EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MUMS/limited market scheme for veterinary medicines

1st Decade Report (01/09/2009 – 31/12/2019)

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Summary

It has been ten years since the launch of MUMS/limited market initiatives aiming to facilitate the access to market of products indicated for MUMS/limited market as part of measures to promote the availability of veterinary medicines.

The MUMS/limited market policy for classification and incentives for veterinary medicinal products indicated for Minor Use Minor Species (MUMS)/limited market (EMA/308411/2014) (the policy) [1] was established with the goal 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 policy provides two types of incentives: reduced data requirements and financial incentives by means of fee exemptions or fee reductions.

In these ten years of application of the scheme, the Committee for Medicinal Products for Veterinary Use (CVMP) successfully reviewed 272 requests for classification as MUMS/limited market either for products indicated for minor species (e.g. rabbits, ducks, guinea pigs, foxes, ferrets, goats, turkeys and bees) or for indications for products to be used in the major species (dogs, cats, chickens, pigs, sheep, salmon and cattle) where the use is considered as minor and the market as limited.

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 (repealing Directive 2001/82) on veterinary medicinal products (the Regulation) [2] introduces for the first time the legal basis for granting marketing authorisations for limited market products and defines conditions and requirements consistent with the aim of EMA policy of promoting availability of veterinary medicinal products for limited markets. The EMA policy and complementary guidance will need to be re-considered on the basis of the new legal provisions.

The experience gained during the success story of the MUMS/limited market scheme for veterinary medicines, which has brought 22 products to the market through the centralised procedure, should allow to continue promoting the limited market products by the implementation of the Regulation.

Background

The MUMS/limited market initiative represents a joint activity between the European Medicines Agency (the Agency or EMA) and the European Medicines Regulatory Network, aiming to facilitate the access to the market of products indicated for MUMS/limited market as part of measures to promote the availability of veterinary medicines.

Activities to promote the availability of veterinary medicines are given a high priority in the EU Medicines Agencies Network Strategy to 2020 | European Medicines Agency (Theme 2; Objective 1) and in the corresponding work plans of the Agency and the Heads of Medicines Agencies (HMA).

The Agency first implemented the policy on 1 September 2009, and this was updated in July 2013. The current revised version of the policy was agreed in December 2014 and subsequently updated in December 2018.

The Regulation entered into force on 28 January 2019 and is applicable from 28 January 2022 onwards. It introduces specific provisions for limited markets that will be further discussed in a specific section of this document.

Annual reports on the operation of the MUMS/limited market scheme have been provided to EMA Management Board (MB) and published on the EMA website. This is the first decade report covering the activities carried out under the MUMS/limited market scheme between 1 September 2009 and 31 December 2019.

MUMS/limited market activities in 2009 – 2019

Classification of products/indications by CVMP

In the ten years of operation of the MUMS/limited market scheme for veterinary medicines, CVMP reviewed 272 requests for classification as MUMS/limited market, including products indicated for the following minor species: ducks, guinea pigs, foxes, raccoon dogs, ferrets, goats, turkeys, bees, fish, rabbits, pigeons, badgers, caged birds, mice, minks, rats, guinea fowls, quails, pheasants, partridges, wild boars and horses. Classification was also sought for minor use/limited market indications for products to be used in the following major species: dogs, cats, chickens, pigs, sheep, salmon and cattle.

In this report a distinction is made between the products which were classified for the first time by CVMP as indicated for a MUMS/limited market and the products for which CVMP confirmed that reclassification for the further 5 years as MUMS/limited market remained appropriate.

Out of the total number of 272 requests, 245 were initial classification requests and 27 were reclassification requests. Of all 272 requests, 233 (86%) were classified as MUMS/limited market. Of these, 207 were classified for the first time and 26 reclassified as MUMS/limited market. 39 requests (14%) were considered as not falling within the scope of the policy. These 39 requests were for indications in major species (dogs, cats, chickens, pigs, cattle and calves) and CVMP considered after detailed evaluation that the market was not limited.

