# A REGULATORY PERSPECTIVE ON STRENGTHENING DRUG APPROVAL AND POST-MARKETING SURVEILLANCE TO MINIMIZE OFF-LABEL DRUG USE

**Miss. Ankita S. Sasane[1*], Miss. Aishwarya R. Bhandare[1], Dr. Atish B. Velhal[1], Dr. Prakash D. Jadhav[1], Mr. Mukul P. Madane[2]**

[1*]Department of Regulatory Affairs, YSPM's, Yashoda Technical Campus, Wadhe, Satara - 415011, Maharashtra, India

[2]Department of Pharmaceutical Chemistry, Shinde Institute of Pharmacy and Research, Pachora - 424201, Maharashtra, India

[1]Student (Miss. Ankita S. Sasane) | ORCID: https://orcid.org/0009-0009-4966-0089 | Email: sasaneankita26@gmail.com

[1]Faculty (Miss. Aishwarya R. Bhandare) | ORCID: https://orcid.org/0009-0005-4344-4212 | Email: aishwaryabhandare1996@gmail.com

[1]Faculty (Dr. Atish B. Velhal) | ORCID: https://orcid.org/0000-0002-4660-792X | Email: atishvelhal@gmail.com

[1]Faculty (Dr. Prakash D. Jadhav) | ORCID: https://orcid.org/0000-0002-6480-3879 | Email: prakash.jadhavagcop@gmail.com

[2]Faculty (Mr. Mukul P. Madane) | ORCID: https://orcid.org/0009-0003-3012-0484 | Email: mukulmadane@gmail.com

***Corresponding Author:** Miss. Ankita S. Sasane, Student, Department of Regulatory Affairs, YSPM's, Yashoda Technical Campus, Wadhe, Satara - 415011, Maharashtra, India | ORCID: https://orcid.org/0009-0009-4966-0089 | Email: sasaneankita26@gmail.com | Mobile: +91 8624053901

**ABSTACT:**

Off-label drug usage (OLDU) is prescription usage of licensed medications for diagnoses, dosage amounts, age categories, or modes for administration that cannot be specified according to authorized prescription. It is important in addressing disorders when prescribed medicines are restricted or not effective, especially in cancer therapy, pediatrics, neurological disorders, and uncommon condition. But, since scientific proof is constrained, unauthorized off-label usage can elevate the possibility of undesirable medication responses and raise ethical problems.This discussion examines the regulatory viewpoints, advantages, dangers, and elements that influence off-label medication prescribing, as well as the responsibilities of medical practitioners or regulatory authorities. It also contrasts the regulatory systems of the United States, Europe, China, and India. Additionally, the role of pharmacovigilance and post-marketing surveillance in assuring the secure and reasonable utilization of off-label medications is explored. Improving scientifically supported prescription and regulatory control is critical for improving security for patients and treatment results.

**Key words -** Off-label drug use, Adverse drug reactions (ADRs), Food and Drug Administration (FDA), clinicians, Regulatory Bodies, Prescription

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## INTRODUCTION:

Off-label drug use refers to the use of pharmaceutical product for an unapproved indication, age category, dose, or mode of administration. In other words, we can describe it as the application of a drug product in patient population, dose, and method of administration for purposes that are not mentioned in approved product labeling.[1]

Labelled indications refer to medications that have been approved for conditions that are listed in the product license.[2] Off-label medication use affects not just doctors and pharmaceutical businesses but also patients and regulatory bodies.[3] Patients with cardiovascular disease, central nervous system disorders, pediatrics, oncology, critical care, and pregnant women are the most frequently impacted by off-label drug use, respectively.[4] Patients with orphan diseases, for which off-label usage may be the only accessible treatment, may benefit from them.[3] Clinical discretion, new research, or personal experience may lead to the off-label prescription of a medication that has been formally approved for a particular ailment or population [5].It can be particularly valuable in an emergency case where there is no normal line of treatment available, or it may offer an alternate treatment strategy that is far less expensive than their standard line of treatment.[1] Off-label medicine use may only be beneficial to patients. [6] On-label use is based on scientifically valid and statistically significant evidence demonstrating that a drug's potential advantages exist; yet, off-label use of several medications can be regarded the cornerstone of treating serious conditions. [7]

