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Review Article

An educational review on over-the-counter drugs- A Pharmacovigilance-based approach

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ABSTRACT

Over-the-counter (OTC) medicines, a crucial component of the healthcare system, can be sold to the consumer without a registered medical practitioner (RMP) prescription. They are safe and effective when used according to the instructions on the label and as directed by healthcare professionals. OTC medications are effective in treating common ailments. Switching drugs from prescription to OTC has increased worldwide, saving time and reducing the burden on the healthcare system. Many people rely on OTC to treat everyday ailments like headaches, colds, fever, coughs, indigestion, flu, and dermatitis. Therefore, a wide safety margin must be established for the OTC drugs. OTC product benefits must outweigh the risks, and the chances of misuse of it should be low. Consumers think that OTC medicines are safe since pharmacists dispense them without a prescription from a registered medical practitioner. However, OTC has adverse effects and could be misused, abused, or interact with prescription drugs. Failure to comply with directions may lead to serious side effects. For example, an overdose of Acetaminophen has been associated with liver damage. Analgesics increase gastrointestinal tract bleeding even when taken at appropriate doses. Cough products such as Dextromethorphan and Diphenhydramine may be abused due to their euphoric and alcohol-like effects. A distinct Pharmacovigilance system should be implemented to optimize the safe use of OTC drugs.³

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1. Introduction

According to WHO, Pharmacovigilance is “The science and activities concerned with detection, assessment, understanding, and prevention of adverse drug reactions and drug-related problems. Its role in ensuring public health and medication safety cannot be overstated.”

1.1. Objectives of pharmacovigilance

1. Improve patient care and safety associated with the use of medicine.

2. Improve public health and safety related to the use of medicine.
3. Evaluate the advantages, efficacy, and risks of medication.
4. Encourage education, understanding, and clinical training in Pharmacovigilance.¹

1.2. Drugs

A drug is any substance other than food used in the prevention, diagnosis, aviation, or treatment of a disease that is called a drug. Drugs are available as legal or illegal drugs.

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1.3. Illegal drugs

The Food and Drug Administration (FDA) has studied these chemical substances and found that they cause more harm than good. A person caught posing, selling, or using can be arrested, fined, and sent to jail.

Examples: Cocaine, Heroin, Illegal steroids.

1.4. Legal drugs

Those drugs that have been studied, tested, approved, and controlled by the FDA, such as prescription and OTC drugs.

1.5. Prescription drugs

These are prescribed by a legal Medical Practitioner who tells the pharmacist to dispense a particular medication. These are prescribed to treat a specific medical problem.²

1.6. OTC drugs

These drugs are easily accessible from pharmacies without a prescription from a health professional. They are safe for short-term use and effective for minor common diseases. The advice of a pharmacist is sufficient as directed on the label. The Food and Drug Administration (FDA) in the USA defines OTC drugs as safe and effective when used according to the label without a prescription or according to a health professional's advice, if necessary. Self-medication is medication taken by patients responsible for treating their minor illnesses.

1.7. Classification of OTC drugs

The most used over-the-counter medications include:

1. Pain relievers - Acetaminophen, Aspirin, Ibuprofen, and Naproxen.
2. Medicines for heartburn and indigestion - Omeprazole, Lansoprazole, Cimetidine, and Aluminum Hydroxide.
3. Laxatives - Bisacodyl and Calcium Docusate.
4. Antidiarrheal drugs - Bismuth Sub Salicylates and Loperamide.
5. Motion sickness medicines - Dimenhydrinate.
6. Nasal steroids - Fluticasone and Triamcinolone.
7. Cough medicines - Guaifenesin.
8. Antihistamines - Fexofenadine and Loratadine.
9. Emollients and mild corticosteroid creams.^{3,4}

1.8. Benefits of using OTC medicines

1. OTC medicines allow greater access to treatment of people at large at lower cost for minor or self-limiting illnesses.
2. Moreover, General Practitioners (GPs) do not have to write prescriptions for minor ailments, which gives them more time to deal with serious health problems.

3. This is extremely useful for countries like India, where the doctor-to-patient ratio is less (1:1800) than in other countries.
4. To ensure the optimum use of OTC medicines, pharmacists can provide a valuable interface by using their professional knowledge to guide patients.⁵
5. Improved Education of the consumer.
6. Rapid access to effective medicines.
7. Allowing an individual to oversee their health.