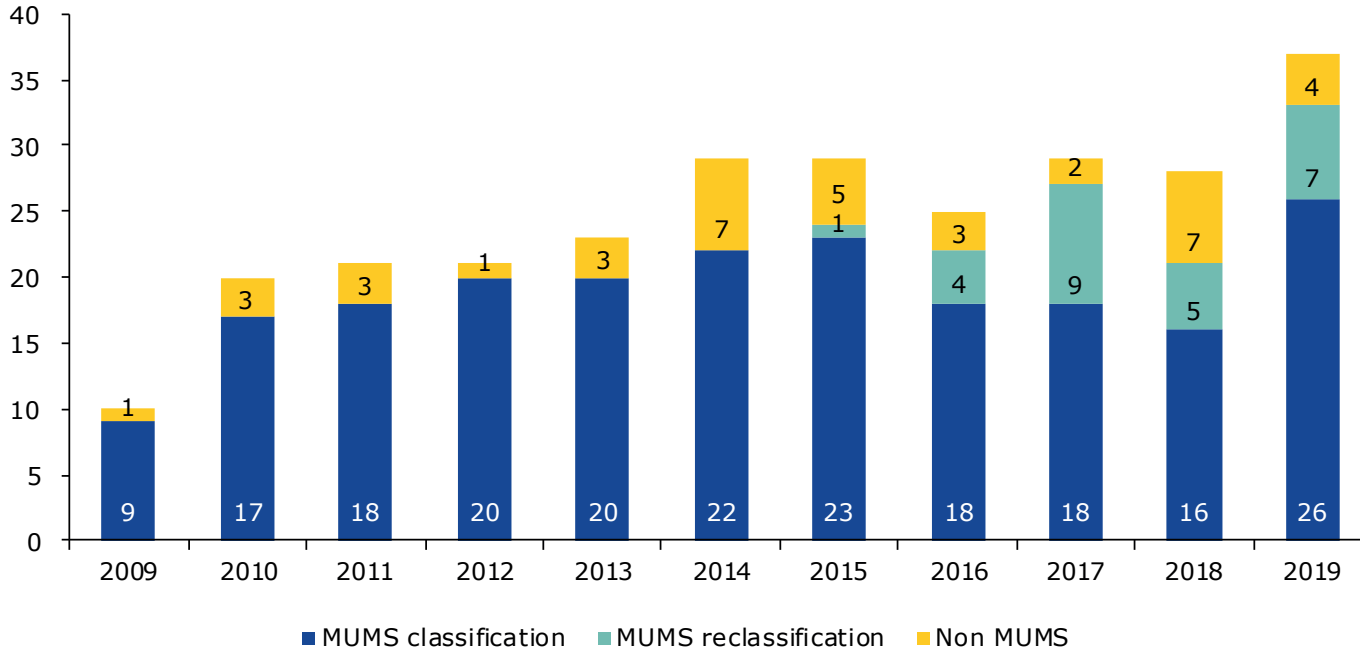
Seventy-three products classified as MUMS/limited market (31%) were recommended as eligible for financial incentives. The remaining 160 (69%), not recommended as eligible for financial incentives, were either not indicated for a food producing species and/or an alternative product was authorised for the same indication.

Table 1. Outcome of MUMS/limited market (re)classification requests in 2009 – 2019

MUMS/limited market classification and reclassification											
Year	2009	2010	2011	2012	2013*	2014	2015	2016	2017	2018	2019
MUMS classification											
With financial incentives	5	11	8	16	10	2	7	1	3	1	4
Without financial incentives	4	6	10	4	10	20	16	17	15	15	22
MUMS reclassification											
With financial incentives						0	1	1	2	0	1
Without financial incentives						0	0	3	7	5	6
Not MUMS	1	3	3	1	3	7	5	3	2	7	4
TOTAL	**10**	**20**	**21**	**21**	**23**	**29**	**29**	**25**	**29**	**28**	**37**

* Restriction of financial incentives to food producing animals only from 1 September 2013

Figure 1. Number of requests for (re)classification by CVMP from 2009-2019



Incentives provided as a result of classification

Approximately 1/3 of the total of 272 requests for classification as MUMS/limited market were from companies registered as micro, small and medium-sized enterprises (SMEs) at the Agency. Where appropriate, applicants are encouraged to register as an SME under Commission Regulation (EC) 2049/2005 and to avail of the financial incentives on offer under this scheme in the first instance. Close liaison is maintained between the Agency's Veterinary Medicines Division and SME office to facilitate that applicants requesting MUMS/limited market classification for their products also register as SMEs, whenever appropriate. This approach has shown beneficial results in terms of a general increase in the number of registered SMEs within the veterinary domain.

