



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Department

## 4th Annual Report Veterinary MUMS/limited market

### Background

The European Medicines Agency (the Agency) implemented the Policy for Classification and Incentives for Veterinary Medicinal Products indicated for Minor Use Minor Species (MUMS)/limited market on 1 September 2009 and updated it in July 2013

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500005157.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005157.pdf). 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. The policy was adopted by Management Board and by HMA in 2009 and it was agreed to provide a report at the end of each year of implementation on the functioning of the policy and the uptake by applicants. Annual reports were presented to Management Board in October 2010 and in October 2011 and in March 2013. During 2013 following discussions with Management Board it was agreed to restrict the financial incentives under this policy to food producing animals only from 1 September 2013, pending a wider review of the policy, to be finalised by the end of 2014.

This annual report covers the activities from 1 January 2013 - 31 December 2013 in line with the request to provide calendar year reporting. This period covers 4 months of operation of the updated policy (September to December 2013) under which fee incentives are now restricted to food producing animals only. Over the calendar year for 2013, 23 separate requests were submitted for classification by the CVMP. Since the inception of this policy in 2009 to the end of 2013, 96 requests for classification in total have been considered.

### Classification procedure

Applicants are requested to complete a template for classification which is available from the Agency website. These requests for classification are then presented to CVMP who decide either, that the product under consideration falls within the policy and that the product is intended for MUMS/limited market, or that it falls outside the policy. Financial incentives are awarded to those products classified as MUMS where no alternative is authorised for the same species with the same indication in the EU and where the market is considered to be limited. These financial incentives are available for a period of 5 years (including free scientific advice, reduced centralised application fees, reduced MRL fees). Since September 2013 these financial incentives are limited to products indicated for food producing animals. Products are not awarded the financial incentives where they are intended for minor species



or minor uses where alternative products are authorised or the market is not considered by the Agency to be limited either in terms of size or return on investment. These products are classified as MUMS/Limited market but are not awarded financial incentives, although applicants may still avail themselves of the CVMP MUMS guidelines in terms of data requirements for an authorisation or establishment of MRLs, where appropriate, along with any administrative assistance the Agency can offer. Procedural guidance has been developed for applicants and is published on the Agency website. A summary of products that have been classified and the outcome are included in general terms in the CVMP press release published following each plenary meeting and also published on the Agency website.

## Products classified in 2013

The CVMP reviewed 23 requests in this, the fourth year of operation, including products intended for the following minor species: horses, ferrets, rats, rabbits, guinea pigs and turkeys. Products intended for major species included products for dogs, cats, salmon and chickens, where classification was sought for minor uses/Limited markets. Of the total of 23 requests; 20 were classified as MUMS (of which 10 were awarded financial incentives and 10 were given no financial incentives as alternative products are authorised for the same indication and/or the market was not considered limited). Full details of all the products are included in Annex 1 to this report.

In comparison to 2012, 50% of requests were classified as MUMS/limited market (78 % last year) **with** the financial incentives and 50 % were classified as MUMS (22 % last year) but **without** the financial incentives. Of the requests received, 13% of the total requests received (or three product indications) were considered as not falling within the MUMS/limited market policy – these requests were for major species (cats and dogs) where the market was not considered limited or alternative products were available.

With respect to the 23 requests for classification, **scientific advice** applications or letters of intent for scientific advice have subsequently been submitted for 7 of them in the past year, including one request submitted for one of the products not classified as MUMS/limited market. Three of the requests submitted were eligible for free scientific advice (all of these were from SME companies where 90% fee waivers are awarded to SMEs for scientific advice requests and then supplemented by 10% from the MUMS/Limited market financial incentives).

Seven of these applicants for the 23 requests are **SMEs** registered at the Agency. Letters of intent for the **centralised procedure** have been received or are pending for three of the products classified as MUMS/limited market whereas three other requests relate to **extensions or Type II variations** (new indications) to existing centrally authorised products. Some intended products that are classified under the MUMS/limited market policy are at an early stage of development and plans for the route of authorisation have not yet been finalised by the applicants. Applicants enquiring about MUMS classification are encouraged to register as an SME under Commission Regulation (EC) 2049/2005, where applicable, and to avail of the financial incentives on offer. Liaison with the SME office has been strengthened for registration of these applicants where appropriate. This has shown beneficial results in the general increase in registered SMEs working within the veterinary domain (currently over 126 - about 10% of total registered companies) where the incentives provided for under the SME scheme may be availed of.

The costs of the scheme to the Agency in terms of fees waived or reduced remained similar to previous years at €294,190 (€355,405 in 2012 over 16 months). It is expected that this figure will decrease in future years following restriction of fee incentives to products for food producing animals.

## Other Activities

In line with the policy the Agency has published a list on the external website of all products classified under this policy as MUMS/limited market for the general public. This list is updated on a regular basis to include all new classifications and therefore includes all applications classified to date

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000499.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05803ddc15](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000499.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05803ddc15). Details of the applicant and active substance are not given, only the general therapeutic area and target species along with the decision of the CVMP.

