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Veterinary Medicines Division

MUMS/limited market scheme for veterinary medicines

9th Annual Report (01/01/2018 – 31/12/2018)

Background

The European Medicines Agency (the Agency) implemented the first policy for classification and incentives for veterinary medicinal products indicated for Minor Use Minor Species (MUMS)/limited market on 1 September 2009 and this was updated in July 2013. The current revised policy for classification and incentives for veterinary medicinal products indicated for MUMS/limited market was agreed in December 2014 and further amendment was introduced on 13 December 2018 (EMA/308411/2014-Rev.1).

The MUMS/limited market 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/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 (Theme 2; Objective 1) and in the corresponding work plans of the Agency and the Heads of Medicines Agencies (HMA).

Annual reports are provided to EMA Management Board (MB) on the operation of the MUMS/limited market scheme. This annual report covers the activities carried out under the MUMS/limited market scheme between 1 January and 31 December 2018.

MUMS/limited market activities in 2018

Classification of products/indications by CVMP

In this tenth year of operation of the MUMS/limited market scheme for veterinary medicines, the CVMP reviewed 28 requests for classification as MUMS/limited market, including products indicated for the following minor species: foxes, raccoon dogs, ferrets, goats, turkeys, bees, fish, rabbits 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 (gilts and sows) and cattle (newborn calves).

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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.

A total of 28 requests were received for products or indications in 2018. Of these, 23 were initial classification requests and 5 reclassification requests. Of all 28 requests, 21 (75%) were classified as MUMS/limited market. Of these, 16 were classified for the first time and 5 reclassified as MUMS/limited market. Seven requests (25%) were considered as not falling within the MUMS/limited market policy. These seven requests were for indications in major species (dogs, chickens and calves) and the CVMP considered after detailed evaluation that the market was not limited.

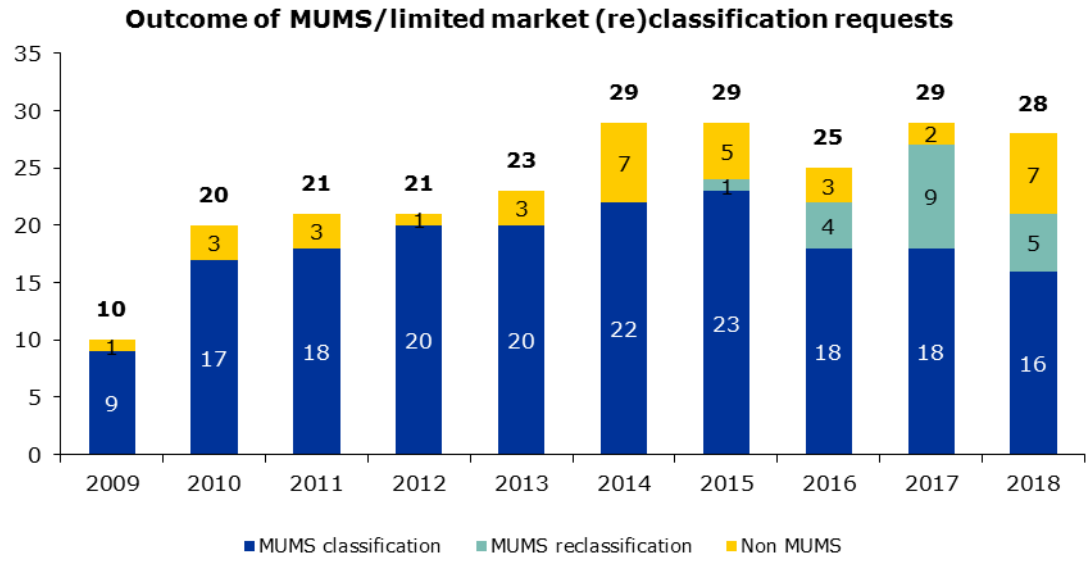
One product classified as MUMS/limited market (5%) was recommended as eligible for financial incentives (19% in 2017) whilst 20 (95%) were not recommended as eligible for financial incentives (81% in 2017) as these were either not indicated for a food producing species and/or an alternative product was authorised for the same indication.

Table 1: Outcome of MUMS/limited market (re)classification requests in 2009 –2018

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

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

Figure 1: Number of requests for (re)classification by CVMP from 2009-2018



Incentives provided as a result of classification

Thirteen (13) out of the total of 28 requests (46%) 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.

By the end of 2018, 151 companies working in the veterinary medicines field were registered as SMEs, representing about 8% of the total number of companies registered as SMEs.

Scientific advice requests or letters of intent to request scientific advice were submitted for five MUMS/limited market products in 2018 (including 3 requests for scientific advice on data requirements). No requests were eligible for free scientific advice under the MUMS/limited market 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:

- Three full new **marketing authorisation applications** for MUMS/limited market products were **validated** for the centralised procedure in 2018 and are currently under assessment.
- In 2018, three **centralised marketing authorisations** were granted for the following products classified by CVMP as MUMS/limited markets:
  - Oxybee (*treatment against Varroa destructor in honey bees in brood free colonies*)
  - Clevor (*new eye drops product containing ropinirole (dopamine agonist) for the induction of vomiting in dogs*)
  - Dany's BienenWohl (*treatment against Varroa destructor in honey bees*)
- In the post-authorisation phase, two **Type II variation applications** (new indications) for MUMS/limited market in an already authorised product were evaluated.
  - Metacam *(new target species, the guinea pig)*
  - One procedure remains under assessment *(new therapeutic indications)*

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.