Of the 1,951 SMEs registered with the Agency at the end of 2019, 71 are developing veterinary products and 86 both human and veterinary products.

Scientific advice requests or letters of intent to request scientific advice were submitted for 52 MUMS/limited market products in the period September 2009 to December 2019. Twenty-one requests were eligible for free scientific advice under the policy.

Applicants for authorisation of MUMS/limited market products are able to refer to **specific reduced data requirements** as specified in the relevant guidelines which can reduce the need for specific studies. In this context, during the 10 years period:

- **MRL applications** concerning an active substance for a product with MUMS classification: three MRL applications were received in 2016, one of which was concluded positively in 2017, and one MRL application was received in 2018 and concluded positively in 2019.
- **22 centralised marketing authorisations** were granted (see list of products in Annex 1), one of which was withdrawn post authorisation and four additional applications are currently under assessment.
- In the post-authorisation phase, several **extensions** and **type II variation applications** to add new indications and/or target species in the already authorised products for MUMS/limited market were evaluated (see list of products in Annex 1).

- In addition, several products that have been classified by CVMP as MUMS/limited market are at an early stage of development, but the planned route of authorisation has not yet been confirmed. Classification by CVMP as MUMS/limited market is intended also to assist Member States in deciding on data requirements for MUMS/limited market products submitted through national procedures.

MUMS/limited market activities in 2019

Classification of products/indications by CVMP in 2019

In 2019, CVMP reviewed 37 requests for classification as MUMS/limited market, including products indicated for the following minor species: ducks, turkeys, fish (sea bass and rainbow trout) and horses (including foals). Classification was also sought for minor use/limited market indications for products to be used in the following major species: dogs, cats, chickens (layers, layer breeders, broiler breeders), pigs, sheep and cattle. Of these 37 requests, 29 were initial classification requests and 8 reclassification requests. 33 (89%) were classified as MUMS/limited market. Of these 33 classifications, 26 were classified for the first time and 7 reclassified as MUMS/limited market. Four requests (11%) were considered as not falling within the policy. These four requests were for indications in major species (dogs, cats, pigs, cattle) and CVMP considered after detailed evaluation that the market was not limited.

Five products (4 classified for the first time and 1 reclassified as MUMS/limited market) (15%), were recommended as eligible for financial incentives. The remaining 28 (85%), not recommended as eligible for financial incentives, were either not indicated for a food producing species and/or an alternative product was authorised for the same indication.

Incentives provided as a result of classification in 2019

In 2019, 14 out of the total of 37 requests (38%) for classification as MUMS/limited market were from companies registered as micro, small and medium-sized enterprises (SMEs) at the Agency.

- **Scientific advice** requests or letters of intent to request scientific advice were submitted for 8 MUMS/limited market products. One request was eligible for free scientific advice under the policy.

- **MRL application** concerning one active substance for a product with MUMS classification was concluded in 2019.

- Three full new **marketing authorisation applications** for MUMS/limited market products were authorised via the centralised procedure in 2019 and four are currently under assessment.

- In the post-authorisation phase, two applications for **Type II variations** to existing centrally authorised products to add indications classified as MUMS were concluded in 2019.

The costs of the scheme to the Agency in terms of fees waived or reduced in 2019 was of € 116,900.00. The restriction of financial incentives to food-producing species was agreed as part of the change in the policy in 2013 and took full effect in the autumn of 2018, therefore its financial effect became visible as from 2019.

MUMS/Limited Markets policy, guidance and CVMP guidelines on data requirements

The policy on MUMS/limited markets [1] was established on 1 September 2009 with the aim 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 policy provides two types of incentives: reduced data requirements and financial incentives by means of fee exemptions or fee reductions. This initiative represents a joint activity between the Agency and the European Medicines Regulatory Network aiming to facilitate the access to market of products indicated for MUMS as part of measures to promote the availability of veterinary medicines.

