VETERINARY MEDICINAL PRODUCTS FOR ZOOTECHNICAL PURPOSES

Guideline Title	Veterinary Medicinal Products for Zootechnical Purposes
Legislative Basis	Directive 81/852/EEC as amended
Date of First Adoption	March 1992
Date of Entry into Force	September 1992
Status	Last revised March 1992
Previous Titles	None
Other References	III/9284/90
Additional Notes	The objective of this document is to provide specific guidance in relation to the documentation of the efficacy of zootechnical products, and should be applied in conjunction with Directive 81/852/EEC as amended, and the note for guidance on *Good Clinical Practice for the Conduct of Clinical Trials on Veterinary Medicinal Products in the European Union.*

CONTENTS

VETERINARY MEDICINAL PRODUCT FOR ZOOTECHNICAL PURPOSES

1. INTRODUCTION

New veterinary medicinal products developed for zootechnical purposes shall satisfy all the usual requirements of approval. This guideline is not intended to replace the note for guidance: *Good Clinical Practice for the Conduct of Clinical Trials on Veterinary Medicinal Products in the European Union*, but to provide specific guidance in respect of the documentation of the efficacy of zootechnical products, and should be read together with Directive 81/852/EEC and the note for guidance: *Good Clinical Practice for the Conduct of Clinical Trials on Veterinary Medicinal Products in the European Union*, taking into consideration the requirements of Directive 88/299/EEC.

For the purposes of this guideline the following definition shall apply:

A veterinary medicinal product for zootechnical purposes is a product applied to a healthy animal for non-pathologic, i.e. non therapeutic claims: to synchronise oestrus, terminate unwanted gestation, prepare donors and recipients for the implantation of embryos, and improve fertility. The improvement of fertility is defined as a modification of the normal undisturbed physiological function of the reproductive systems in breeding farm animals, which are domestic animals of the bovine species, swine, sheep, goats, solipeds and poultry, and wild animals of these species and wild ruminants which have been raised on a holding. These modifications are relatively short term management tools. In case no response is obtained, the condition must be regarded as one requiring therapeutic intervention by veterinary medicinal products which consequently are not covered by these guidelines. Synchronisation of oestrus must also be regarded as a short term treatment for management purposes.

2. STUDIES CONCERNING THE EFFECTS OF THE ZOOTECHNICAL PRODUCT ON THE TARGET ANIMAL

2.1 Experimental conditions

The studies usually conducted as clinical trials should be performed on each target species in comparison with untreated groups and, possibly, groups receiving zootechnical products of known effectiveness and approved in accordance with Directive 81/851/EEC. The observation period should cover a pre-treatment, a treatment and a post-treatment period of time suitable to recognise long-term effects also.

Clinical trials should be performed in several geographical areas and on animals representing the range of husbandry practices likely to be encountered in the use of the product as labelled. When relevant, the trials are conducted in animals representing the diverse physiological situations encountered in the target population, for example: lactating, nursing, dry, pregnant or nulliparous females. The animals undergoing treatment must be clinically examined before the beginning of the test, to ensure the absence of pathological conditions.

2.2 Clinical trials

The following studies should prove that the zootechnical product is effective for the purpose claimed and is without adverse effects in the animals under the proposed conditions of use. They should be performed taking into consideration the results of preclinical trials on target animal pharmacology conducted in accordance with the requirements of the note for guidance: *Good Clinical Practice for the Conduct of Clinical Trials on Veterinary Medicinal Products in the European Union*.

2.2.1 Dose determination studies

The purpose of these studies is to explain the rationale for the selection of the dose levels and the dose intervals claimed to be effective, and, possibly, to demonstrate simultaneously the dose/response relationship. The dose determination will be based on a control (untreated) and at least 3 non-zero levels in target animals.

2.2.2 Clinical trials for the demonstration of efficacy

These studies will be based on the effective dosage regimen selected from the dose determination studies.

The purpose of these studies is also to demonstrate the therapeutic range, possible adverse effects and contra-indications occurring under correct usage of the product taking into account different physiological conditions (e.g. lactation) and the results of the studies on pharmacology/toxicology. In addition, with products intended for intramuscular and/or subcutaneous injection, the injection site shall be examined carefully with regard to local tolerance.

The submission of data listed below should be decided on a case by case basis taking into consideration the choice of more suitable and/or additional parameters:

a) Desired clinical response

Identification of the desired clinical response:

Animal:

- interval from treatment to clinical response;
- concentrations of endogenous hormones interfering with the product (e.g. progesterone, oestradiol, LH and FSH in blood and/or in urine and /or in milk);
- gynaecological status (e.g. signs of abortion, the onset and signs of oestrus, control of ovulation).

b) Fertility of the animal and/or herd

Animal/herd:

- calving interval(s);
- oestrus interval(s);
- insemination or mating ratio, conception rate after first or after subsequent inseminations;
- treatments for infertility;
- occurrence of infertility;
- service interval.

2.2.3 Health of the progeny of treated animals

Studies on the health of neonates born to treated animals should be performed in the target species, if non-target animal studies suggest problems in this area, (e.g. birth weight, sex ratio, size and general health at birth; growth characteristics; development and subsequent reproductive performance and fertility).

2.2.4 Yield and quality of animal produce

– increase or decrease of the yield of animal produce;

– organoleptic, nutritional, hygienic and technological qualities of animal produce depending on the kind of produce;

3. CONCLUSIONS

From the target animal safety point of view the administration of a veterinary medicinal product for zootechnical purposes to healthy animals is only justified if animal welfare is not adversely affected. Therefore, the data shall be reported in such a way that a careful judgement of the benefit/risk ratio can be made.