EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines and Product Data Management

2nd 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 /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 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 had been 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. This second annual report covers the activities from 1 September 2010 - 31 August 2011 where 26 separate requests were classified by the CVMP under this policy. This is a 30% increase on the 20 requests classified in the last year.

Classification Procedure

Applicants are requested to complete a template for classification which is published on the Agency website. These requests for classification are then presented to CVMP who decide that the request falls within the policy and is intended for MUMS/Limited market or 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 intended for minor species or minor uses where alternative products are authorised or the market is not limited either in terms of size or return on investment are not awarded the financial incentives. These products classified as MUMS/Limited market but without financial incentives, may avail 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 classified are included in the CVMP press release published following each plenary meeting.

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Products Classified

The CVMP reviewed 26 requests in the second year including intended products for the following minor species: donkeys, horses, wild boar, rabbits, bees, goats, turkeys, pigeons and birds. Major species included dogs, cats, cattle and pigs where minor uses/Limited markets in these species were requested. Of the total of 26 requests, 23 were classified as MUMS (of which 11 were awarded financial incentives and 12 were given no financial incentives as alternative products are authorised for the same indication and/or the market was not considered limited). 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, 42% of requests were classified as MUMS/Limited market (50% last year) with the financial incentives and 46% were classified as MUMS/Limited markets (30% last year) but without the financial incentives either due to the existence of an alternative authorised products for the same indication or due to the fact that the market was not considered limited. 12% were considered as not falling within the MUMS/Limited markets policy – all requests were for major species where the market was not considered limited. Once classified the product is awarded the incentives for a period of up to 5 years.

Of these 26 products the financial incentives availed of to date are included in Annex to this report. Seven of these products requested scientific advice in the past year of which 5 were eligible for free scientific advice (3 of these were SMEs where 90% fee waivers were awarded as SMEs and then topped up by 10%). Fees were applicable for the other 2 requests one of which was a request for parallel scientific advice with FDA and the other request was for a product for bees where a fee waiver under Article 9 of the fees regulation was granted by the acting Executive Director of the Agency.

Thirteen of these applicants (50%) are SMEs registered at the Agency. Letters of intent for the centralised procedure have been received for intended products classified as MUMS/Limited market and some requests are extensions to 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 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 e.g. 90% fee waiver for scientific advice for SME company and the additional 10% from MUMS policy instead of 100% scientific advice fee waiver from MUMS policy to eligible products. Liaison with the SME office has been strengthened for registration of these applicants where appropriate. This has shown results in the general increase in veterinary applicants (currently over 60) registered as SMEs where the incentives provided for under the Regulation 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.

It is intended to organise a focus group meeting in 2012 with invited participants from CVMP, industry and academia to discuss definitions for a limited market and market potential. The DISCONTOOLS project, a joint initiative with industry and other stakeholders conducted under the European

Technology Platform for Global Animal Health has also discussed the concept of market potential for the vaccines identified for major animal diseases. The focus group will also invite participation from that group.

CVMP in principal agreed that the policy was working well at the end of the first year and in the second year decisions on specific applications take into account decisions already reached in relation to requests received and 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 such as prevalence figures for specific diseases in the EU or if a market is limited in terms of size/return on investment pose a challenge 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.

Conclusion

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 to attract specific applications to fill certain availability gaps. It is hoped that the ongoing review of the veterinary legislation will provide a sound legislative framework to address availability needs for veterinary medicines. Experience gained in this policy will be extremely valuable in providing information to that review process. Positive feedback has been received from industry and applications/enquiries have been forthcoming throughout the whole of the second year of operation and this looks set to continue going forward. It is anticipated that a similar number of requests will be presented in the third year of operation. Most products that are classified intend to avail of scientific advice at some stage in the development process which is in line with the recommendations of the Agency Road Map to 2015.

This report shows that the scheme is attractive to industry and is achieving the objective of incentivising the development and authorisation of new veterinary medicinal products for MUMS. Applications for classification have increased in the second year. The policy has contributed to an increase in the number of requests for scientific advice (21 requests in 2010 and 26 forecast for 2011 in total) and also potential new marketing applications. By mid 2011 CVMP have issued positive Opinions for two centrally authorised products classified under this policy Canileish a vaccine for leishmaniosis in dogs and Nobivac Myxo RHD a vaccine for rabbit haemorrhagic disease and myxomatosis. Three further applications classified as MUMS/Limited market are expected to come to Opinion in the second half of 2011.

In terms of the financial impact of the policy, less than half the requests are classified as MUMS with the financial incentives and of these approximately 50 % are SME companies who benefit from the SME incentives first of all. To date 4 requests for scientific advice have been processed without any fee for the 46 applications classified to date in the first two years. 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 with the 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 a 50% fee reduction for authorisation. Therefore at the present time the Agency and the network are able to cope with the additional financial and staffing resources required to operate the scheme. This situation will be reviewed again in January 2013.