Publication

New perspectives in CNS safety pharmacology.

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Abstract

International requirements for central nervous system (CNS) safety pharmacology are reviewed. Procedures for initial CNS safety screening (core battery studies) can be conducted from the beginning of the drug discovery process, but at latest before first studies in man. They should include assessment of general behaviour, locomotor activity and motor coordination, but can also include studies of pain sensitivity, convulsive threshold and interaction with hypnotics. Follow-up studies, to be conducted later in the drug development process but before product approval, cover assessment of higher cognitive function, electroencephalogram (EEG) and drug dependence/abuse liability. Procedures for assessing cognitive function can include, in order of complexity, passive avoidance, Morris and radial mazes and operant behaviour tasks (delayed alternation, repeated acquisition). EEG can include the quantified EEG (QEEG) and studies of the sleep/wakefulness cycle. Drug dependence/abuse procedures can include precipitated and nonprecipitated withdrawal (drug dependence), and place preference, drug discrimination and self-administration (drug abuse). In contrast to core battery CNS procedures, conducted exclusively in rodents, follow-up studies can include higher species, in particular primates.