the scope of this policy.

3. Principles for MUMS/limited market classification

The concept for classifying a veterinary medicinal product as MUMS/limited market is based on the consideration whether an indication for a certain species constitutes a limited market or not. This is true for pharmaceutical as well as immunological veterinary medicinal products.

Historically, and originating from reflections regarding the establishment of maximum residue limits for food-producing species, the categorisation into minor and major species based on relative consumption of food of animal origin, was developed for pharmaceuticals; in respect to marketing authorisations in addition the element of minor use was introduced. As explained in the definition in Section 3, minor use is generally associated with a major species; its essence being indicated for a smaller market sector is embedded also in the concept for minor species.

The overriding element for both pharmaceuticals and immunologicals for the conclusion whether incentives, in particular deviations from standard data requirements, are applicable is the consideration whether the product under consideration represents a minor use/limited market.

In practice the classification for MUMS/limited market follows a stepwise approach (see flowchart below): In a first step it is established whether the product concerns a minor or major species and whether it constitutes a minor use/limited market or not.

Products intended for minor species (as defined above in Section 3) or classified as a minor use/limited market are eligible for the MUMS data requirements, where applicable. In rare cases, the CVMP may decide that although a product is indicated for a minor species, the market for the product is not limited (e.g. anthelmintics for horses) and thus for marketing authorisation applications the MUMS data requirements may not apply.

In respect of the consideration whether a product constitutes a minor use, classification depends on prevalence within the EU of the condition concerned. Low prevalence/incidence of the condition or disease may result from the natural epidemiology of the disease and/or limited geographical spread of the disease within the EU in one or a few areas.

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 to present a minor market. The CVMP will review the data presented by applicants and continue to consider products on a case-by-case basis, thereby continuing to gain experience and establish precedence.

This document describes the factors that will be taken into account for classification of products as MUMS/limited market in the EU/EEA. Whilst the CVMP will take note that products have been designated as MUMS in other regions, this will not directly affect classification by CVMP as the definition of MUMS may not be the same and the prevalence and incidence of a disease may be different in different regions. MUMS status in other regions can be provided for information to CVMP.

Principles for financial incentives

The recommendation if the product under consideration is awarded financial incentives is taken as a second step provided the product is indicated for MUMS/limited market.

It has long been recognised by the veterinary community that the availability of veterinary medicines is most restricted in terms of products indicated for MUMS/limited market in food-producing species, whereas the situation is less acute with respect to products for companion animals. There are many reasons underlying this situation but the major factor is the high cost and relatively low return on investment for the development of MUMS/limited market products for food-producing species, making the potential market for such products extremely limited. Therefore financial incentives are restricted to MUMS/limited market products for food-producing animals.

Products classified by CVMP as MUMS/limited market but indicated for a non-food producing species are not eligible for fee incentives from the EMA under this policy, unless they have already been granted the financial incentives before the implementation of this revised policy. However, in line with Article 9(1) of the EMA Fee Regulation (Council Regulation (EC) No 297/95, as amended) [5] in exceptional circumstances and for imperative reasons of public or animal health, fee reductions may be granted on a case by case basis by the Executive Director after consultation of the competent scientific committee. Applicants are advised to contact the EMA (vet.applications@ema.europa.eu) if they consider that their product might fall within this definition.

In general the CVMP will not recommend financial incentives for products where an alternative veterinary medicinal product is authorised for the same indication in the same target species, unless significant therapeutic benefit is shown by the product requesting classification. The product must therefore represent a significant improvement in terms of availability either by being of added therapeutic benefit compared to existing treatments, or filling an unmet need (i.e. no other product available).

An alternative product is a product that falls within the same broad therapeutic area and not generally sub-classifications within it (for example, for an alternative cardiovascular product to reduce blood pressure a beta blocker and ACE inhibitor would fall in the same broad therapeutic category). Pharmaceutical and immunological products are considered separately on their own merits and the two types of medicine are not compared when deciding on added benefit in a particular therapeutic area (e.g. vaccines to prevent a bacterial infection are not compared with antibiotics to treat the same infection).

In the absence of any authorised veterinary medicinal product, where an applicant submits a request for classification and the application is deemed to meet the eligibility requirements listed above for financial incentives, then the product will be recommended for financial incentives, irrespective of whether or not another product for the same indication in the same target species is already receiving financial incentives prior to its authorisation. However once a product has been authorised by a licensing authority for that indication in the target species within the EU then no new recommendations for financial incentives will be given in the same therapeutic area, as a product will already be available in the marketplace for the proposed indication. Products which have already benefited from financial incentives prior to the first authorisation will continue to benefit from the incentives in place.

