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Editorial Paper

Snapshot of Off-Lable Use of Drugs: Perspectives and Practices in India

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After the completion of the clinical trials, a pharmaceutical product is only allowed to market. They can only "prescribed by a physician, dispensed by a pharmacist and used by a patient, after marketing authorization is given for a specific indication(s). All medication should be sold with a summary of product characteristics (SmPC)" in it. All "SmPC must contain all the information about the indications of medicinal product, its dosages, route of administration, who cannot use it (Children or pregnant women). All of the indications and guidelines included in the SmPC and summarised in their package insert are referred to as label drugs. Meanwhile, 'Off-label usage' refers to the "use of a pharmaceutical "product for any indication, patient category, mode of administration, dosage, or treatment regimen"" not stated in the SmPC. When a doctor prescribes you a prescription that the US Food and Drug Administration (FDA) has approved to treat a condition other than yours, this is known as off-label prescribing. This is a common and legal practise. Today, one out of every five medications is for an off-label usage. Even if the indication hasn't been approved by regulatory bodies, a practitioner has the ability to prescribe any licenced medicine for any indication. Pharmaceutical companies are not allowed to market non-approved indications in most nations' prescribing information and promotional materials [2]. Off-label drugs are mostly used by doctors in certain situations, such as when regular treatment regimens are unavailable or when standard treatment regimens fail [3]. Furthermore, physicians have complete discretion to utilise new therapeutic interventions based on the most recent research, but there is no guarantee of scientific legitimacy due to a lack of safety and efficacy evaluations. When prescribing medications for off-label use, the physician must be aware of the scientific validity and medical evidence [3,4]. In some patient populations, therapeutic options may be limited if off-label prescribing is not used. Off label applications of medicine can be beneficial for patients suffering from orphan diseases, for example, a drug approved for one type of cancer can be used off label for many other types of cancer. Mitomycin, for example, is prescribed for the treatment of gastric and pancreatic carcinomas. Furthermore, it meets the widely accepted standard of care in the treatment of lung, bladder, breast, cervical, and other carcinomas, despite the fact that these applications are not approved by the US Food and Drug Administration. Lack of paediatric indications on prescription labels frequently leads to off-label prescribing; as a result, many pharmaceuticals intended for adults are also administered off-label in the child population. In psychiatry, off-label medication is also widespread. [2,5,6]. During the medication development period, the majority of pharmaceutical companies' research was done for a specific indication. The cost is one of the most important elements in determining the number of indications applied for; more indications necessitate more costs and more participants. Furthermore, any delay in receiving regulatory approval will shorten the time a medicine can be marketed during its patent term [5,7]. Many countries lack clear restrictions for off-label drug use and instead rely on marketing strategies to promote them [8]. In these situations, the idea of Good Off-Label Use Practice (GOLUP)" are critical, as it gives prescribers therapeutic latitude. We can utilise off-label medications in the following situations, according to GOLUP: When there is no authorised

treatment option for the condition, when "there is a severe or life-threatening condition, when authorised treatment has failed repeatedly or is not available, when the off-label use is supported by strong scientific evidence in the literature, when patients have been fully educated and have given their informed consent, and when physicians and patients report adverse events and outcomes linked to the use of the off-label product through reported route.

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