Off-label prescription of a medication is normally allowed, but off-label promotion by a drug manufacturer is regarded prohibited because the company is still

unaware of the negative consequences of these medications[2]. The fundamental difficulty with off-label use is that there is inadequate evidence to support the use of the substance.[7] Off-label usage can have major side effects, from infectious or allergic responses to further serious disorders like hormonal imbalances, cardiovascular difficulties, mental health conditions, addiction, violent social episodes, and even death.[5] It is important to differentiate between off-label use from unlicensed or unauthorized use, which includes using a pharmaceutical product in a country where no marketing authorization has been issued by the appropriate licensing body, even if the product has a license in another country.[8]

Although using OLDU can offer essential therapeutic alternatives in some circumstances, there are risks and difficulties associated with it for pharmacists and other healthcare workers in addition to medical specialists.[9] Although off-label prescribing is frequently founded on good clinical judgment and backed by scientific proof, consumers could be at danger because there is insufficient regulatory supervision and thorough safety data for such usage.[10] Prescription drugs prescribed for illnesses the patient does not have (off-label use) and maybe improper drug use. When a medication has been prescribed for disorders not covered by these authorized indications, this is known as off-label use. Off-label prescribing is frequent in medical practice and is legal, but it indicates that the drug is being taken without the same level of proof that is needed for uses that have been approved by the Food and Drug Administration.[6]

**TERMS ASSOCIATED WITH VARIOUS SUBSTANCE USES :**

| Terminology | Definitions |
|---|---|
| Off- label drug use | A case in which a medicine is purposefully utilized for a clinical reason that is not permitted by the product's marketing authorization is known as off-label use. |
| Unlicensed drug use | Medications that drug regulatory bodies do not examine for safety and effectiveness. |
| On label drug | On-label use relies on scientifically valid and statistically significant evidence that a medicine has potential advantages. |

Table no.1

**ROLE OF DOCTOR :**

Doctors are typically permitted to administer licensed prescriptions in ways that varied from those specified on the drug label. Several nations allow clinicians to make decisions whether or not off-label use in individuals is justified. A physician responsibilities is to ensure what is best for the people they treat. Off-label medication use can be therapeutically justifiable due to the scarcity of alternative effective licensed treatments or the intricate nature of the patient's condition. With rapid developments in medical research and innovative treatments appearing yearly, drug manufacturers are finding it challenging to obtain clearance for each and every chemical, usage, dose, and method they propose.[11] Physicians are more likely to employ off-label treatments when traditional therapy regimens do not available or fail.[12] When recommending medicines for off-label consumption, physicians must consider scientific validity and medical proof.[12]

Off-label drug use allows clinicians to utilize novel therapeutic choices according to the most recent research, although there cannot be a proof of their scientific validity due to a lack of effectiveness and safety evaluations. As a result, when prescribing medications for off-label usage, physicians must consider both research acceptability and clinical proof.[2] When deciding to prescribe off-label, clinicians should conduct a comprehensive study into the potential complications and adverse effects. When drugs are used off-label, doctors must be conscious of the possibility of adverse drug reactions (ADRs), regardless of the amount of scientific proof supporting their usage.[13]

Off-label usage may be justified in patients when an appropriate benefit-risk ratio is demonstrated.[1]To allow doctors to provide patients with quality care and a few therapeutic alternatives, sometimes off-label prescribing may be allowed. However, this may be the exception rather than the standard, and regulatory bodies should use specific guidelines to examine and regulate such prescriptions.[3] The Food and Drug Administration supports off-label use as long as certain requirements are met.[8] When it comes to off-label pharmaceutical usage, clinicians need to carefully consider these risks, rely on the best available information, and maintain open lines for connecting with patients and providers.[9]