Regulation (EC) No 2049/2005 [8] 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.

Financial incentives are limited to products indicated for food-producing animals since September 2013.

Only sponsor/applicant (owner) established in the EU may benefit from the financial incentives that are available from the EMA under this policy.

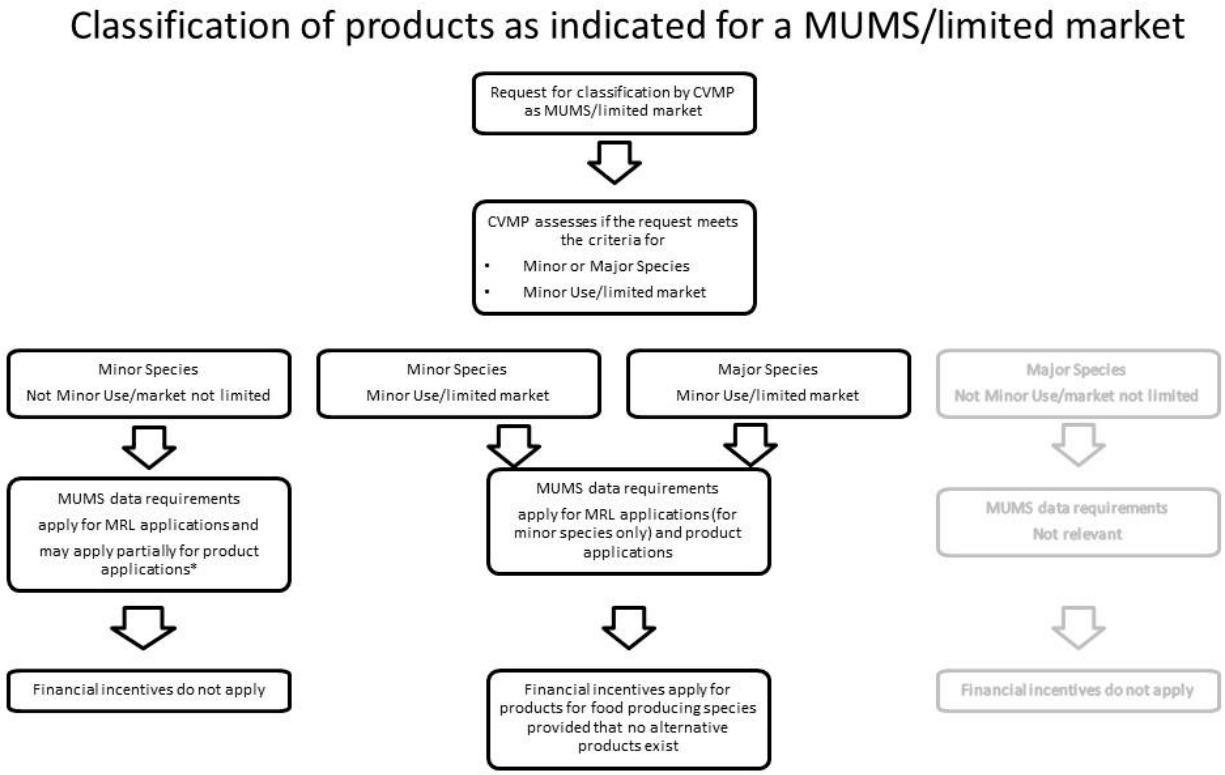
Horses - special considerations

Horses are considered a minor species and veterinary medicinal products for horses are therefore eligible for MUMS data requirements, with possible exceptions in rare cases as explained in section 4. As with all MUMS products, the actual level of data requirements will depend on the particular product and applicants will therefore be recommended to seek scientific advice on the specific data requirements that would apply.

Horses are considered as a food producing species unless declarations have been provided in accordance with Commission Decisions 93/623/EEC and 2000/68/EC as not being intended for slaughter for human consumption. Most veterinary medicinal products indicated for horses in the EU are administered to horses at a time when their ultimate fate with respect to the food chain is unknown. Only a minority of products are administered to horses that are clearly destined for the food chain at the time of treatment. Horses will therefore not be considered as food producing animals within the scope of the revised MUMS/limited market policy and products for horses will therefore not generally be eligible for fee incentives.