1.9. Risks of OTC medications

1. Increase Drug Resistance
2. Increase cost to the patients.
3. Failure to follow label instructions.
4. Increase risk of drug-drug Interactions.
5. Potential for misuse and abuse.
6. Incorrect self-diagnosis.
7. Delayed diagnosis.
8. Incorrect treatment for serious illness.

2. Role of Pharmacist in OTC Medication Dispensing

Pharmacists play a vital role in controlling the number of medications being dispensed as OTC drugs. They are as follows,

1. Carefully read and follow all directions on the medicine bottle and box.
2. Dispense the minimum effective dose.
3. Call your doctor if you are having a problem with your medicines.
4. Do not give a medicine if the patient has had an allergic reaction.
5. Inform the patient to take the medicine exactly as directed.
6. Pharmacists must be careful when dispensing more than one drug.
7. Keep your doctor informed.

2.1. OTC drugs in India

The trend of 'Over-the-counter (OTC) Medicines' use has grown steadily in the last few years. This trend is responsible for various reasons, such as easy availability, affordability, and increased patient awareness. OTC or nonprescription medicines are terms used interchangeably to refer to medicines that can be bought without a prescription. Many countries recognize OTC medicines as a separate category of drugs and have established regulations for their use. In India, there are no guidelines for licensing OTC medicines. No separate category is allotted for OTC medicines in India, and the drugs that do not come under the prescription medicines schedule are generally sold as over-the-counter medicines.⁶

Indian OTC market ranks 11th position in the global OTC market size, and it is expected to grow further due to more reasons: the expansion of more pharmaceutical companies and chemist shops in rural and semi-urban areas, people's higher tendency to self-medicate, the need to save on health care spending. Increasing the trends in enhancing self-care activities and managing minor ailments through non-prescription drugs.⁷

In India, medicines are listed under different schedules in the Drugs and Cosmetics Act and Rule. Drugs listed in Schedules H, H1, and X should carry a label stating that they are to be sold by retail only on the prescription of a registered medical practitioner. The drugs listed in Schedule G (mostly antihistamines) must carry a mandatory text on the label stating, "Caution: it is dangerous to take this preparation except under medical supervision."

Surprisingly, specific important drug categories such as diuretics and aminosalicylates (Sulfasalazine, Mesalamine) are not included under any drug schedule. This confuses pharmacists about whether to sell these drugs as OTC or prescription medicines.⁸ It must be stressed that the phrase "OTC" has no legal recognition in India. Here, the term OTC is used for how drugs are used (self-medication without prescription or allowed to be sold by pharmacists without a Registered Medical Practitioner) rather than being a recognized official category of medicines, unlike other countries.

The medicines that do not fall under Schedule H, H1, and X can be given without prescription through pharmacists and drugstores in India. Moreover, it is a common observation that prescription drugs are also sold without a prescription, like over-the-counter medicines. Ayurvedic drugs and traditional treatments are manufactured under a manufacturing license issued by the State Licensing Authorities.

These drugs are freely sold over the counter by non-pharmacists. Thus, there are no specific unifying regulations related to the use and sale of OTC products, and inappropriate use impacts both accessibility to better health care and patients' safety.

A study by Phalke et al., reported the prevalence of self-medication in the rural population of the state of Maharashtra in India to be 81.5%. However, in Tamil Nadu, only 23% of the rural population resorted to self-medication or household remedies, and almost 77% consulted a doctor. The prevalence of self-medication in Urban Delhi was found to be 92.8%, whereas a study conducted at Berhampur in Odisha found the prevalence of OTC medication use to be 18.72%. Overall, 52% of Indians were estimated to self-medicate in India according to a web portal-based survey of 20000 people across 10 cities. The reasons were lack of time, the need to avoid doctors' fees, and dependence on the Internet. One Indian study reported that more than 90% of the qualified pharmacists interviewed were aware

of the concept of OTC drugs, 96.5% asked the patients their complaints when they were approached to purchase OTC drugs, but only 51% counselled the patients regarding instructions for use.⁵

