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Veterinary Medicines Department

MUMS/limited market for veterinary medicines

7th Annual Report (01/01/2016 – 31/12/2016)

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 (EMA/308411/2014).

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 EMA and HMA. Annual reports are provided to EMA Management Board 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 2016.

MUMS/limited market activities in 2016

Classification of products by CVMP

The CVMP reviewed 25 requests for classification as MUMS/limited market in this, the seventh, year of operation, including products indicated for the following minor species: honeybees, horses, goats, racing pigeons and guinea pigs (Table 1). Classification was also sought for minor use/limited market indications for products to be used in the following major species: dogs, cats and cattle.

During the year the Agency reviewed and formalised the procedure for applicants seeking to reclassify their products as MUMS/limited market after the original 5 year period of classification had come to an

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end. For this reason, 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 as MUMS/limited market remained appropriate.

Of the total of 25 MUMS requests received, 18 were classified and 4 reclassified as MUMS/limited market (88% in total). Three requests (12 %) were considered as not falling within the MUMS/limited market policy. All these three requests were for indications in major species (cattle, dogs and cats) where, the CVMP considered after detailed examination that the market was not limited.

Two products/indications (9% of products classified as MUMS/limited market) were recommended as eligible for financial incentives (33 % in 2015) whilst 20 (91 %) were classified or reclassified as MUMS but not recommended as eligible for financial incentives (66 % in 2015). These products/indications were either not indicated for a food producing species and/or an alternative product(s) was authorised for the same indication.

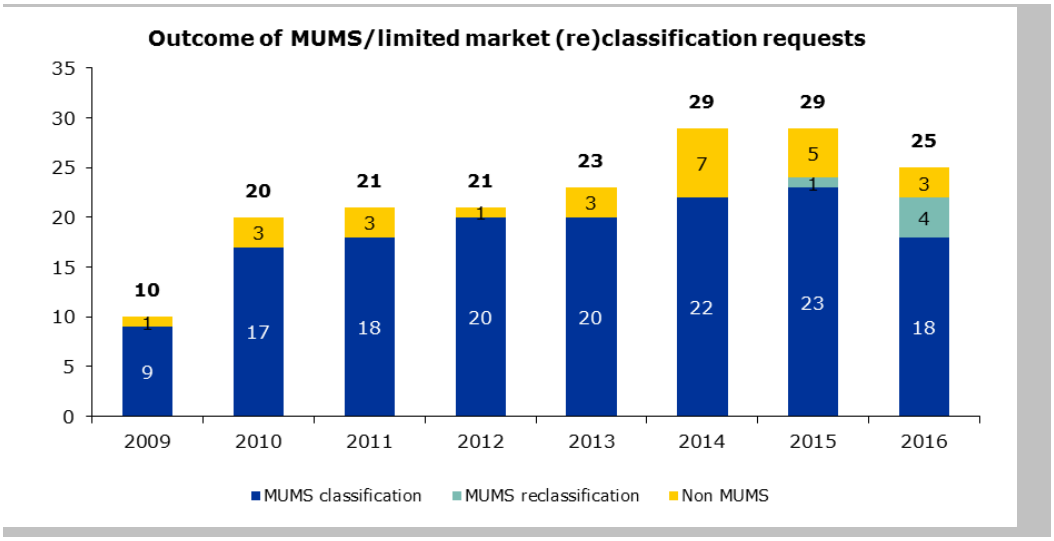
Four reclassification requests were submitted in 2016 following the expiry of the initial 5 year classification and all were reclassified as MUMS/limited market for a further 5 year period.

Table 1: Outcome of MUMS/limited market (re)classification requests in 2009 – 2016

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

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

Figure 1: Number of requests for (re)classification by CVMP from 2009-2016



Incentives provided as a result of classification

Three of 25 requests (12 %) 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 with the Agency's SME office to ensure that MUMS applicants register as SMEs, where 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 2016 over 150 companies were registered as SMEs working in the veterinary domain, representing about 9 % of the total number of companies registering as SMEs.