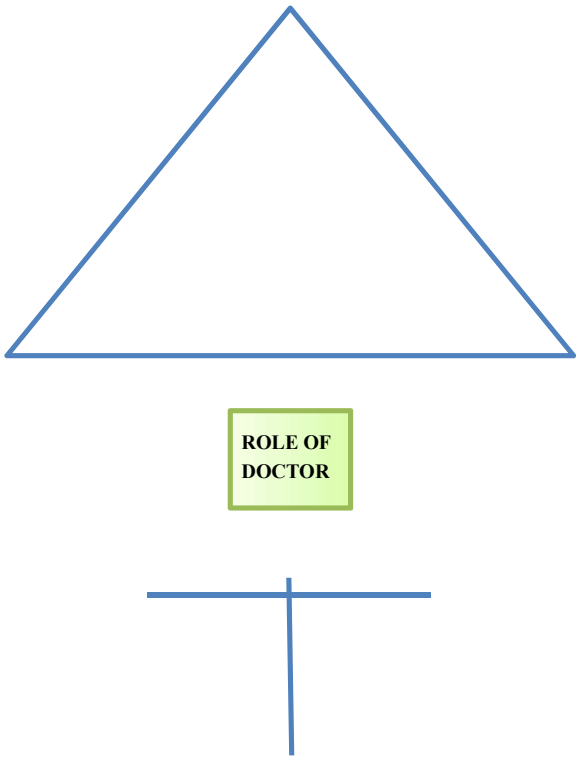


Figure No.1

**ROLE OF PHARMACIST :**

Pharmacists play a critical role in proper marketing methods, patient advice, product security, and reducing the negative impacts of drugs and medicinal products on consumers and patients by interacting effectively together with the pharmacologic surveillance team in the health care sector to guarantee the safety of pharmaceutical products. Some off-label drugs remain to be distributed in the market despite the fact that adverse drug reactions are still unreported.[14] Pharmacists perform an important role in overcoming patients' gaps in understanding about the drug procedure for authorization and the related risks as well as advantages of medications. It is the pharmacist's role to be informed of drug applications and to check that a drug has been licensed by the Food and Drug Administration for a certain use.[14] Off-label drug use is well-known among doctors and pharmacists, but patients are less aware. As a result, anytime an off-label medicine is provided, patients should be informed and appropriately advised about both the hazards and benefits of the treatments. The pharmacist is the most accessible healthcare expert to the consumer; thus, the pharmacist may clarify and highlight crucial aspects about off-label medication and address queries from patients.[15] Community pharmacists typically agree on off-label treatment, with the majority describing it as an action that addresses unfulfilled therapeutic requirements. They further underline that off-label usage should be done in in the most secure manner and in close consultation with the prescribing clinician. Informed permission, particularly from caregivers, is an important topic for discussion because it is an essential component of off-label activity.[15]

The regulatory body has a significant role in regulating the marketing of off-label drug use and minimizing its spread to alternative platforms such as social networks. Such advertising may create ambiguities and disinformation about off-label drug use. These issues can be efficiently managed with the active participation of pharmacists, who give proper guidance and useful advising services to prescribers and patients.[14]

**ROLE OF PATIENT:**

Off-label medications are given as novel or exclusive treatments for patients with severe clinical problems that do not respond to the current standard regimen or for whom there is insufficient therapy.[11] Off-label applications are frequently the result of patients demanding a new method or treatment when the best available therapeutic choice fails.[12]This appears appropriate if the decision is supported by valid scientific facts that provides the greatest benefit to the patient while outweighing any danger. Furthermore, clinicians are ethically expected to share off-label medication consumption to their patients, including the risk/benefit ratio, and acquire their or the caregiver's approval. This maintains the patient's autonomy while also ensuring that the ethical norms of beneficence and nonmaleficence are met. Knowing the facts and transparency in the relationship between physicians and patients through the process of collaborative decision-making will improve the patient's belief in his or her physician; otherwise, the patient may lose believe in their treating clinician.{11*} Many medications that are given for adults exclusively are prescribed as well off-label in the pediatric patient group due to the lack of pediatric indications on prescription labels.{12*}