The costs of the scheme to the Agency in terms of fees waived or reduced in 2018 was of € 113,776.85 (€383,482.34 reported in 2017). The restriction of financial incentives to food-producing species was only agreed as part of the change in policy in 2013 and took full effect in the autumn of 2018. Financially, the effect will be visible as of 2019.

Revision of MUMS/limited market guidance

Revision of MUMS/limited market policy

The MUMS/limited market policy has been developed 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 (these only applicable to food producing species for which no alternative is available).

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. Considering that marketing authorisation applications can only be submitted by companies established in the EU, specific data requirements regarding assessment or post-authorisation would only apply.

The policy and guidance were revised and adopted by the MB in 2018 to clarify that fee incentives can be granted only to applicants placed within the EU: only a sponsor/applicant (owner) established in the EU may benefit from the financial incentives that are available from the Agency under this policy.

Revision of CVMP guideline on safety and residue data requirements

CVMP guidelines on MUMS/limited market data requirements 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.

Due to the publication of the Commission Regulation (EU) 2017/880, the draft revised guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended MUMS/limited market (EMA/CVMP/SWP/66781/2005-Rev.2) was adopted in December 2018 for release for an 8-month period of consultation. The aim of the revision is to take account of the extrapolation criteria to be considered by the CVMP when assessing applications for MRLs as detailed in this regulation.

Promotion of the MUMS/limited market scheme

The Agency continues to promote the MUMS/limited market scheme to stakeholders. Information has been published on transfer of MUMS status granted to the product in the *European Commission/EMA Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure*.

The new Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary medicinal products (repealing Directive 2001/82) entered into force on 28 January 2019 and starts to apply three years later. The Agency followed closely the discussions in European Parliament and the Council and provided advice to the European Commission on request based on experience of operating the MUMS/limited market scheme. Establishing a clear basis for MUMS/limited market in legislation will address the concerns raised by industry during the consultation on the revised guidelines on data requirements for MUMS/limited market products. The aim of this amendment therefore is to provide an increased predictability, and possibly further appropriate reductions in terms of the data requirements for these types of product.

Discussion and conclusions

The tenth year of operation shows 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 appears to be more or less consistent year on year with an average of 28 in previous five years. The number of requests for reclassification decreased in 2018 (Table 1 and Figure 1), however all submitted requests were reclassified. Reclassification can be requested for products reaching the fifth anniversary of their original classification.

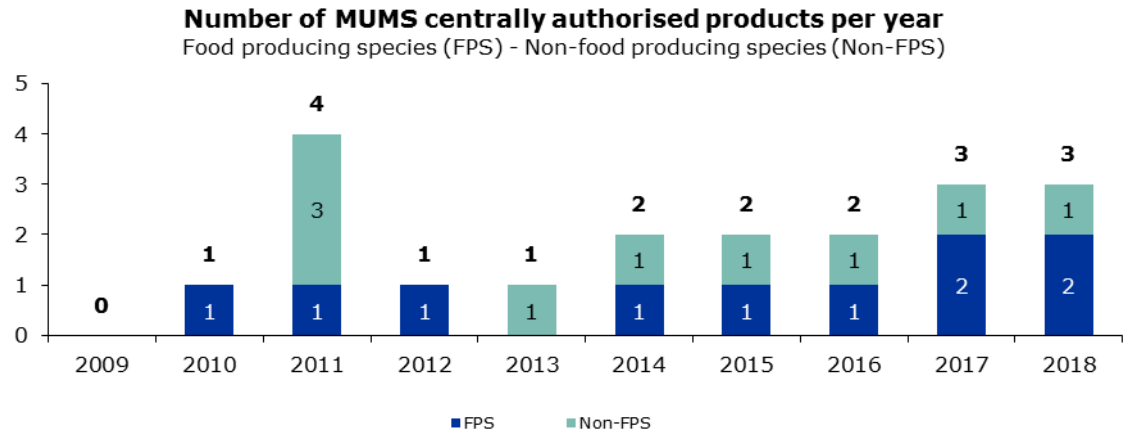
The great majority of requests for classification were confirmed as MUMS/limited market by CVMP indicating that applicants are in general able to follow the guidance available and identify potential MUMS/limited market products with advice and assistance from the Agency. In 2018 the trend in the proportion of unsuccessful classification requests continued to be similar as in the previous years, suggesting that the measures taken to promote the policy and facilitate the understanding of the scheme are successful.

In terms of the financial impact of the policy, a decrease in the number of requests (re)classified as MUMS/limited market and recommended as eligible for financial incentives (See Table 1 above) was observed in 2018 in comparison to 2017. This is in line with the principle to restrict eligibility for such incentives to products indicated for food producing animals agreed in 2013 and implemented in the revised policy adopted in 2014. This reduction in the proportion of MUMS/limited market requests that are eligible for fee incentives has started to feed through into a reduction in the overall costs of scheme as shown by a decreased cost in 2018 (€113,776.85) compared 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. Considerations on a possibility for fee reductions for marketing authorisations going through the decentralised/mutual recognition procedure is a matter for the Member States concerned.

Figure 2 shows the number of veterinary medicine products with MUMS/limited market classification authorised centrally over the period 2009-2018. 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=19) in both food-producing (n=10) and non-food producing species (n=9).

Figure 2: Number of centrally authorised products with MUMS/limited market classification 2009-2018



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 (re)classifications have resulted in newly authorised MUMS/limited market products (or new indications) becoming available for use on the EU market. 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.

In conclusion, 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.

Background information

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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: https://www.ema.europa.eu/en/efficacy-target-animal-safety-data-requirements-veterinary-medicinal-products-intended-minor-uses

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