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Off Label Use of Drugs with Special Focus On CNS: Views From the Industry

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- Introduction

The common off label use of drugs will be reviewed from the perspective of drug development and the support of marketed products.

- Objectives, Aims and Methods

A review of the current effects of off label use, using publically available information with conclusions based on the experience of an active drug development scientist.

- Results

Off label drug prescription (OLP) is common, it has been estimated that 20% of prescriptions are for a not approved use. While legal and sometimes useful, OLP presents serious challenges. Doctors often prescribe a drug off label without realizing it is not approved and do not know if commonly used drug treatments are approved. This makes it difficult for pharmaceutical representatives. Manufacturers are prohibited and most have been fined for promoting OLP.

OLP is common when a drug is newly approved. Doctors want to prescribe without waiting for formal proof. This can make recruitment for clinical trials difficult. Also populations at special risk are usually not fully studied at the time a new drug is approved. It is often felt to be not ethical to withhold treatment from these groups while waiting for drug approvals. However, this practice can harm patients, as has been seen with the use of antipsychotics in the elderly.

- Conclusions

Guidelines are needed to help the use and development of drugs understanding that approval is a needed and worthwhile goal for all medications; the practice of medicine should not be harmed by the drug approval process.

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