Scientific advice requests or letters of intent to request scientific advice were submitted for 2 MUMS/limited market products in 2016. Neither request was eligible for free scientific advice under the MUMS/limited market policy however one applicant was able to access incentives as a registered SME company.

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:

- **MRL applications** were submitted in 2016 for substances contained in three different products classified as MUMS/limited market.
- Five full new **marketing authorisation applications** for MUMS/limited market products were validated for the centralised procedure in 2016 and are currently under assessment. One additional letter of intent was received for such product in 2016 for later submission of a marketing authorisation application.
- In 2016, **centralised marketing authorisations** were granted for the following products classified by CVMP as MUMS/limited markets:
  - **Letifend (vaccine against leishmania in dogs),**
  - **Poulvac E. coli (vaccine against colibacillosis in turkeys) and**
  - **Eravac (vaccine against rabbit haemorrhagic disease in rabbits).**
- In the post-authorisation phase, four applications were received in 2016 for **Type II variations** to existing centrally authorised products to add indications classified as MUMS. Three such Type II variations were adopted and one remains under assessment.

In addition, several intended products that have been classified by CVMP as MUMS/limited market are at an early stage of development and plans for the route of authorisation have not yet been finalised by the applicants. 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 2016 in terms of fees waived or reduced was € 297,625, in comparison to the second full year of operation of the revised policy (€ 138,443 reported in 2015).

Support to applicants for determination of data requirements

In 2014, CVMP identified the need to revise/update the CVMP guidelines on the data requirements applicable to products indicated for MUMS in light of the experience gained to date and to provide clarification to applicants on those requirements. The CVMP working parties responsible for these four individual guidelines initiated the revision in 2015. The revised guidelines were adopted for public consultation in February 2016 and adopted in December 2016 following consideration of comments received with the exception of the guideline for immunologicals which will be finalised in the first half of 2017 to take into account extensive substantial comments received from industry on this guideline.

Requests to the CVMP Scientific Advice Working Party for scientific advice on data requirements or letters of intent to request such scientific advice were submitted for 2 MUMS/limited market products in 2016.

The Agency continues to promote the MUMS/limited market policy at stakeholder meetings and an update on progress with revision of CVMP guidelines for MUMS was included on the agenda of the CVMP Interested Parties Meeting in April 2016.

Discussion and conclusions

The seventh 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 number of requests for classification appears to be more or less consistent year on year with an average of 24 over the last 5 years. The number of requests for reclassification increased in 2016 as an increasing number of products reached the fifth anniversary of their original classification (see Figure 1 above).

The great majority of requests for classification are confirmed as MUMS/limited market by CVMP indicating that in general applicants are able to follow the guidance available and identify potential MUMS/limited market products with advice and assistance from the Agency. In 2016 the trend continued for a reduction in the proportion of unsuccessful classification requests suggesting that the measures taken to promote the policy and facilitate the understanding of the scheme are successful.