Recognising the limited interest from companies to invest in these types of products and in order to maximise the possibilities for attracting interest in this area, the policy did not restrict consideration of requests for MUMS/limited market classification to companies established in the EU. Incentives regarding fee reductions on assessment or post-authorisation would only apply to those companies established in the EU territory.

The policy was updated in July 2013 to restrict the financial incentives to food producing animals only. The change came into force in September 2013. The policy was further revised in 2018 in order to clarify that fee incentives can be granted only to sponsors /applicants (owners) placed within the EU.

To complement the policy a guidance document for applicants "Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market" (EMA/CVMP/388694/2014) (the guidance) [3], was adopted in December 2014.

The guidance gives directions 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.

Further to the revision of the guidelines on data requirements for veterinary medicinal products intended for MUMS/limited market (adopted by CVMP in 2016-2017), the guidance on the classification of veterinary medicinal products for MUMS/limited markets was revised in October 2017. The opportunity was taken to simplify the request process for applicants.

A second revision of the guidance was adopted in 12 December 2018, to align it with the policy clarifying that incentives regarding fee reductions on assessment or post-authorisation would only apply to those companies established in the EU territory.

In order to assist the companies further, the "Q&A - EMA guidance for companies requesting classification for products/indication as Minor Use Minor Species (MUMS)/limited market" (EMA/CVMP/370663/2009) [4] document was created in 2009. It describes the current practice for processing MUMS/limited market applications and addresses in detail a number of questions that applicants requesting (re)classification of products/indications for minor use or minor species (MUMS)/ limited market may have.

Support to applicants for determination of reduction of data requirements

CVMP guidelines on MUMS/limited market data requirements (quality [5], safety [6], efficacy [7] and immunologicals [8]) assist applicants in the preparation of their dossiers for marketing authorisations. The specific data requirements that apply in the case of MUMS/limited market products or indication in a product are important for industry as they can reduce the number of the studies needed to support a new application, and hence reduce the overall cost for product development.

In 2014, CVMP identified the need to revise/ update these CVMP guidelines considering the experience gained to date and to provide further clarification to applicants. The CVMP working parties responsible for the four individual guidelines initiated the revision in 2015. The revised guidelines were finalised in 2016-2017.

Following the publication of the Commission Regulation (EU) 2017/880 on the establishment of maximum residue limits (MRLs), the guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for MUMS/limited market (EMA/ CVMP/SWP/66781/2005-Rev.2) [6] was revised in December 2018 and released for public consultation. The aim of the revision is to take account of the extrapolation criteria to be considered by CVMP when assessing applications for MRLs as detailed in this regulation.

The guidelines will be revised further in the context of Regulation (EU) 2019/6. CVMP will consider how the 'limited markets' provision in the Regulation can best be implemented to increase availability of veterinary medicinal products. In November 2019, the CVMP adopted a Concept paper for the revision of scientific guidelines on limited market for veterinary medicinal products (EMA/CVMP/539861/2019) [9] which was available for public consultation until 31 January 2020.

The revisions of the guidelines are to be finalised well in advance of the implementation date of the Regulation to allow sufficient time to prepare applications to be submitted after January 2022. It is therefore foreseen that the revised guidelines are released for consultation by mid-year 2020 and finalised beginning of 2021.

Promotion of the MUMS/limited market scheme

As previously mentioned, the policy provides two types of incentives with respect to products classified by CVMP as indicated for MUMS/limited market: reduced data requirements and financial incentives for applications.

MUMS data requirements are applicable to any product that has been classified by CVMP as indicated for a MUMS/limited market. These 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 and therefore 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. These financial incentives include free scientific

advice and fee reductions for applications for establishing MRLs for minor species and fee waivers for applications for extensions of existing MRLs. The policy specifies a list of minor species and explains fee reductions for submission of marketing authorisation applications under the centralised procedure.

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).

Veterinary Medicines Regulation (EU) 2019/6. Implications for limited markets

The Regulation 2019/6 entered into force on 28 January 2019 and will be applicable in January 2022. Increasing the availability of veterinary medicinal products was one of the aims of the Regulation which introduces now specific provisions for limited markets, including a definition, conditions and the procedure for granting marketing authorisations, and their renewal.

