8 March 2013
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Management Board meeting of 21 March 2013

Annual report and review of the operation of the Minor Use/Minor Species (MUMS) scheme for Veterinary Medicines

Issues for consideration

This third annual report on the operation of the MUMS/limited market policy covers the period September 2011 – December 2012 and is presented for endorsement. The report provides information on the products classified under this policy and details of the types of products for which support is provided.

Management Board is asked to note that the policy has been highly successful in terms of increasing interest from the animal health industry in submitting applications for MUMS products. However, there is rising concern both on the financial implications of the current policy for the Agency and the network during a time of austerity and that the current criteria for financial incentives do not necessarily identify those products most deserving of public support.

For these reasons, having consulted with the CVMP, the Agency proposes that, in line with the statement in the MUMS policy and as part of the current review of the operation of scheme, the Management Board recommends that financial incentives should be suspended pending the development of criteria that more consistently identify those products appropriate for public support. The Agency proposes that CVMP continues to classify products as MUMS/limited market in view of the fact that one of the major benefits of the scheme is that it provides assurance to applicants on eligibility for the MUMS data requirements. Whilst the current criteria can be improved, they should continue to be applied for the purposes of classification until improved criteria are developed as the major challenge is not to identify MUMS products per se but to differentiate those that are appropriate for public support from those that are not.

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Veterinary Medicines and Product Data Management

3rd Annual Report Veterinary MUMS/Limited Markets

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 markets (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005157.pdf) on 1 September 2009. 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. This annual report covers the activities from 1 September 2011 - 31 December 2012 in line with the request to move to calendar year reporting in 2011. In these 16 months, 27 separate requests were submitted for classification by the CVMP under this policy. Since the inception of this policy in 2009 to the end of 2012, 73 requests for classification were 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 request falls within the policy and that the product is intended for MUMS/Limited market, or that it falls outside the policy. Financial incentives are available for a period of 5 years (including free scientific advice, reduced centralised application fees, reduced MRL fees) to products 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. 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

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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

The CVMP reviewed 27 requests in the third year (covers 16 months) including products intended for the following minor species: horses, mice and rats, rabbits, bees, goats, turkeys, farmed foxes and mink. Major species included dogs, cats and cattle where classification was sought for minor uses/Limited markets in these species. Of the total of 27 requests; 23 were classified as MUMS (of which 18 were awarded financial incentives and 5 were given no financial incentives as alternative products are authorised for the same indication and/or the market was not considered limited); one request was withdrawn when the applicant was asked to provide further supporting information as a minor use; three requests, all for major species, were considered as not falling within the definitions of the policy. Full details of all the products are included in Annex 1 to this report.

In comparison to last year, 66% of requests were classified as MUMS/Limited market (42% last year) **with** the financial incentives and 19% were classified as MUMS/Limited markets (46% last year) but **without** the financial incentives. Of the requests received, 15% were considered as not falling within the MUMS/Limited markets policy – these requests were for major species where the market was not considered limited and one was withdrawn during the procedure. Of these 27 products the financial incentives availed of to date are included in Annex 2 to this report. Six of these products requested **scientific advice** in the past year or have submitted letters of intent, all of which are eligible for free scientific advice (1 of these is an SME where 90% fee waivers are awarded to SMEs and then topped up by 10% from the MUMS/Limited market financial incentives).

Eight of these applicants for the 27 requests are **SMEs** registered at the Agency. Letters of intent for the **centralised procedure** have been received or are pending for eleven intended products classified as MUMS/Limited market and some requests are extensions or Type II variations to centrally authorised products. One extension application for a product for goats was submitted and subsequently withdrawn during the assessment phase. 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 are encouraged to register as an SME under Commission Regulation (EC) 2049/2005, where applicable, and to avail of the financial incentives on offer which may then be “topped up” by MUMS policy incentives. 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 veterinary applicants (currently over 80) registered as SMEs where the incentives provided for under the SME Scheme may be availed of.

Other Activities

In line with the policy the Agency has published a listing on the external website of all products classified under this policy as MUMS/Limited markets for the general public. This listing is updated on a regular basis to include all new classifications and 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.

CVMP in principal agreed that the policy was working well in attracting applications on a consistent basis (averaging two requests per month since the policy started). Decisions on individual

applications take into account decisions already reached in relation to requests received and previously classified. 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 issues pose a challenge, such as prevalence figures for specific diseases in the EU or if a market is limited in terms of size/return on investment and to make recommendations. Applicants have 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 and a recommendation to CVMP based on the best available information.

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 a lag time for these to be 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 third year shows the continued interest shown by potential applicants in developing products to fill availability gaps. To date centralised authorisations have been given for Canileish (leishmania in dogs), Nobivac Myxo RHD, (myxomatosis and rabbit haemorrhagic disease), Suprelorin (ferrets), TruScient (long bone fractures, dogs), Coxevac vaccine (cattle and goats) and MS-H vaccine (chickens); an application for the extension of Zolvix (goats) was withdrawn.

Reflections are ongoing at CVMP level on the need to address specific availability issues for certain species/indications (in particular food producing species) and how best to address this within this policy. The Committee recognised that the scheme is currently completely reactive to requests from applicants whereas there would be benefits in terms of animal health to attract specific applications to fill certain availability gaps. Discussions have been held during 2012 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. CVMP have considered establishing a ‘gap list’ of products that are needed to fill specific availability gaps and invite applications to address those. Some concerns have been expressed on the feasibility of establishing and agreeing such a list and how to prioritise one indication/species over another. In addition some indications for certain species may not be attractive or feasible to the industry and applicants may never be incentivised to submit an application to fill that particular gap. For these reasons, the CVMP is not proposing to develop further the concept of a ‘gap list’.

In terms of the financial impact of the policy, about 60% of the requests received during this time period are classified as both MUMS and eligible for financial incentives and, of these, many are SME companies who benefit from the SME incentives first of all.

Decisions on eligibility for fee reductions apply only to products submitted through the centralised procedure and any fee reduction for a marketing authorisation through the decentralised/mutual recognition route needs to be agreed on a case by case basis with the Member States concerned. For centralised submissions MUMS/Limited market products eligible for financial incentives (approx. 45% of requests not all of which will be eligible or choose to come centrally) pay the same fee as for a generic application i.e. 50% of the fee that applies for a pioneer product.

Conclusions

In their reflection on the operation to date of the MUMS scheme, CVMP noted that an average of 22-24 products are classified each year and this appears to be more or less consistent year on year. The Committee therefore concluded that the scheme had been very successful in incentivising the submission of requests for classification of products as MUMS. These classifications are starting to result in new authorised products for minor species and limited markets and had also resulted in increasing applications for scientific advice. Industry has welcomed the policy and continues to submit on a monthly basis since the start in 2009 requests for classification. Amended data requirements in line with the published guidelines to support the marketing authorisations submissions are very important for these products. However the awarding of the financial incentives to a large number of products, incentives which last for 5 years, means a reduction in financial income compared to full fees paid for normal dossiers. The best use of the available budget to support the development of products to fill availability gaps remains a priority for the CVMP and for the Agency.