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Veterinary Medicines Department

6th 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/limited market 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 2011, March 2013, 2014 and 2015. During 2013 following discussions with Management Board it was agreed to restrict the financial incentives under this policy to food producing animals 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 2015 - 31 December 2015 in line with the request to provide calendar year reporting. Over the calendar year for 2015, 28 requests were submitted for classification by the CVMP. Since the inception of this policy in 2009 to the end of 2015, 152 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. Decisions on individual applications continue to be made on a case-by-case basis, taking into account decisions already reached in relation to requests received and

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previously classified. Consistency in decision making is therefore enhanced and experts are consulted on specific requests for review, where necessary. 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.

Financial incentives may be awarded to those products for food producing animals 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 a minor use where alternative products are authorised or the market is not considered to be limited either in terms of size or return on investment. In these cases 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. 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. This list is updated on a regular basis and includes all applications classified up to the end of 2015 http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000499.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05803ddc15.

Products classified in 2015

The CVMP reviewed 28 requests in this, the sixth year of operation, including products intended for the following minor species: bees, horses, rabbits, goats, sea bass, trout, mink, pigeons, wild boar, turkeys. Products intended for major species included products for dogs, cats, cattle, sheep and pigs where classification was sought for minor use/limited market. Of the total of 28 requests; 23 were classified as MUMS (of which 7 were awarded financial incentives and 16 were not). Reasons for not awarding financial incentives included; the product is not indicated for a food producing species; an alternative product(s) is authorised for the same indication and/or the market was not considered limited. According to the MUMS policy, horses are not considered as food producing animals and not generally eligible for financial incentives unless an MRL application is made for the product intended for horses destined to enter the food chain. For the purposes of the MUMS/limited market policy other than in exceptional cases no financial incentives apply to products for horses. Full details of all the products are included in Annex 1 to this report.

In comparison to 2014, 30% of requests were classified as MUMS/limited market (10 % last year) **with** financial incentives and 70 % were classified as MUMS (90 % last year) but **without** financial incentives. Of the requests received, 18 % of the total requests received (or five product indications) were considered as not falling within the MUMS/limited market policy – these requests were mainly for major species (chickens, pigs) and one minor species (horse) where the market was not considered

limited. The first renewal request was submitted in 2015 following the expiry of the initial 5 year classification and this was classified as MUMS/limited market for a further 5 year period.

With respect to the 28 requests for classification, **scientific advice** applications or letters of intent for scientific advice have subsequently been submitted for 2 of them in the past year. One of the requests is eligible for free scientific advice (both are from SME companies).

Thirteen of these applicants for the 28 requests (46%) are **SMEs** registered at the Agency. A letter of intent has been received for an **MRL application** to be submitted in 2016 for one product classified in 2015. A letter of intent for the **centralised procedure** has been received for one of the products classified as MUMS/limited market. One product application is currently under accelerated assessment and due for opinion in 2016. Two other requests relate to **Type II variations** (new indications) to existing centrally authorised products, one already under assessment and the second due in 2016. 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 140 - about 10% of total registered companies).

At €138,443, the costs of the scheme to the Agency in terms of fees waived or reduced was about 40% lower in 2015, the first full year of operation of the revised policy, than in 2014 (€241,140).

Other Activities

The Agency continues to highlight the policy at meetings with stakeholders. An update on the MUMS policy was on the agenda of the EMA/IFAH-Europe Info day in March 2015 to publicise and allow feedback on the current policy.

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 and to provide greater clarity for applicants. The CVMP working parties responsible for the individual guidelines included this task on their published workplans for 2015. During 2015 work continued to revise/update the guidelines as appropriate, including a new standardised introductory text and these guidelines were adopted for release for consultation in 2016. It is intended that these guidelines will be finalised during 2016 following the 6 months of consultation.

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/limited market 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 sixth 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) and Zycortal (Addisons disease in dogs). An application for an extension to the existing authorisation for the anthelmintic Zolvix to include goats was submitted but ultimately withdrawn. Two full new centralised applications for MUMS/limited market products were validated in 2015. A negative outcome was recorded for one product which was classified as MUMS/limited market in 2015; Lodipressin to treat hypertension in cats.

