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Veterinary Medicines Department

5th 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 and in December 2014 following a review process. 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, October 2011, March 2013 and in March 2014. 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. The policy was reviewed in more detail with stakeholders in 2014 and a policy document (Agency Policy no 75 - see link below) and separate guidance document adopted by Management Board in December 2014 and published on the Agency website.

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/09/WC500172928.pdf

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

This annual report covers the activities from 1 January 2014 - 31 December 2014 in line with the request to provide calendar year reporting. This period covers the updated policy (from September 2013) under which fee incentives are restricted to food producing animals only. Over the calendar year for 2014, 28 separate requests were submitted for classification by the CVMP. Since the inception of this policy in 2009 to the end of 2014, 124 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 may be awarded to those products

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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. Applicants that have products classified as intended for MUMS/limited market are contacted 6 months prior to the expiry of the 5 year time period of validity of the classification to remind them that they need to re-apply under the current policy to maintain the incentives. Procedural guidance has been developed for applicants and the updated guidance document elaborated in 2014 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 2014

The CVMP reviewed 28 requests in this, the fifth year of operation, including products intended for the following minor species: bees, horses, rabbits, goats, rainbow trout, mink, guinea pigs, homing pigeons, foxes, raccoon dogs. Products intended for major species included products for dogs, cats, cattle, sheep and pigs where classification was sought for minor uses/limited markets. Of the total of 28 requests; 21 were classified as MUMS (of which 2 were awarded financial incentives and 19 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 2013, 10% of requests were classified as MUMS/limited market (50 % last year) **with** the financial incentives and 90 % were classified as MUMS (50 % last year) but **without** the financial incentives. Of the requests received, 25 % of the total requests received (or seven product indications) were considered as not falling within the MUMS/limited market policy – these requests were mainly for major species (cats and dogs) where the market was not considered limited.

With respect to the 28 requests for classification, **scientific advice** applications or letters of intent for scientific advice have subsequently been submitted for 3 of them in the past year. None of the requests are eligible for free scientific advice (two are from SME companies where 90% fee waivers are awarded to SMEs for scientific advice requests).

Ten of these applicants for the 28 requests are **SMEs** registered at the Agency. Letters of intent for the **centralised procedure** have been received or are pending for two of the products classified as MUMS/limited market whereas three other requests relate to **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. Close liaison is maintained with the SME office to ensure 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

130 - about 10% of total registered companies) where the incentives provided 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 €241,140 (€294,190 in 2013). 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. 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 previous annual reports 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 increase in this reporting period since restricting eligibility for financial incentives to food producing animals). 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 working parties have been consulted on specific requests. 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. On one occasion in the reporting period, following a review of data by CVMP to support prevalence of a condition in the EU, updated information was requested from an applicant where the initial conclusion did not support a MUMS/limited market classification. The cover pages for the classification at CVMP are standardised to consistently provide the requisite information together with a recommendation to CVMP based on the best available information.

The Agency continues to highlight the policy at meetings with stakeholders. The MUMS policy was on the agenda of the EMA/IFAH-Europe Info day in March 2014 to enable a wider and more general discussion on the policy. At the 9th annual TOPRA Veterinary Medicines Symposium in October 2014 a presentation outlining the industry perspective was given and led to further discussion of the policy with stakeholders.

During 2014 CVMP identified the need to revise/update the MUMS guidelines on the data requirements applicable to products indicated for MUMS/limited market in view of the experience gained to date. The CVMP working parties responsible for the individual guidelines have therefore included this task on their adopted workplans for 2015. A concept paper has been released for consultation in November 2014 and during 2015 work will continue to revise/update the guidelines as appropriate.

In line with the Agency working practice, the existing guidance has now been separated out into a high level EMA policy document (EMA/308411/2014) and a separate guidance document for applicants (EMA/CVMP/388694/2014). The objective of the revision was not to introduce any significant changes

but rather to clarify the definitions that are applied within the policy, the requirements for non-food producing (sports) horses and the procedural steps for classification. At the request of Management Board, the criteria for classification as MUMS/limited market have been clarified and made as objective as possible. However, it has not been possible to set criteria based on fixed figures for prevalence or incidence due to the shortage or complete absence of data on the prevalence and incidence of many diseases and conditions of animals in the EU. CVMP therefore proposes to continue to consider requests on a case-by-case basis and to gain experience with a view to developing more objective criteria over time. CVMP has also held discussions on the possible creation of a 'gap list' listing conditions for which veterinary pharmaceutical products are needed. These updated guidance and policy documents were circulated to the September 2014 CVMP meeting for endorsement and then released for a short consultation with stakeholders. Minor comments were received from IFAH-Europe and CVMP quality working party and the updated guidance document was adopted by CVMP at its plenary meeting in November. The policy and guidance were then presented to HMA for information in November 2014. Management Board adopted this revised policy in December 2014 which is now published on our website and in operation.

