



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

EMA/CVMP/199/97-FINAL

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Position Paper on Premixes for medicated feeding stuffs for veterinary use versus powders/granules for oral use or use in drinking water

APPROVAL BY CVMP FOR RELEASE FOR CONSULTATION	15 - 17 JULY 1997
END OF CONSULTATION	1 JANUARY 1998
ADOPTION BY CVMP	AUGUST 1998



EMEA/CVMP/199/97- FINAL

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Position Paper on Premixes for medicated feeding stuffs for veterinary use versus powders/granules for oral use or use in drinking water

In some Member States there are certain formulations of veterinary medicinal products, mainly powders or granules, which are used as premixes for medicated feeding stuffs as well as for other routes of administration, notably for use in drinking water or for oral use.

Premixes are considered to be a separate pharmaceutical form - different from powders or granules for use in drinking water or for oral use as the criteria established to ensure their quality can differ considerably. The European Pharmacopoeia has its own monograph on premixes for medicated feeding stuffs for veterinary use. This monograph requires that premixes are used exclusively in the preparation of medicated feeding stuffs.

Therefore premixes administered via the animals feeding stuff need a separate application for marketing authorisation and a separate SPC from powders/granules that might be administered directly by the oral route or via the drinking water, according to the testing requirements consistent with the formulation concerned.

For an existing product which is authorised in a Member State for use as a premix as well as for other routes of administration, the Reference Member State should, in the case of request for mutual recognition, clarify this problem with the applicant. In this case the applicant should submit two applications with two different SPCs to the Concerned Member States.