In exceptional cases, applicants may request fee incentives on the basis that they intend to make (an) MRL application(s) so that the veterinary medicinal product concerned can be used in horses that are intended for the food chain. This specific exemption from the general approach is intended to support the objective of increasing the availability of products that can be used in horses which ultimately enter the food chain, whether their ultimate fate is known at the time of treatment or not.

A flow chart outlining the classification procedure described in the text above is presented below (for illustration purposes only).



* Applicants are advised to seek scientific advice on the extent to which MUMS data requirements would apply to any product for minor species where CVMP considers that the market is not limited as data requirements depend on both the type of the product and on the extent of expected use

** The financial incentives will only apply to sponsor/applicant (owner) established in the EU.

4. Procedure

A general outline of the procedure for MUMS/limited market classification is provided in the SOP - CVMP MUMS Classification procedure SOP/V/4055 [15].

The applicant should complete the template for a request for classification and send this to the EMA providing all relevant information. The request should clearly indicate if it concerns a minor species or a minor use/limited market where additional information should be provided as detailed in the template.

The information supporting a request for a MUMS/limited market classification should be submitted using the Request form Template [6].

The applicant should provide information on:

- The product (e.g. active substance, finished product, mechanism of action, proposed indication and method of use);
- The status of the development of the product relevant for the classification;
- The species - major or minor - and if food producing or not – intention to establish an MRL, or physiological status of species (e.g. sows), as appropriate;

- The prevalence of the condition in the EU - best available evidence for the incidence/prevalence of the disease including peer-reviewed published literature;
- The current and/or alternative approaches to therapy and available treatments;
- The product indication (i.e.: if the product is indicated for a disease that is subject to Community control measures).

Applicants should complete the template with the information requested and also provide any additional relevant information to support their request.

Requests for classification that are received 20 days in advance of the CVMP meeting will be forwarded to the next monthly CVMP meeting for consideration. A request for classification in order to avail of the incentives offered should be addressed to EMA "*Veterinary Medicines Division – MUMS*" at 30 Churchill Place, Canary Wharf, London E14 5EU, UK or by email to VetMUMSapplications@ema.europa.eu.

The Agency checks if sufficient information and justifications are provided by the applicant in the request to substantiate the classification of their product. The applicant is informed if there is a need to complement the information provided. If major additional information is needed that cannot be provided within 5 working days, the procedure is deferred to the next starting date.

The requests received will be evaluated by the CVMP taking into account the information provided in order to decide whether or not the proposed use of the product can be considered as MUMS/limited market. Requests will be evaluated based on the information provided by the applicant in the completed template along with any supporting information. In straightforward requests the CVMP will classify the product as MUMS/limited market and the applicant will be informed following that CVMP meeting by the EMA secretariat.

In more complex cases, there may be a need to appoint a CVMP member or alternate to review in more detail the request and provide a recommendation to the CVMP. This will normally be done within one month, but can exceptionally require longer time if e.g. additional consultation is needed, and the applicant will then be informed of the outcome. It is also envisaged that additional information may need to be requested in some cases and the timetable will then depend on the timing of the response of the applicant with the requested information.

There is no fee for classification or for any pre-submission meeting with the EMA in order to discuss if a product may be considered eligible for classification as MUMS/limited market, for financial incentives, or for any advice on what information should be provided within a request.

Once an applicant has received confirmation that the CVMP has classified the product as indicated for MUMS/limited market and in the case of products for food producing species has recommended the granting of financial incentives, the applicant then has access to the respective benefits with respect to the scientific advice, MRL application or centralised marketing authorisation procedures.

An applicant may request classification for any product irrespective of the intended route of authorisation. Incentives such as free scientific advice or extension of an MRL may be requested for all routes of authorisation (centralised or decentralised routes). Specific financial incentives for authorisation that relate only to the centralised procedure will be dependent on the veterinary medicinal product having shown eligibility for the centralised procedure. Requests for eligibility to the centralised procedure should be sent in the usual way (see pre-submission guidance documents on EMA website).

It is necessary to set a reasonable period of validity to provide applicants with the predictability they require to invest in bringing a new product to market. Conversely, it is necessary periodically to review the classification of indications to take into account changes in the epidemiology of the condition concerned. The classification is therefore valid for five years from the notification by the CVMP. Applicants should apply for any of the benefits outlined above, within this time period. At the end of the five years a request to extend the MUMS/limited market classification (including the financial incentives awarded if applicable) should be submitted to the CVMP in writing. While the EMA aims to notify applicants 6 months prior to the expiry of the 5 year classification time period, it remains the responsibility of the applicant to submit a request for renewal in time.