In the preamble of the Regulation (recital 30) it is acknowledged that companies have less interest in developing veterinary medicinal products for markets of a limited size. The recital also states that: 'In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, the grant of such marketing authorisations should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.'

The Regulation introduces a specific legal basis for veterinary medicinal products intended for limited markets, a summary of which is outlined below.

- Article 4 (29b) defines 'limited markets' as follows:
  - *'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 introduces a derogation in relation to data requirements for applications for limited markets as follows:
  - *1. 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.

- Article 24 introduces the validity of a marketing authorisation for a limited market as follows:
  - 1. By *way of derogation from Article 5(2), a marketing authorisation for a*

limited market shall be valid for a period of 5 years.

» *2. Before the expiry of the five-year period referred to in paragraph 1 of this Article, marketing authorisations for a limited market granted in accordance with Article 23 shall be re-examined on the basis of an application from the holder of that marketing authorisation. That application shall include an update benefit-risk assessment.*

» *6. The competent authority or the Commission, as applicable, may at any time grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised for a limited market, provided that the holder of the marketing authorisation for a limited market submits the missing data on safety or efficacy referred to in Article 23(1).*

The Regulation foresees reduced data requirements for the authorisation of a product intended for limited markets on safety and efficacy. Authorisations will be valid for a period of five years (that can be renewed) and allows - once the missing data on safety or efficacy have been provided – to grant a full marketing authorisation valid for an unlimited period of time.

The Regulation introduces some significant changes in relation to the current EMA policy and CVMP guidelines, e.g.:

- Products intended for salmon are considered limited market while under the EMA policy products intended for salmon do not benefit from MUMS classification,
- Marketing authorisations for limited markets are granted for a limited period of time (5 years), which can be renewed;
- No reduction of data requirements on quality is foreseen;
- Requires the inclusion in the SPC of a statement indicating that the marketing authorisation was granted on the basis of a reduced data package;
- The Regulation does not refer to financial incentives for limited markets.

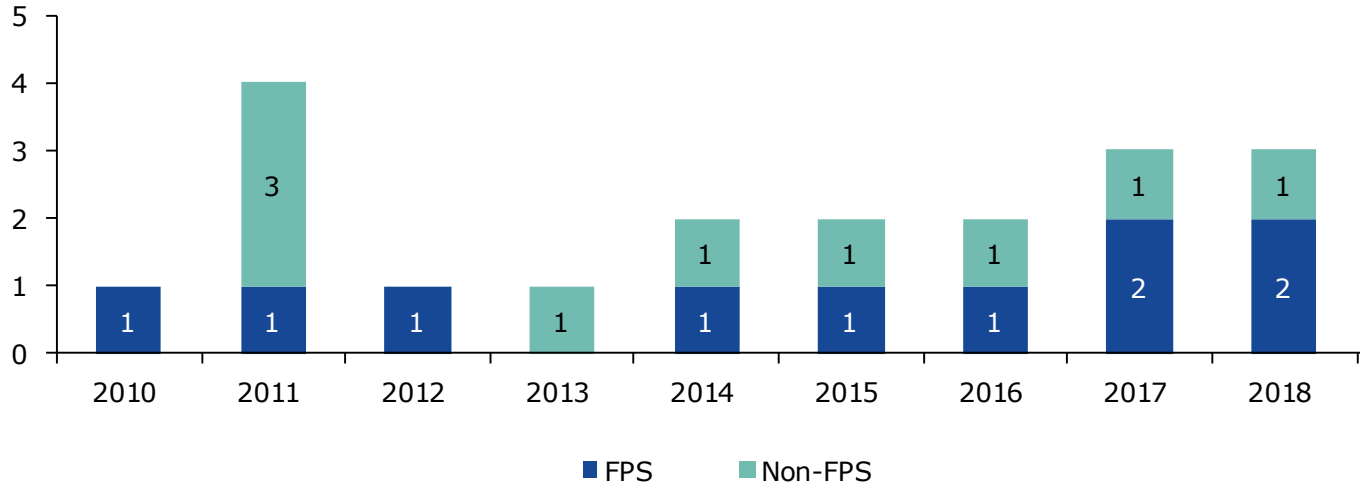
Discussion

The ten years of operation show the continued interest from potential applicants in developing products to fill existing gaps in availability for MUMS/limited market products (Table 1 and Figure 1). The total number of requests for classification in 2019 increased by 30% in comparison to the more or less consistent average yearly figure of 28 in the previous five years. The number of reclassification requests for products reaching the fifth anniversary of their original classification also increased slightly in 2019. All but one product maintained their MUMS classification.

