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Veterinary Medicines Division

MUMS/limited market scheme for veterinary medicines

8th Annual Report (01/01/2017 – 31/12/2017)

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 2017.

MUMS/limited market activities in 2017

Classification of products/indications by CVMP

In this ninth year of operation of the MUMS/limited market scheme for veterinary medicines, the CVMP reviewed 29 requests for classification as MUMS/limited market, including products indicated for the following minor species: sea bass, sea bream, bees, turkeys, guinea fowls, ducks, quails, pheasants, partridge, 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, sheep, pigs and cattle.

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

A total of 29 requests were received for products or indications in 2017. Of these, 19 were initial classification requests and 10 reclassification requests. Of all 29 requests, 27 (93%) were classified as MUMS/limited market. Of these, 18 were classified for the first time and 9 reclassified as MUMS/limited market. Two requests (7%) were considered as not falling within the MUMS/limited market policy. These two requests were for indications in major species (cats and dogs) and the CVMP considered after detailed evaluation that the market was not limited.

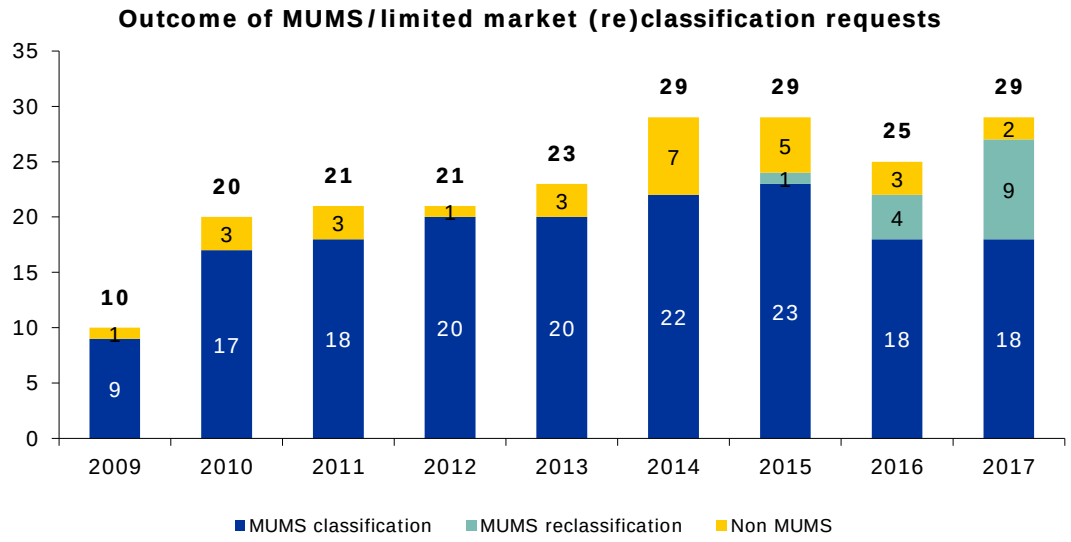
Five of the products/indications classified or reclassified as MUMS/limited market (19%) were recommended as eligible for financial incentives (9% in 2016) whilst 22 (81%) were not recommended as eligible for financial incentives (91% in 2016) as these were either not indicated for a food producing species and/or an alternative product was authorised for the same indication.

Table 1: Outcome of MUMS/limited market (re)classification requests in 2009 – 2017

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

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

Figure 1: Number of requests for (re)classification by CVMP from 2009-2017



Incentives provided as a result of classification

Nine out of the total of 29 requests (31%) 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 2017 over 150 companies were registered as SMEs working in the veterinary domain, representing about 8% of the total number of companies registering as SMEs.