Where classification of a product as MUMS/limited market is rejected by the CVMP the applicant can ask for re-examination. The applicant shall ask for re-examination by written request to the CVMP within 60 days of receipt of the notification letter. The applicant has to provide detailed grounds for re-examination. He may also provide additional data to substantiate any grounds on which re-examination is made. The timetable for the CVMP consideration of the re-examination will be similar to that outlined for initial requests. The outcome of the re-examination will be notified to the applicant following the final recommendation of the CVMP. There is no fee for a re-examination procedure.

5. Incentives provided

The incentives available for products classified as MUMS/limited market include data requirements that recognise the limited markets for the products concerned, financial incentives in terms of fee waiver/fee reduction for eligible MUMS/limited market products for food producing animals as well as incentives in the form of additional administrative and procedural advice.

Financial incentives for MUMS/limited market products only apply to sponsor/applicant (owner) established in the EU.

MUMS data requirements

The confirmation of data requirements is an important measure to assist applicants. Products classified by CVMP as indicated for MUMS/limited market should refer to the individual CVMP guidelines on data requirements for veterinary medicinal products classified as MUMS [9-12]. However, potential applicants are strongly advised to check with the relevant regulatory authority the application of these data requirements (specifically, reductions in requirements) for any intended application. Reductions will most likely be limited for novel therapeutic products or for any first in class authorisation for a veterinary medicine. The extent of reduction depends on the nature of the product and the indication. Applicants may also request scientific advice on their individual data package to provide additional reassurance on the data package required in each specific case.

Financial incentives for eligible products classified as MUMS/limited market

The following reductions or waivers are available for products classified as MUMS/limited market intended for food producing animals for which the CVMP has issued a recommendation:

Scientific advice

There will be no fee for requests for scientific advice relating to products indicated for MUMS/limited market that are recommended for financial incentives.

The standard procedure will apply for companies requesting scientific advice (see EMA guidance for companies requesting scientific advice (EMEA/CVMP/172329/2004-Rev.4) [7].

Scientific advice is restricted to purely scientific issues and the main areas of advice are quality, safety, clinical development, MRLs and bioequivalence. Scientific advice may be requested with respect to the determining the compliance of a proposed development plan with the published guidelines on dossier requirements for MUMS/limited market products. These requests enable an applicant to put together an outline of their dossier and to receive assurance that the proposed dossier will contain the necessary information for authorisation in compliance with the possibilities for the reduction of data in the different sections of the dossier. The review carried out within this type of scientific advice request will not take the form of a pre-assessment of scientific data but will simply confirm whether or not the proposed approach is compliant with relevant MUMS guidelines.

Applications for the establishment of MRLs (including extension of MRLs)

For a substance confirmed by CVMP as indicated for MUMS/limited market with financial incentives, the applicant can obtain:

1. Fee reduction for the MRL applications:

A fee reduction of 50% is applicable for MRL applications for a pharmacologically active substance for which no MRL is established and is intended exclusively for a product classified as MUMS/limited market and for applications for the extension of an existing MRL to a minor species where the need to assess new data exists.

Requests for the extension of MRLs, i.e. the extension of existing MRLs to an additional, species based on existing data and provided that the criteria as described in the up-to-date Note for Guidance on the risk analysis approach for residues of veterinary medicinal products in food of animal origin (EMEA/CVMP/187/00-Final) [13] have been fulfilled, will be processed by the EMA/CVMP free of charge.

2. Fee exemptions in the event of failure of validation

A fee exemption will be given on the normal fee charged in the event of failure of validation of a dossier for an MRL application for an eligible substance.

Centralised marketing authorisation application

If eligibility for the centralised procedure is confirmed by CVMP for an application that concerns a product/indication the CVMP has previously classified as MUMS/limited market with financial incentives, the applicant can obtain:

1. Fee reduction for authorisation applications and maintenance

As a general rule, applications for MUMS/limited market will attract the same fee as generic medicinal products where financial incentives apply. This will reduce the cost of obtaining and maintaining a

centralised authorisation as a 50% fee reduction for authorisation and 75% reduction for annual fees will apply.

A centralised application that concerns more than one target species at the time of submission, only one of which is MUMS, will not attract a reduced fee as the current fee structure is set up so that additional target species do not attract an additional fee.

