



**VETERINARY MUTUAL RECOGNITION
FACILITATION GROUP (VMRF)**

QUESTION FROM INDUSTRY

Extension of Pharmaceutical Form to a New Species

Adopted	Status
December 2003	Public

QUESTION

The Veterinary Pharmaceutical Product is intended for therapeutic use in poultry and presented as an oral powder.

1. Would it be possible to extend the use of this oral powder to fish?
2. What are the studies required for that extension to a new species?
3. Is it possible to keep the “oral powder” form for fish or is it necessary to introduce it in a medicated premix? Is it necessary to change the “oral powder” denomination for use in fish?

ANSWER

The group discussed this question and decided that would be possible to extend the use of this Veterinary Medicinal Product to fish. However it is not possible to use the same pharmaceutical form, therefore the applicant is advised to develop another pharmaceutical form and consequently this would involve extensions of the Marketing Authorisation according to Annex II of Commission Regulation No.1084/2003 to include the target species fish and the new pharmaceutical form.

Any such application should also satisfy the requirements of the Annex to Directive 2001/82/EC.