In their consideration of the 2012 report on the MUMS/limited market scheme, CVMP in principle agreed that the policy was working well in attracting applications on a consistent basis (averaging two requests per month since the policy started with a slight decrease noticeable since updating eligibility for financial incentives). Decisions on individual applications take into account decisions already reached in relation to requests received and previously classified. The Agency makes recommendations to CVMP for consideration. Consistency in decision making is therefore enhanced and there is an appeal procedure for applicants where they may provide additional data relevant to their request for consideration. Members of the CVMP have been appointed on a number of occasions to review in more detail requests where reaching a decision on MUMS status poses a particular challenge, such as interpreting prevalence figures for specific diseases in the EU or to reflect in more detail if a market is limited in terms of size/return on investment and to make recommendations. Applicants have also been encouraged to provide more detailed information in the submission to allow the Committee to reach a decision. The cover pages for the classification at CVMP have also been standardised to consistently provide the requisite information together with a recommendation to CVMP based on the best available information.

The classification procedure was presented to SME stakeholders at a workshop dedicated to veterinary SMEs held at the Agency in November 2013. This included the change in the policy to restrict financial incentives to food producing animals only. The subject is also on the agenda of the forthcoming EMA/IFAH-Europe Info day in March 2014 to enable a wider and more general discussion on the policy. This feedback from stakeholders will be very valuable in finalising the in-depth review due for completion by the end of 2014.

## Discussion

Since its inception this policy has consistently attracted requests for classification by CVMP and has resulted in additional requests for scientific advice and also resulted in centralised marketing authorisations (both finalised and under assessment) for MUMS products. Many requests concern products at an early stage of development and there is therefore a delay before applications are submitted for marketing authorisations. Not all products will be eligible for the centralised procedure and some will be authorised via the decentralised route or nationally. The fourth year of operation shows the continued interest from potential applicants in developing products to fill availability gaps. To date, centralised authorisations have been granted for Canileish (leishmania in dogs), Nobivac Myxo RHD, (myxomatosis and rabbit haemorrhagic disease in rabbits), Suprelorin (fertility control in ferrets), TruScient (long bone fractures in dogs), Coxevac vaccine (Q Fever in cattle and goats) and MS-H vaccine (mycoplasma synoviae in chickens), Oncept IL-2 (fibrosarcoma in cats), Fungitraxx (fungal infection in avian species), Equisolon (respiratory disease in horses); an application for an extension to the existing authorisation for the anthelmintic Zolvix to include goats was withdrawn.

Reflections are ongoing at Agency and CVMP level on how to build on the success of this policy and how to ensure that financial incentives are provided where they will be most beneficial. Currently

products are classified on a case by case basis as requests are submitted by applicants and only food producing animals are now eligible for financial incentives. A specific ad-hoc group was held in October 2013 with representatives of the Agency, CVMP, HMA and an observer from the European Commission to initiate the further review of the policy requested by the Management Board, and in particular to develop more objective criteria for classification as MUMS. Discussions on how to revise the policy took place at the Presidency meetings held during 2013. The Federation of Veterinarians of Europe was consulted and asked for input into the methodology for determining prevalence for conditions and their outline views on the proposed revisions to the policy. The general conclusions of these meetings will be taken into account in the revision of the policy, along with comments received from the Federation of Veterinarians of Europe and IFAH-Europe. Prior to finalisation of the policy review it is envisaged that a further ad-hoc group will be held in 2014.

In terms of the financial impact of the policy, 50% of the requests received during 2013 were classified as both MUMS and eligible for financial incentives compared to 78% in 2012 and, of these, seven are SME companies. The proportion of MUMS products eligible for financial incentives is expected to be considerably lower in future years as eligibility will be restricted to products for food producing animals.

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.

## Conclusions

In their previous reflections on the operation to date of the MUMS/Limited market scheme, CVMP noted that an average of 22-24 products are classified each year. This number appears to be more or less consistent year on year and applies again in 2013. Since the implementation of the restriction of the financial incentives in mid-2013 to food producing animals only, there has been a decline in the number of applications submitted, with only 4 requests received in the last 6 months of 2013. Whether this reduction arises due to the change of eligibility or whether it merely represents a fluctuation in the number of requests for MUMS/Limited market classification will become apparent during 2014.

The MUMS/Limited market scheme continues to be very successful in incentivising the submission of requests for classification of products as MUMS. These classifications are starting to result in new authorised products becoming available for minor species and limited markets and have also resulted in increasing applications for scientific advice. Industry has welcomed the policy and continues to submit requests for classification, although there are possibly early signs that limiting financial incentives to products for food producing animals may be reducing the number of requests for classification. However, this temporary reduction in requests needs to be interpreted with caution. It is important to note that the specific data requirements that apply in the case of MUMS products are very important for the industry as they reduce the number of the studies needed to support a new application, and hence can reduce the overall cost for product development.

In 2013 there has been an increase in the proportion of successful applications for classification and consequently fewer applications were considered as not intended for MUMS/limited market. However a lower percentage of applications were eligible for financial incentives than previously. Looking ahead to 2014, the policy will be refined further taking into account the experience gained to date and the feedback from the stakeholders and partners involved. In this way, the best use of the available budget can be assured to support the development of products that are most needed in terms of availability.