Bioavailability and Bioequivalence in veterinary drugs - The European issue

Mario GIORGI
Veterinary School, University of Pisa, Italy

Bioequivalence (BE) studies are scientific methods that allow comparison of different medicinal products containing the same active substance, or different batches of the same medicinal products or, in a broad sense, different routes of administration of the same product. In Veterinary Medicine, this issue can involve a dual aspect: i) the effectiveness of the drug in patients (animal) and ii) the consumers’ health (human). High efficiency in the field of Veterinary Medicine, particularly in animal production (globally requested for the food supply), is achieved nowadays by the employment of veterinary medicines and feed additives. Because of the lower cost of development and competition in the market place, generic drugs usually sell for less than the brand name drug products from the original manufacturers (innovators or pioneers). This fact has led many to believe that generic drugs are somehow inferior to brand-name products. The use of animal health products in animal production however, should be done following the standards on Good Clinical Practice (GCP) on Veterinary Drugs Use. Thus, only products approved for food producing animals use and their generic formulation (that have statistically proven BE) should be employed.

Several problems concerning peculiar routes of administrations, variability among the subjects, etc., have been recovered in veterinary drugs rather than the human drugs, for the assessment of the BE. The new EU guidelines report narrow rules on BE determination, but lack of rigid rules on excipients. Anyhow, EMEA mandates that the generic veterinary drugs must be as safe and effective as the brand-name drugs.

Biography

Mario Giorgi has completed his PhD and pharmacology specialization studies at the age of 27 years in Pisa University School of Pharmacy/Medicine. He is aggregate professor in P&T and in charge for the direction of the Veterinary Pharmacology & Toxicology Research Division of the University of Pisa. He has published 50+ papers in reputed journals and assists several journals in reviewing processes. He is a member of several Pharmacology & Toxicology international societies as well as Italian Olympic Committee. He has several international scientific partnerships (China, Israel, Poland, Iran, South Korea, and Kazakhstan).