Scientific advice requests or letters of intent to request scientific advice were submitted for eight MUMS/limited market products in 2017. Two 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:

- One **MRL application** concerning an active substance for a product with MUMS classification was concluded in 2017.
- Three full new **marketing authorisation applications** for MUMS/limited market products were **validated** for the centralised procedure in 2017 and are currently under assessment.
- In 2017, **centralised marketing authorisations** were granted for the following products classified by CVMP as MUMS/limited markets:
  - **Clynav (vaccine against pancreatic disease in salmon),**
  - **Rabitec (vaccine against rabies in foxes and raccoon dogs) and**

  - **VarroMed (treatment against *varroa* in honey bees).**

- In the post-authorisation phase, two applications were received in 2017 for **Type II variations** to existing centrally authorised products to add indications classified as MUMS. Both Type II variations remain under assessment.

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 2017 in terms of fees waived or reduced was € 383,482.34, in comparison to the third full year of operation of the revised policy (€ 297,625 reported in 2016). The restriction of financial incentives to food-producing species only was agreed as part of the change in policy in 2013 and will take full effect in the autumn of 2018. Financially, the full effect will be applicable as of 2019.

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 revision of the guidelines was finalised in 2016-2017 and the guidance with the related Q&A were updated.

Requests to the CVMP Scientific Advice Working Party for scientific advice on data requirements were submitted for eight MUMS/limited market products/indications in 2017.

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*.

Discussion and conclusions

The ninth 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 27 in previous five years. The number of requests for reclassification increased in 2017 as an increasing number of products reached the fifth anniversary of their original classification (see Figure 1 above).

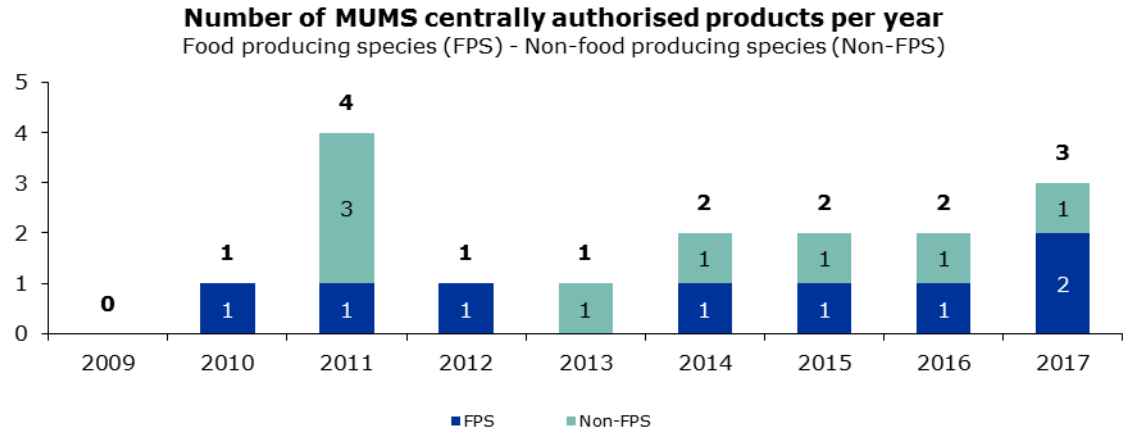
The great majority of requests for classification are confirmed as MUMS/limited market by CVMP indicating that applicants are in general able to follow the guidance available and identify potential MUMS/limited market products with advice and assistance from the Agency. In 2017 the trend continued for 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, an increase was observed in the number of requests received during 2017 that were (re)classified as MUMS/limited market and recommended as eligible for financial incentives in comparison to 2016 (See Table 1 above). The overall proportion of MUMS/limited market products eligible for financial incentives has decreased since the principle to restrict eligibility for such incentives 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 2017 (€ 383,482.34) compared to 2016 (€ 297,625). However, previous concern that this restriction in eligibility may result in a significant reduction in submission of requests for classification under the scheme appears 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. 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.

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 markets products becoming available for use. Figure 2 shows the number of veterinary medicines subject to MUMS/limited market classification authorised centrally over the period 2009-2017. It is encouraging to note that there is now a steady stream of products being centrally authorised year on year for MUMS/limited market indications (total n=16) in both food-producing (n=8) and non-food producing species (n=8).

Figure 2 – Number of centrally authorised products with MUMS/limited market classification 2009-2017



Revised CVMP guidelines concerning MUMS data requirements were finalised in 2016-2017, 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 including 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.

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