**FACTORS AFFECTING OFF-LABEL DRUG USE (OLDU):**

| | |
|---|---|
| 1. Clinical Requirements | • Absence of authorized therapies for specific ailments.[10]<br>• Lack of an appropriately licensed medication to address patient needs.[16]<br>• When the most effective therapeutic choice fails, there is a need for replacements.[17] |
| 2. Factors based on evidence and experience | • New scientific proof supports alternative applications .[10]<br>• Clinicians are investigating new unauthorized applications according to practice and medical understanding.[18] |
| 3. Factors Associated with the Patient's Condition | • FDA-approved or not, life-threatening or terminal conditions demand the use of any acceptable and affordable medication.[18] |
| 4. Choice and Risk-Benefit Considerations | • For physicians and patients, off-label use offers alternative therapy options with possible advantages and disadvantages.[14] |
| 5. Influence from Professionals and Regulatory Bodies | • Healthcare professionals, pharmacists, and regulatory bodies' role in informing the public concerning off-label drug usage.[14]<br>• FDA efforts to control and oversee off-label use via post-marketing monitoring.[14] |

Table no.2

**BENEFITS AND RISKS:**

| Benefits | Risks |
|---|---|
| In the case that approved therapies are unavailable or fail, they may offer the best possible intervention and act as the standard of care.[3] | In cases when scientific reliability is insufficient, and people may be exposed to unidentified health risks or poor therapy.[3] |
| In clinical practice fields like psychiatry, pediatrics, geriatrics, obstetrics, and oncology, crucial.[3] | It was linked to severe negative pharmacological effects, such as verified injury from improper usage.[3] |
| Expands medicinal alternatives, including treatment for orphan diseases and pediatric children with no authorized indications.[3] | Off-label usage is associated with more frequent and severe side effects in children.[3] |
| OLDU resulted in a greater number of adverse drug reactions than indicated for labeled usage.[14] | Off-label use can help patients and doctors to enhance treatment despite the hazards.[14] |
| Has resulted in considerable clinical advantages, including higher recovery rates in pediatric malignancies.[3] | It gets around regulatory checks, which puts more responsibility on prescribers along with raises ethical issues if it is used often.[3] |
| While OLDU can be helpful and even life-threatening for certain individuals, there generally is not much or no scientific proof to support its effectiveness.[14] | OLDU is useful, particularly when patients have used any other approved treatment choices, like in the case of uncommon disorders or malignancies.[14] |

Table no.3

**In Us , Europe, China and India – Off-Label Pharmaceutical Use:**

Off-label can be interpreted differently in several locations, including the United States, South Korea, Europe, and China. Although the essential principle is the same, the way it is defined varies slightly; for example, a medicine may be regarded on-label in one nation but off-label in another, or even within the same country for an alternative ailment.[19]The main issue is that most nations, particularly developing and impoverished ones, lack clear legislation governing off-label pharmaceutical use. As a result, many medications are prescribed without proper consideration for their potential adverse effects. This unauthorized practice has placed a significant financial demand on healthcare systems while also contributing to medicine shortages for approved indications.[16]

**EUROPE - OFF-LABEL USE:**

According to surveys published in the last decade, off-label drug use is common in the European Union (EU), particularly in pediatrics, cancer, neurology, infectology, and geriatrics. For example, up to 90% of newborn therapies in the intensive care units of hospitals are believed to be off-label.[20] considering the fact that using off-label pharmaceuticals is common, there is little regulation across the EU. There is no legal description of off-label use in the EU. However, supporting the prescription of a medicinal product for an unauthorized purpose is clearly prohibited.[4] When clinicians may recommend drugs off-label is dependent upon the regulations of the various Member States.[20]

Before beginning any off-label treatment, doctors must fully explain to patients the risks of using the medication, such as the fact that it is not approved for its intended purpose, that the adverse effects of administering it are unknown, and additionally that there may be challenges to getting health insurance companies to pay for the therapy. Patients may be able to file claims for damages if they get insufficient details on any of these issues.[20]

