ADDRESS COLLOQUIA

Venue: Medical University Vienna, Center for Physiology and Pharmacology,

Institute of Pharmacology, Conference room, 3rd floor

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Thursday 19.04.2018 12:00 s.t. Host: Harald Sitte

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Evaluating the Abuse Potential of Psychedelic Drugs for Medical Use in Humans

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A systematic evaluation of the potential risks for human abuse is a mandatory part of the Safety Pharmacology Assessment for all CNS-active, drug-candidates for human use. Guidance documents on the abuse/dependence evaluation of drug-candidates have been published by EMA and FDA. An outline of the regulatory framework and the non-clinical tests to evaluate of abuse/dependence risks, i.e. drug-discrimination, intravenous self-administration and physical dependence liability, will be described as an introduction to the topic.

Psychedelics comprise drugs from various pharmacological classes including 5-HT2A agonists, indirect 5-HT agonists, e.g. MDMA, NMDA antagonists and κ-opioid receptor agonists. There is resurgence in developing psychedelics to treat psychiatric disorders; however, many, but not all, psychedelics are Schedule 1 controlled drugs (CDs), i.e. they have no approved medical use. For many of the psychedelics that are undergoing clinical evaluation, regulatory approval will require a move from Schedule 1 to a CD schedule for drugs with medical use, i.e. Schedules 2-5. Although abuse of the psychedelics is well documented, a systematic preclinical and clinical evaluation of the risks they pose in a medical-use setting does not exist. The existing data for the various classes of psychedelics together with our experiences and findings will be described. I will also critically review the recently released FDA guidance, discuss the impact this document is having on non-clinical abuse/dependence testing, and offer advice on how non-clinical abuse/dependence experiments can be designed to meet not only the expectations of FDA, but also other regulatory agencies. Finally, I will suggest how the non-clinical abuse/dependence tests can be refined to provide more meaningful information to aid the assessment of the risks posed by CNS drug-candidates for abuse and physical dependence.

Professor David Heal - biography

David Heal is an Executive Director of RenaSci Consultancy Ltd; a company that he co-founded in 2001. RenaSci is an independent provider of consultancy and experimental services to the pharmaceutical industry in the areas of diabetes, obesity and CNS disorders. David started his career in academic research at the MRC Clinical Pharmacology Unit, Oxford University before transferring to pharmaceutical R&D in the mid-1980's. During his career at Boots Pharmaceuticals and BASF Pharma, he led teams, which put several novel compounds successfully through clinical development, including the anti-obesity drug, sibutramine, (Meridia) and the antipsychotic, zotepine (Zoleptil). Since co-founding RenaSci, he has assisted pharmaceutical industry clients in achieving the successful European and US registration of novel drugs for the treatment of ADHD and epilepsy. He has published 150 scientific articles and reviews, given over 350 presentations at international scientific symposia and is a Visiting Professor in the Department of Pharmacy and Pharmacology at the University of Bath.