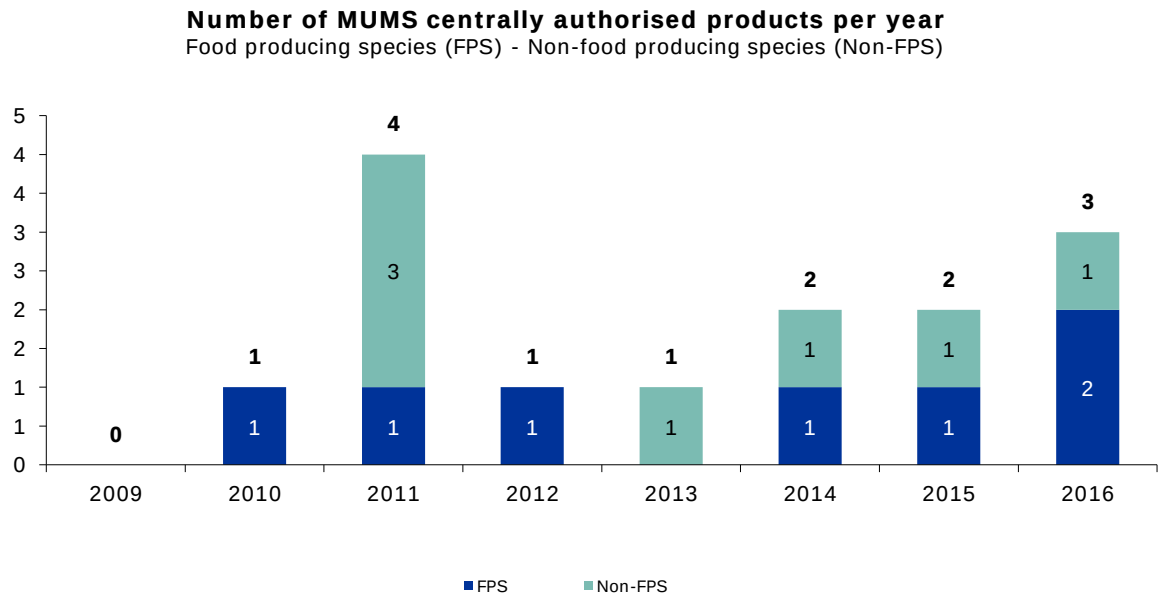
In terms of the financial impact of the policy, a decrease was observed in the number of requests received during 2016 that were (re)classified as MUMS/limited market and recommended as eligible for financial incentives in comparison to 2015 (See Table 1 above). The overall proportion of MUMS/limited market products eligible for financial incentives has decreased since the principle to restrict eligibility to products indicated for food producing animals was agreed in 2013 and implemented in the revised policy that was finally adopted in 2014. This reduction in the proportion of MUMS/limited market requests that are eligible for fee incentives has yet to feed through into a reduction in the overall costs of scheme as shown by the increased cost of the scheme in 2016 compared to 2015. However, concern that this restriction in eligibility may result in a significant reduction in submission of requests for classification under the scheme has proven unfounded.

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 and the possibility of fee reductions for marketing authorisations going through the decentralised/mutual recognition procedure is a matter for the Member States concerned.

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 are starting to result in newly authorised MUMS/limited markets products becoming available for use. Figure 2 shows the number of centrally authorised veterinary medicines subject to MUMS/limited market classification over the period 2009-2016. It is encouraging to note that there is now a steady stream of products being centrally authorised for MUMS/limited market indications (total n=14) in both food-producing (n=7) and non-food producing species (n=7).

Figure 2 – Number of centrally authorised products with MUMS/limited market classification 2009-2016



Three revised CVMP guidelines concerning MUMS data requirements were finalised following consultation in 2016 and one is intended for finalisation in the first half of 2017, to assist applicants in the preparation of their dossiers for marketing authorisations. The specific data requirements that apply in the case of MUMS products 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 September 2014, the European Commission adopted a proposal for a new regulation governing the authorisation of veterinary medicines which included for the first time measures to provide a clear legal framework for products indicated for MUMS/limited markets. The Agency is following closely the discussions in European Parliament and the Council and providing 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 could address the concerns raised by industry in response to the consultation on the revised MUMS guidelines that there is a need for increased predictability, and possibly further appropriate reductions in terms of the data requirements for this type of products.

References

Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market, Agency Policy no 75, adopted in December 2014 and published on the Agency website (EMA/308411/2014)
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/09/WC500172928.pdf .

Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) limited market, adopted by Management Board in December 2014 and published on the Agency website (EMA/CVMP/388694/2014)

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/12/WC500179577.pdf

List of MUMS/limited classification outcomes up to the end of 2016

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000499.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05803ddc15