The European Commission's goal is to guarantee that all medications are sold according to their intended usage, dose, and mode of administration. Although European pharmaceutical regulations does not specifically prohibit or permit off-label use, doctors are nonetheless free to prescribe drugs off-label on their own initiative.[21] Off-label medication administration may be appropriate when certain requirements are satisfied, as described in the 2016 Declaration on Good Off-Label Use Practice (GOLUP Declaration), which was created by the European Medicines Agency's expert group.[22]

**US - OFF-LABEL USE:**

Off-label prescriptions in the United States are large, topping 50% in some patient categories or circumstances. Pharmaceutical companies frequently assess established medications for their efficacy and safety for new indications, which may lead to formal approvals. According to economist Alexander Tabarrok's analysis, the majority of hospital patients receive at least one off-label medicine.

Physician prescriptions are not explicitly regulated by US legislation; instead, doctors employ medical judgment for off-label use if clinically justified and FDA-approved. Off-label applications cannot be marketed or promoted by drug manufacturers after FDA approval for specified indications, as this constitutes "misbranding". Off-label instances may be punished under the False Claims Act if advertising result in false submissions to government healthcare programs for non-covered uses.

Federal and state authorities, regulators, and prosecutors devote significant resources to monitoring off-label use, with notable prosecution achievements. The United States aggressively prosecutes off-label instances; pharmaceutical corporations have paid tens or hundreds of millions of dollars in penalties over the last 10 years, with some reaching $1 billion. The US Department of Justice (DOJ), the HHS-OIG, state Attorneys General, and federal/state fraud teams are among the key

prosecutors involved. The FDA initiated the HEAT (2009) and Bad Ads (2010) campaigns. Fines and settlements resulting from these acts totaled billions of dollars. "Qui tam" whistleblowers (workers, rivals, and healthcare professionals) can earn millions of dollars as a reward percentage. Individual accountability is strictly enforced: CEOs may face criminal charges, incarceration, exclusion from government healthcare programs, and FDA debarment from working in the business.[20]

Off-label usage is encouraged by the American Medical Association "when such use depends on sound scientific proof and appropriate medical opinion." In a similar vein, off-label prescriptions that are "done in the best advantage of the patient" and "based on sound scientific evidence, expert medical judgment, or published literature" are approved by the American Academy of Pediatrics (AAP) Committee on Drugs.[20]

**CHINA - OFF-LABEL USE:**

Although being essentially illegal, off-label drug use is common in China. Off-label medication prescriptions are prohibited in China. According to China's legal system, doctors must strictly administer medications in accordance with the approved label or package insert; if they don't, they risk formal warnings, a 6- to 12-month suspension of their medical practice certificate, or license revocation (this also applies to pharmacists). Nonetheless, there have been instances of exceptions amid public health crises. Off-label antibiotic overdose beyond approved labels was either encouraged or allowed by authorities during the 2004 SARS outbreak.

In China, off-label advertising is not strictly regulated. However, it is legally forbidden to market off-label; all pharmaceutical commercials must adhere to the State Food and Drug Administration-approved product label and insert.[20] In China, little limited survey data on off-label use is available. According to studies from pediatric wards in Beijing and Suzhou, up to 22% of prescribed drugs being taken off-label.[20]

In China, the 2021 pediatric off-label guidelines prompted an expert panel to suggest an evidence-based framework for risk-benefit evaluation, informed consent, expert committee oversight, adverse-effect monitoring, and patient and family education. However, according to a 2024 survey, clinicians ranked informed consent documentation, learning resources, and adverse drug reaction tracking systems as lesser requirements, implying that in critically needed pediatric settings, instant lifesaving treatments frequently take position over official authorization protocols.[23]