Discussion

Since its inception this policy has consistently attracted requests for classification by CVMP (see table 1) 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 fifth year of operation shows the continued interest from potential applicants in developing products to fill availability gaps despite the restriction of financial incentives to food producing animals. 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) Zulvac SBV (vaccine for cattle and sheep to prevent viremia associated with infection by Schmallenberg virus); an application for an extension to the existing authorisation for the anthelmintic Zolvix to include goats was withdrawn. Two full new centralised applications and one extension application for products classified as MUMS with financial incentives were validated in 2014.

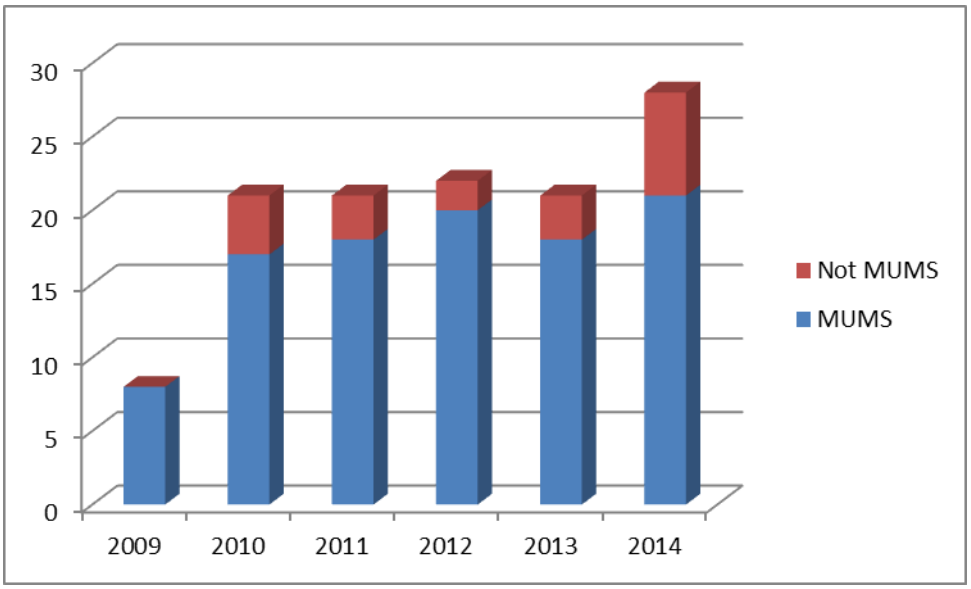

Table 1 – number of requests for classification by CVMP from 2009-2014

In terms of the financial impact of the policy, only 10% of the requests received during 2014 were classified as both MUMS and eligible for financial incentives compared to 50% in 2013. With regard to applications for veterinary scientific advice in 2014 of which there were 31 in total, 20% of these requests came from products classified as MUMS/limited market by CVMP and half of those requests were eligible for financial incentives (3 requests). 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

The number of requests for classification appears to be more or less consistent year on year with a slight increase in 2014 (see table 1 above). Since the implementation of the restriction of the financial incentives in mid-2013 to food producing animals only, concerns that there may be a reduction in the number of requests to CVMP were unfounded and industry continues to benefit from the amendment in data requirements for the submission of a marketing authorisation application for a MUMS product. The slight reduction in requests seen at the end of 2013 therefore represents a normal fluctuation in the number of requests for MUMS/limited market classification.

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 newly 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 with the highest number of requests yet in 2014. The updated policy and guidance document will clarify the requirements for applicants in particular the situation concerning horses not considered as a food producing animal (sports horses). 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. These guidelines on data requirements will be revised in 2015.

In 2014 there has been an increase in the proportion of unsuccessful applications for classification and consequently fewer applications were considered as intended for MUMS/limited market. This is due to the fact that more requests for products in major species were reviewed where the market was not considered limited. However a much lower percentage of applications were eligible for financial incentives than previously. Looking ahead to 2015, the policy continues to attract applications for classification and the requests classified in the early years are now being authorised and starting to fill some gaps in animal health. 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. The first draft of the revised veterinary legislation was published in 2014 by the European Commission and the discussions on the draft will be closely monitored during 2015 in relation to the text on availability of medicines and measures to provide a clear legal basis for specific measures for MUMS.