The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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Centralised Procedure for Authorisation of Veterinary Medicinal Products in the EU

Some confusion has arisen over the interpretation of Community legislation requirements concerning authorisation of veterinary medicinal products through the centralised and decentralised systems. A recent report that the possibility exists whereby the regulations will be interpreted to mean that no medicine will be authorised through the decentralised system if it contains the active ingredient of any medicine already centrally authorised (or vice versa) is incorrect in this regard.

Two veterinary medicinal products containing the same active substance can be authorised through both the centralised and decentralised systems provided they do not carry the same trade name. The only conditions being that the product authorised by the Community meets one of the criteria listed in Parts A or B in the Annex to Council Regulation (EEC) No 2309/93.

A suitable example might be a substance formulated in a medicinal product indicated for cattle meeting the criteria in List B of the Annex to Council Regulation (EEC) No 2309/93 but which has been authorised nationally in non-food producing animals even prior to entry into force of the aforementioned Council Regulation.

It may also be useful to remind readers that the Committee for Veterinary Medicinal Products when agreeing a positive opinion on a centrally approved product is required to recommend the conditions under which the veterinary medicinal product may be available to users. Because the availability of new veterinary medicinal products in the majority of Member States will be entirely restricted to prescription only status throughout its lifespan, and such decisions at CVMP are agreed in the main by consensus; it is extremely unlikely that for centrally approved products availability by any other means than veterinary prescription could be considered.

Finally, the availability and distribution of veterinary medicinal products authorised centrally is not determined by the EMEA but is subject to Community law which foresees that *a prescription shall be required for new veterinary medicinal products containing an active ingredient which has been authorised for use in a veterinary medicinal product for less than five years.*

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