**INDIA – OFF-LABEL USE:**

The Drug Controller General of India (DCGI) is the regulatory authority in India in charge of awarding approval for new pharmaceuticals, however there are no clear guidelines regarding off-label drug use.[19] because the legislation and standards for off-label usage lack consistency and unity, the decision to utilize them is left to specialists (doctors). Furthermore, there is an increasing need for rapid access to novel therapies, but the limited availability of safety and efficacy data in a short period of time is a significant barrier for authorities who cannot make decisions in a hurry. If they tighten the reins, many patients may be denied access to alternative treatment choices, while being too permissive may result in abuse and harm to the patient.[11]

The federal regulatory system places restrictions on off-label use, even if doctors are free to prescribe it. For regulatory authorities, balancing information on their benefit-risk ratio for those uses is a significant task.[3] When a benefit-risk ratio is determined, it can be justified for the patient. Currently, medications cannot be prescribed for indications for which they have not been approved under Indian law. It was prohibited to prescribe off-label medication two years ago when the Indian Medical Council Act was amended. In India, off-label marketing by pharmaceutical corporations is considered illegal under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.[3]

The DCGI can certainly control pharmaceutical corporations' advertising of off-label use, but it cannot control doctors' off-label prescriptions because it does not govern the consumption of medicine.[3]

The Drug Controller General of India (DCGI), the Drugs and Magic Remedies (Objectionable Advertisements) Act (1954), and the Central Drugs Standard Control Organization (CDSCO), which creates the National Formulary of India (NFI), are the main organizations and laws pertaining to medicine regulation in India. On the other hand, neither the CDSCO nor the DCGI govern the practice of medicine. The Indian Medical Council's Professional Conduct, Etiquette, and Ethics Regulations (2002) govern the practice of medicine. According to this rule, "physicians should strive to continually enhance their medical knowledge and skills and should make available to their patients and colleagues the benefits of their professional achievements."[17]

After using the drug off-label, the owner corporation must go through various clinical phases to approve it for this use, as well as additional quality control tests such as stability testing. This means that the medicine will remain under study until approved by the FDA.[4]There are numerous potential areas of research in India including the use of off-label drugs. These include an evidence-based approach to improving the rationality of pharmacotherapy (particularly in pediatrics and cancer treatment), the development of dosage guidelines, pharmacovigilance for assessing the causality of adverse events and risk-benefit analysis, and the potential role of Health Technology Assessment (HTA) in studying cost-effectiveness.[17]

All areas are working hard to provide secure regulation of off-label pharmaceuticals, but India still has to build a regulatory paradigm to protect patients in the case of off-label drugs and remove any shadow of doubt among physicians by providing accurate information on drug use. Insight, by building a paradigm that allows physicians and healthcare providers to obtain information on off-label pharmaceuticals, Indian regulatory agencies can alleviate physician concerns about prescribing off-label drugs and potentially reduce the potential negative effects of off-label drugs.[19]

**MARKETING AND POST MARKETING SURVEILLANCE:**

Although using medications off-label is not prohibited, it may be dangerous and detrimental or advantageous and creative. Since the pharmaceuticals are used in ways that are not authorized by regulatory bodies, the issue with this practice is the absence of mechanisms for tracking adverse drug reactions. Protection of public health is therefore not assured. The use of off-label medications has drawbacks in addition to benefits. Thus, using drugs off-label is not an excellent choice.[26]

Before a medicine can be advertised or marketed, marketing permission is required to ensure the drug's efficacy, safety, and quality. Manufacturers must provide regulatory bodies with all data pertaining to scientific trials and animal research in order to compare the safety and efficacy of a drug's intended usage.[1] However, there are no precise guidelines regarding the usage of the medicine off-label.[13]

In order to provide pharmaceutical authorities with fresh information regarding the safety of particular medications, marketing authorization holders routinely submit safety update reports.[24] Post-market drug monitoring is crucial for gathering long-term data and ensuring the safety and effectiveness of these medications.[25] It is possible to identify high-risk populations and develop methods to reduce potential harm by investigating the factors linked to the occurrence of adverse drug reactions (ADRs) in patients receiving drugs off-label.[10]

