ORANGE HOUSE PARTNERSHIP vzw

MB/M/BD(2010)1B

OHP PRESENTATION AT THE 4TH INTERNATIONAL CONGRESS OF PHARMACOLOGY AND THERAPEUTICS HAVANA, CUBA, 13-16 DECEMBER 2010

REGULATORY RISK ASSESSMENT AND THE USE OF ANIMALS

Koëter, HBWM[1]

[1] Orange House Partnership, Kampendaal 83, 1653 Dworp, Belgium;
email: herman.koeter@orangeOhouse.eu

Although our food and drugs have never been safer than today, yet we are finding more contaminants in it than 20 years ago because analytical tools have become much more sophisticated. New technologies include nanotechnology application and the genetic modification of plants, animals and micro-organisms. Although there are currently already more than 20 pieces of legislation in the food and feed safety area in the EU alone, animal welfare considerations are hardly mentioned, and no guidance is provided on how to reduce the need for experimental use. At global level discrepancies and contradictory data requirements exist which should give rise to actions to reconsider several regulations currently in use. These discrepancies are not limited to food and chemicals risk assessment, they also occur in the area of pharmaceuticals. Harmonization of data requirements is needed to contribute significantly to the reduction of experimental animal use in regulatory safety assessment.

Recent new scientific developments in risk assessment justify a rather fundamental reconsideration of current approaches and principles. The use of predictive hazard characterization tools based on existing data, in particular QSARs and TTC (thresholds of toxicological concern) deserve a prominent role in risk assessment. In addition, the newest generation *in vitro* hazard identification methods have very much matured and the reliability and relevance of test methods aiming at the identification and characterisation of pertubated molecular and cellular metabolic pathways strongly contribute to a better understanding of toxicity. These novel computational and *in vitro* approaches, complemented with the latest proteomic, metabonomic and carcinogenomic profiling techniques are expected to provide in the near future adequate predictive power to assess the safety (or risk) of substances thus allowing a significant reduction (or abandoning) of the traditional observational animal studies in risk assessment.

The presentation will highlight current developments and will point a way forward to embed the novel approaches into regulatory risk assessment requirements.