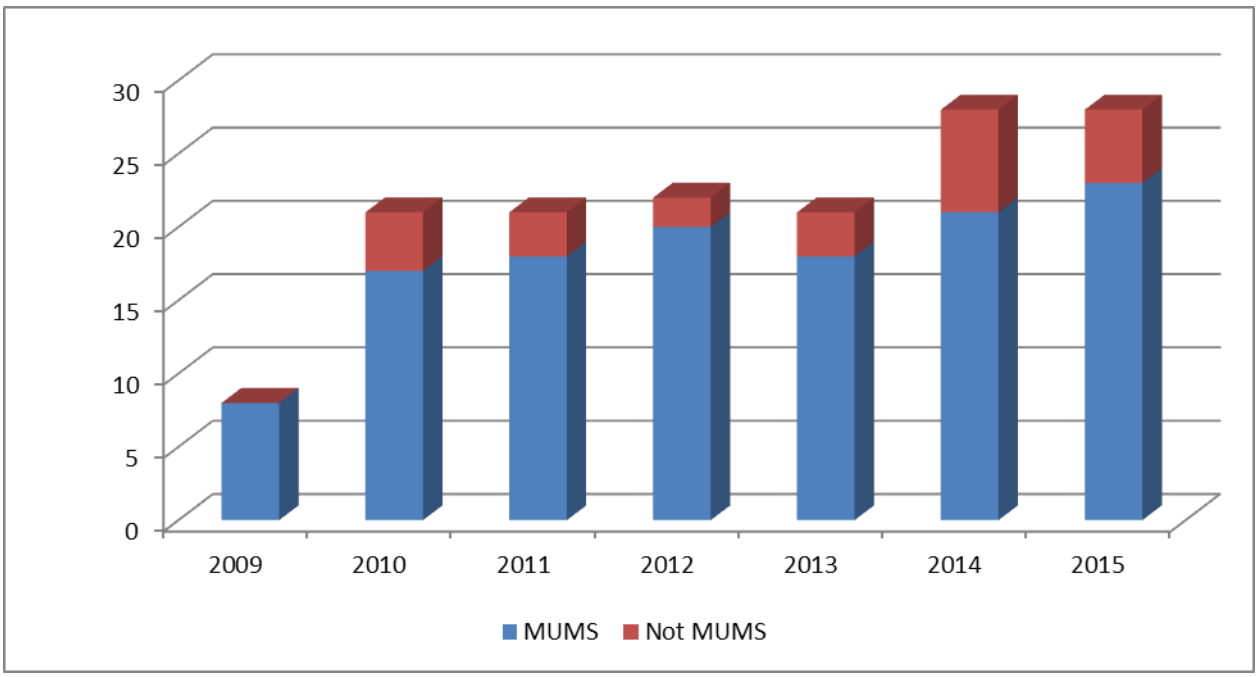

Table 1 – number of requests for classification by CVMP from 2009-2015

In terms of the financial impact of the policy, an increased number of the requests received during 2015 were classified as both MUMS and eligible for financial incentives compared to 2014. With regard to applications for veterinary scientific advice in 2015, of which there were 27 in total, eight of these requests came from products classified as MUMS/limited market by CVMP and three of those requests were eligible for financial incentives. The proportion of MUMS products eligible for financial incentives overall has fallen as eligibility is now restricted to products for food producing animals. This is reflected in the reduced cost of the scheme in 2015 compared to previous years.

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 now to be more or less consistent year on year with the same number received in 2015 as 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 have proved unfounded. The guidelines on the MUMS/limited market data requirements have been updated in 2015 and released for consultation to be finalised in 2016. These updated guidelines will assist applicants in the preparation of their dossiers for marketing authorisations. It is important to note that the specific data requirements that apply in the case of MUMS products are very important for 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.

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 leading to more authorised products increasing availability of veterinary medicines.

In 2015 there has been a reduction in the proportion of unsuccessful applications for classification and consequently more applications submitted were considered as intended for MUMS/limited market. More applications were eligible for financial incentives than in the previous year, reflecting the number of requests for food producing animals. 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 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. There was an overall reduction in the cost of the policy in 2015 compared to previous years. In September 2014, the European Commission adopted its proposal for revision of the legal framework governing the authorisation of veterinary medicines which included for the first time measures to provide a clear legal basis for a specific legal framework for products indicated for MUMS/limited markets. The ongoing discussions on the proposal will be closely monitored during 2016 and the Agency will provide advice, as necessary, in relation to the text on availability of medicines based on the experience gained to date on operating the MUMS/limited market policy.