EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2013
EMA/327514/2013 Adopted

European Medicines Agency amends MUMS/limited market policy

The Management Board of the European Medicines Agency reviewed the operation of the Minot Use Minor Species (MUMS)/limited market policy[1] (MUMS policy) at their meeting on 13-14 June 2013. The Board concluded that the policy has been highly successful at stimulating the submission of requests for classification of products as MUMS by the Committee for Veterinary Medicinal Products (CVMP), with over 70 products classified in the first three years of operation.

In line with the policy, the Board also considered the need to refine the criteria by which products are classified as 'MUMS' and 'limited market' in light of the experience gained. The Board considered that the criteria for classification as MUMS currently remain appropriate and there is therefore no need to change the policy with respect to eligibility for MUMS data requirements. However, the Board identified a need to refine the criteria for the definition of a 'limited market' and thereby limit access to financial incentives for products classified by CVMP as MUMS. In view of the current scarcity of financial and human resources, the Board considered it essential to ensure that the limited resources available are directed to those products most deserving of public support that would otherwise not be developed. In reaching the decision on how best to focus the limited financial resources that are available, the Board took into account the widespread recognition within the veterinary community that the availability of medicines is most restricted in terms of products indicated for MUMS in food producing species, whereas the situation is less acute with respect to products for companion animals. In addition, such products have the greatest potential for improving animal and public health at an EU level. The Agency will continue to accept requests for classification of products as MUMS and, if classification in confirmed, the MUMS data requirements in accordance with the CVMP MUMS guidelines will apply. In future, only products indicated for food producing species will be accepted for classification by CVMP as also indicated for a 'limited market' and thereby eligible for fee incentives.

As a consequence, the MUMS policy and EMA guidance documents for companies requesting classification as MUMS/Limited markets [2] will be updated to reflect this amendment to the criteria for eligibility for financial incentives. The revised policy will be published on the EMA website following adoption by the Management Board and will come into immediate effect. Applications under the current policy will continue to be accepted up until the first meeting of the CVMP after adoption of the revised policy, after which the new policy will apply.

[1] Policy for classification and incentives for veterinary medicinal products indicated for Minor Use Minor Species (MUMS)/Limited markets (EMEA/429080/2009)
[2] EMEA Guidance for companies requesting classification as MUMS/Limited markets (EMEA/CVMP/370663/2009)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Products that have previously been classified under this policy by the CVMP are not affected and their classification will remain valid until the review date agreed at the time of classification (i.e. five years after first classification).

The Management Board has also requested the Agency to conduct a more fundamental review of the MUMS policy and its implementation to ensure that the policy is effective in terms of targeting incentives to those products most deserving of support with a focus on food producing species. The timescale for completion of this in-depth review has yet to be defined but it is anticipated that it will be complete by early 2014.