

# Navigating the off-label drug use: Ethical and Legal guidance for clinicians

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## Abstract

Off-label drug use which could be defined as the practice of prescribing a drug for a different purpose than what is permissible by the regulation is a common practice among clinicians, nevertheless, it is often subject to ethical and legal uncertainties. In general, clinicians must balance the need to provide patients with the best possible care while complying with the regulatory requirements governing drug use. This paper will review the current literature on off-label drug use, including its prevalence, the regulatory landscape, and the ethical issues involved with the aim of formulating an ethical and legal framework that could guide clinicians in using off-label drugs in clinical practice in Malaysia. The framework will include ethical considerations that are centred on the principles of beneficence, non-maleficence, and autonomy, which require clinicians to balance the benefits and risks of using off-label drugs while respecting patients' autonomy. The legal framework consists of federal and state regulations governing drug use, including the Control of Drugs and Cosmetics Regulations (CDCR) 1984 and other regulations published by the National Pharmaceutical Regulatory Agency (NPRA). The aim of this paper is to provide guidance on how clinicians can navigate the ethical and legal terrain of off-label drug use by understanding the regulatory requirements, being obliged to the requirements of obtaining informed consent from patients and documenting the rationale for off-label use. Ultimately, by understanding the ethical and legal framework, clinicians can provide patients with the best possible care while complying with the regulatory requirements governing drug use.

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