

## **Abstract**

**Background:** The off-label use refers to the use of an authorized medicinal product in an unauthorized manner. This raises many legal, ethical and safety issues, especially when taking into account the prevalence of this practice. Nevertheless, a significant number of healthcare professionals have limited awareness of the definition, extent, and clinical implications of off-label drug use. This study aimed to assess the knowledge and views of pharmacists and physicians regarding off-label drugs in Libya.

**Methodology:** A prospective questionnaire –based cross-sectional study was conducted among doctors and pharmacists in Libya. 374 of Licensed Libyan Doctors and pharmacist were included in the duration between September 2024 and March 2025.

**Findings:** 160 were included in the final analysis. Most of the respondents were females (n=106, 66%), the majority of the respondents were pharmacists and clinical pharmacists (37%, 23%) respectively. However, 131 (82%) Of the participants affiliated with a tertiary care setting. The majority of the healthcare professionals had 1-4 years of working experience (n=110, 69%). 69 (44%) were aware of the correct definition of off-label drugs especially the pharmacists and clinical pharmacists (p-value= 0.02, 0.002) respectively. 63 (43%) of the respondents prescribed off label medication, especially males (p = 0.002). Respondents don't know if there was a policy of off label prescribing in their hospitals or in Libya were (64%, 72%) respectively. The respondents were concerned with both the efficacy and safety of off-label prescribing (61% 68%, respectively). Notably, 62% reported encountering adverse drug reactions linked to off-label prescribed medications. Additionally, 131 respondents (82%) emphasized the importance of pharmacist involvement when off-label drug use is required. These

findings hold considerable relevance for stakeholders involved in off-label practices—especially physicians—as they highlight the need for tailored training initiatives and the implementation of formal regulatory guidelines. Such efforts would support safer prescribing practices and contribute to enhanced patient outcomes

**Keywords:** Off-label Prescribing, OLDU, Off-label promotion, Patient Safety