TERM OF OFF-LABEL USE IN MEDICINE

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Introduction. Off-label use of drugs is relatively common in medical practice, even if it's often not supported by strong scientific evidence. The term “off-label drug use” refers to drugs that have not yet acquired “approved” status or drugs that have acquired “approved” status but are used with a different dosage, route, or administration method other than that for which the drug has been approved. Some off-label prescribing should be permitted to allow physicians to take good care of patients and offer them some therapeutic options, but such prescriptions must remain the exception to the rule and should be scrutinized and controlled by regulatory agencies using well-defined frameworks. No comprehensive studies, however, exist that analyse in full all prescriptions for all dispensed drugs, especially in view of the recent intervention by the European Medicine Agency to tackle this issue. So far, several prospective and retrospective studies have been conducted in various healthcare contexts (general medical and surgical wards, neonatal and pediatric intensive care units) in the USA, Europe and Australia . These studies have brought to light a high proportion of unlicensed and off-label use, reaching up to 72% of all prescriptions and 93% of all pediatric patients.

Aim. Several studies have documented the high prevalence of off-label use in medicine.

Materials and methods. A leading example of how regulatory agencies approach off-label use is provided by the United States Food and Drug Administration (FDA)'s Center for Drug Evaluation and Research, which reviews a company's New Drug Application (NDA) for clinical trial data to see if the results support the drug for a specific use or indication.

Results and discussion. If satisfied that the drug is safe and effective, the drug's manufacturer and the FDA agree on specific language describing dosage, route of administration, and other information to be included on the drug's label. Pharmaceutical companies are not allowed to promote a drug for any other purpose without formal FDA approval.

Conclusion. However, once a drug has been approved for sale for one purpose, physicians are free to prescribe it for any other purpose that in their professional judgment is both safe and effective, and are not limited to official, FDA-approved indications. This off-label prescribing is most commonly done with older, generic medications that have found new uses but have not had the formal (and often costly).