The great majority of requests for classification were confirmed as MUMS/limited market by CVMP indicating that applicants are in general able to follow the guidance available and identify potential MUMS/limited market products with advice and assistance from the Agency. The overall proportion of unsuccessful classification requests continued to be low as in the previous years, suggesting that the measures taken to promote the policy and facilitate the understanding of the scheme are successful.

There was an increase in the number of requests (re)classified as MUMS/limited market and recommended as eligible for financial incentives (See Table 1 above) in 2019 in comparison to 2018. However, in terms of the financial impact of the policy, the overall reduction in the proportion of MUMS/limited market classifications that are eligible for fee incentives (restricted since 2013 to food producing animals only) has started to feed through into a reduction in the overall costs of the scheme,

Figure 2. Number of centrally authorised products with MUMS/limited market classification 2009-2019



as shown by a decreasing trend in in 2019 (€ 116,900.00) and 2018 (€113,776.85) in comparison to 2017 (€383,482.34).

It is noted that the restriction in eligibility has not resulted in a significant reduction in submission of requests for classification under the scheme.

In terms of estimating the total financial impact of the scheme, it is important to note that decisions on eligibility for fee reductions apply only to products submitted through the centralised procedure.

In view of the new provisions in the Regulation a discussion is required whether it is possible to maintain financial incentives for limited market applications/products after January 2022.

Figure 2 shows the number of veterinary medicinal products with MUMS/limited market classification authorised centrally over the period 2009-2019. In addition, a number of Type II variation applications have been adopted extending products use to MUMS/limited indications.

It is encouraging to note that there is now a steady stream of products being centrally authorised year on year for MUMS/limited market products (total n=22) in both food-producing (n=12) and non-food producing species (n=10).

Conclusions

The MUMS/limited market scheme continues to be successful in incentivising the submission of requests for classification or reclassification of products as indicated for MUMS/limited market. These (re)classifications have resulted in newly authorised MUMS/limited market products (or new indications) becoming available for use on the EU market.

Requests classified in the early years are now being authorised and starting to fill some gaps in animal health, meeting the objective of increasing availability of veterinary medicines. The best use of the available budget remains a priority in order to support the development of products that are most needed in terms of availability.

For the implementation of the Regulation on veterinary medicinal products in January 2022 it will be necessary to establish criteria for eligibility of products as limited markets and the relevant procedures for handling the eligibility requests as well as the applications, including their renewal.

Annex 1

Centrally authorised products that benefited from MUMS/limited market scheme

Arti-Cell Forte (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/arti-cell-forte)

Advocate (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/advocate)

Aivlosin (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/aivlosin)

Broadline (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/broadline)

CaniLeish (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/canileish)

Clevor (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/clevor)

Clynav (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/clynav)

Coxevac (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/coxevac)

Dany's BienenWohl (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/danys-bienenwohl)

Econor (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/econor)

Equisolon (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/equisolon)

Eravac (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/eravac)

Fungitraxx (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/fungitraxx)

HorStem (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/horstem)

Letifend (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/letifend)

Metacam (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/metacam)

MS-H vaccine (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/ms-h-vaccine)

Nobivac Myxo RHD (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/nobivac-myxo-rhd)

Nobivac Myxo RHD Plus (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/nobivac-myxo-rhd-plus)

Oncept IL-2 (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/oncept-il-2)

Oxybee (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/oxybee)

Poulvac E. Coli (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/poulvac-e-coli)

Profender (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/profender)

Rabitec (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/rabitec)

Suprelorin (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/suprelorin)

TruScient – withdrawn (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/truscient)

VarroMed (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/varromed)

Zulvac SBV (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/zulvac-sbv)

Zycortal (https://www.ema.europa.eu/en/medicines/veterinary/EPAR/zycortal)

Annex 2

References

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[8] 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:

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European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000
Send a question www.ema.europa.eu/contact

www.ema.europa.eu

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