doi:10.4172/0975-0851.1000053

TITLE

PK-PD INTEGRATION / MODELING OF NSAID IN VETERINARY PHARMACOLOGY

Mario Giorgi

Dept. Veterinary Clinics,
University of Pisa, Pisa, Italy

In veterinary drug development procedures, pharmacokinetic (PK) and pharmacodynamic (PD) data have generally been established in separate, parallel studies to assist in the design of dosage schedules for subsequent evaluation in clinical trials. The concept of PK/PD modelling, is approach in which PK and PD data are generated in the same study, and used to derive numerical values for PD parameters based on drug plasma concentrations. The PD parameters define the efficacy, potency and sensitivity of the concentration–effect relationship. It is proposed that the parameters derived from PK/PD modelling may be used as an alternative and preferred approach to dose titration studies for selecting rational dosage regimens (both dose and dosing interval) for further evaluation in clinical trials. In PK/PD modelling, the explicative variable for effect is the plasma concentration profile. The PK/PD approach provides several advantages over dose-titration studies, including determination of a projected dosage regimen by investigation of a single dose, in contrast to dose-ranging studies which by definition require testing of multiple dosage. Implementation of PK/PD modelling in the veterinary drug development process is currently constrained by the limited number of veterinary studies performed to date, and the consequently limited understanding of PK/PD concepts and their absence from regulatory authority guidelines. Nevertheless, PK/PD modelling has major potential for rational dosage regimen determination, as it considers and quantifies the two main sources of interspecies variability (PK and PD). It is therefore applicable to interspecies extrapolation and to multiple species drug development. As well as the currently limited appreciation of PK/PD principles in the veterinary scientific community, a further constraint in implementing PK/PD modelling is the need to validate PK/PD approaches and thereby gain confidence in its value by pharmaceutical companies and regulatory authorities.