Improve postmarketing monitoring systems to generate reliable safety data to support evidence-based prescribing guidelines by methodically identifying, describing, and measuring adverse events resulting from the use of off-label medications in pediatric emergency situations.[23] Dresser & Frader's (2009) regulatory affairs module includes information from the label such as drug purposes, strength, patient age group, and mode of consumption. The knowledge presented above refers to off-label drug use. This study demonstrates that every medical professional have to handle risks associated with the utilization of drugs.[26]

**NEEDS OF OFF-LABEL DRUGS :**

Off-label drug use is required when the best available approved therapeutic choices fail and the patient's clinical situation necessitates a novel method or alternative treatment. In such cases, off-label use permits clinicians to investigate other, potentially successful medicines. Off-label use also allows for early availability of potentially beneficial pharmaceuticals, particularly when approved treatments are unavailable, ineffective, or delayed. As medical knowledge increases, this technique facilitates the rapid provision of medications to people in demand.

Many off-label usage are scientifically supported and provide considerable clinical advantages to patients. Aspirin, for example, has a number of off-label uses and is routinely used to prevent myocardial infarction in people at moderate or high risk of coronary artery disease (CAD). Furthermore, researchers have investigated the use of aspirin to prevent colon cancer, esophageal cancer, and other disorders.

Appropriate off-label prescribing may only be promoted by providing accurate and non-misleading data. If off-label prescribing were fully prohibited, many new medicines and clinical data wouldn't become available since pharmaceutical companies have little motivation to secure regulatory approval for new uses of existing pharmaceuticals through clinical trials.[12]

Overall, the advantages of off-label prescribing include faster access to medicine, lower costs compared to creating novel treatments, and utility in circumstances when mainstream drugs fail or patients have varied reactions. Additionally, off-label use encourages clinical experimentation and surprising findings, which contribute to future advances in medical profession.[2]

**CONTRAINDICATION OF OFF LABEL DRUG :**

Since it may have to do with possible advantages or disadvantages for patients, it is a bipolar term.[1]

When there is uncertainty regarding the scientific validity of off-label use, the patient may be exposed to unrestricted experimentation, unknown health risks, or ineffective medication. The FDA also outlines when a drug is contraindicated, which refers to clinical situations where the risk of use outweighs any potential therapeutic benefit. .[6]

Serious side effects have been linked to off-label medication use.

For example, phentermine was frequently administered with the appetite suppressant fenfluramine, which was authorized for short-term use but was used over an extended period of time. Valvular heart disease was brought on by the off-label combo "fen-phen."Off-label drug usage in children is linked to a higher frequency and intensity of side effects.[2]

**PHARMACOVIGILANCE:**

WHO defines pharmacovigilance as the identification, assessment, and management of all drug-related adverse events. Pharmacovigilance's primary goal is to determine whether a specific medicine is safe to use. According to WHO, the primary goal of pharmacovigilance is the rational use of medications for safe and effective treatment, as well as assuring patient care and safety.[26]

The primary goal of pharmacovigilance is to promote health and safety in the use of medications. Pharmacovigilance's primary goal is to reduce risk by preventing and managing adverse drug reactions (ADRs). However, a significant hurdle to accomplishing this goal is the ineffective communication of safety signals, adverse drug responses, and drug interactions to healthcare providers and patients.

The primary responsibility of pharmacovigilance is to gather all information about adverse effects, receive reports of all ADRs, and further evaluate and analyze novel ADRs. Pharmacovigilance also entails keeping ADR databases and alerting the public, healthcare professionals, and pharmaceutical manufacturers. Pharmacovigilance is primarily concerned with adverse medication reactions, which are characterized as

unpleasant and unexpected reactions arising at levels commonly utilized for normal functions.[26]

**CONCLUSION :**

Off-label medication usage remain a valuable medical treatment alternative if authorized medicines are inaccessible or not effective. Though, using it must be based on good evidence from science, thorough advantage-risk evaluation, informed consent from patients, and proper pharmacovigilance. Enhancing regulatory guidelines as well as post-marketing surveillance will encourage a secure, sensible, and evidence-supported utilization of off-label medications whereas also enhancing outcome for patients.

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