For SMEs an applicant may request deferral of the fee payable for a centralised application for marketing authorisation to within 45 days of the date of the final decision on the marketing authorisation or, in the event of withdrawal of the application, to within 45 days of the date of notification of withdrawal.

2. Fee exemptions in the event of failure of validation

A fee exemption will be given on the normal fee charged in the event of failure of validation of a dossier for a marketing authorisation.

Current fees applicable are published on the Agency website in the document entitled 'Explanatory note on fees payable to the European Medicines Agency' [14].

Requests for a fee reduction for an MRL application or centralised marketing authorisation submission of a product classified as MUMS/limited market should be submitted in the usual way at the time of the indication of the intent to submit an application. For details and timelines of the submission of the request please refer to the pre-submission guidance published on the EMA website http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000171.jsp&mid=WC0b01ac058002d9ab.

Administrative and procedural assistance

A greater level of advice and assistance for products classified as MUMS/limited market are provided in terms of pre-submission meetings for potential centralised applications and advice in relation to putting an application together for any type of application where scientific advice or MRL applications are being considered. The administrative and procedural incentive already applies to SME companies.

Assistance with translations of the product information is applicable only if the submission of the application for marketing authorisation comes from a currently registered SME at the Agency (see SOP/EMA/0100 - *Translation of product information for SME applicants of the centralised procedure).*

6. Transparency

The classification will be published in order to be transparent in line with the Agency policy and to allow potential applicants to view previous classifications. The outcome of the request for consideration for MUMS/limited market classification will be published in the press release of the relevant CVMP meeting in general terms.

The publication will consist of the following information:

- Product description e.g. pharmaceutical or immunological;
- Species concerned;
- Broad Therapeutic area in accordance with the ATCvet coding system;

- Outcome of the classification whether or not the CVMP considered that the product was indicated for MUMS/limited market;
- Date of CVMP meeting.

Details of the applicant or active substance would not be included. This information may also be published in the Agency annual report as part of a report of measures provided by the Agency to applicants to assist with authorisation of products for limited market under Article 79 of Regulation 726/2004. A table of recommendations related to these applications will be maintained on the EMA website.

7. Reference documents

It should be highlighted that this document has been produced for guidance only and should be read in conjunction with applicable legislation.

1. Regulation (EC) 726/2004 of the European Parliament and Council of 31 March 2004.
2. Policy on Classification and Incentives for Veterinary Medicinal Products indicated for Minor use Minor species (MUMS)/limited market (EMA/429080/2009-Rev.1) – *superseded.*
3. Revised Policy on Classification and Incentives for Veterinary Medicinal Products indicated for Minor Use Minor Species (MUMS)/limited market (EMA/308411/2014).
4. Position Paper regarding availability of products for Minor Uses and Minor Species (MUMS) (EMA/CVMP/477/03-Final). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Position_statement/2009/10/WC500005163.pdf
5. Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the EMA. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103547.pdf
6. Template for a Request to the CVMP to classify a veterinary medicinal product as (MUMS)/limited market. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2013/10/WC500153358.doc
7. Guidance for companies requesting scientific advice (EMEA/CVMP/172329/2004-Rev.4). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004147.pdf
8. Commission Regulation (EC) No 2049/2005 laying down 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. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:329:0004:0007:EN:PDF
9. Guideline on quality data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/QWP/128710/2004-Rev.1). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/01/WC500219322.pdf
10. 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/docs/en_GB/document_library/Scientific_guideline/2017/01/WC500219323.pdf

11. 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-Rev.1). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/01/WC500219321.pdf

12. Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/IWP/123243/2006-Rev.3). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/04/WC500226133.pdf

13. Note for Guidance on the risk analysis approach for residues of veterinary medicinal products in food of animal origin (EMEA/CVMP/187/00-Final). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004534.pdf

14. 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

15. SOP/V/4055 - CVMP MUMS Classification procedure.

If you seek further information on any of the included topics and/or want to request further information not included in this document please contact:

Veterinary Medicines Division
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
Telephone +44 (0)20 3660 6000
Facsimile +44 (0)20 3660 5555

E-mail: VetMUMSapplications@ema.europa.eu

8. Abbreviations

CVMP: Committee for Medicinal Products for Veterinary Use

EC: European Commission

EMA: European Medicines Agency

MRL: Maximum residue limit

MUMS: Minor use minor species

SME: Micro, small and medium-sized enterprises