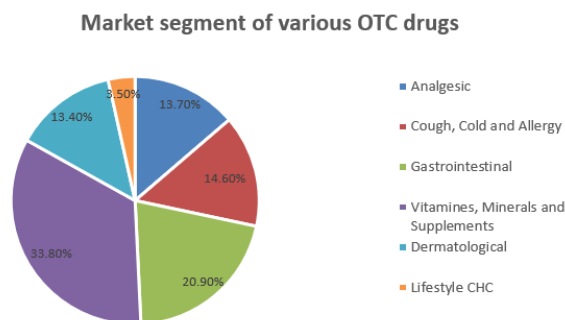


Figure 1: Market segment of various OTC products⁹

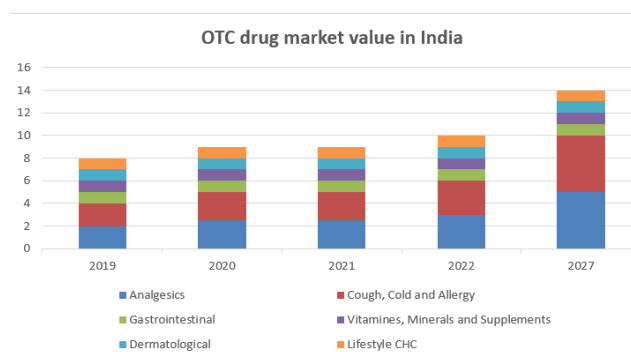


Figure 2: OTC Drugs market, value in India 2019-2027¹⁰

3. India OTC Market Recent Developments

1. The top OTC products available in India include Dabur Honitus lozenges, cough syrups, Vicks VapoRub, Zandu balm, Iodex, Moov, cough drops, and lozenges. One of India's most significant economic sectors is the pharmaceutical industry, which exports \$15 billion worth of goods yearly and boasts some of the world's best manufacturers.
2. OTC and prescription medicines are India's second-largest export to the US.
3. Bayer announced its intention to join India's OTC Drug market in June 2022. According to the company, Bayer's consumer health business in India, which recently introduced the new Saridon Advance for severe headaches, is scheduled to introduce another product in the nutrition category in July.
4. The Union Government suggested in May 2022 that the law should be altered to introduce OTC drugs into India according to the Drugs and Cosmetics

Table 1: Popular OTC Brands across various categories¹¹

OTC Categories	Popular Brands
Aches/Pain	Volini, Moov, Iodex, Vicks Multi-pain, Fast Relief
Digestives	Pudin hara, Hajmola
Antacids	Gelusil, Digene, Eno, Pepfiz
Cold rubs and Analgesics Balms	Vicks. Amurtanjan, Zandu
Vitamins/Health Supplements	Chayawanprash, Nutrigain, Revital, Calcium Sandoz
Medicated Skin Treatment	Krack, Itchguard, Mederma, RingGuard
Analgesic /Cold Tablets	Dolo, Aspirin, Crocin, Vicks Action 500, D'Cold
Antiseptic Creams/Liquids	Dettol, Savlon, Boroplus
Glucose Powders	Glocon-D, Gluco vita, Dabir Glucose-D
Cough Syrups	Benadryl, Dabur Honitus
Throat Lozenges	Halls, Vicks, Streptisils
Medicated Dressings	Johanson & Johanson Band-Aid
Baby Gripe water	Woodwards, Dabur
Ayurvedic medicines/Preparation	Himalaya, Ayur, Vicco labs & lots more

Rules, enabling their retail sale without a medical prescription.

5. As a result of the development of technology and marketing, higher levels of workplace stress, and rising health awareness, urban India has picked up the idea of OTC drugs.
6. A few FMCG companies, including Hindustan Unliver and P&G, are expanding their markets by joining the OTC space and reaching previously inaccessible regions. Pharmacies' inability to get to the country's remote areas is one of the primary challenges they face.
7. India's Pharmaceutical sector makes up around 2.5% of the global pharmaceutical market in terms of value and 10% in terms of volume.
8. Continuous improvement innovation and rising investments in substantial research and development (R&D) efforts further drive the industry. Other factors affecting the marketplace include increasing disposable income levels among the public, growing stress levels among working professionals, and rising health consciousness among many citizens.
9. In April 2020, Cipla Health will transport over-the-counter wellness products to customers' homes in India in collaboration with Zomato, Swiggy, and Dunzo.
10. GSK Consumer Healthcare announced in December 2020 the launch of a novel nasal decongestant portfolio in India under the Otrivin brand. Additionally, Otrivin Breathe Clean Daily Nasal Wash was launched.

3.1. India OTC market top players

1. Emami limited
2. Dabur India Limited
3. Procter & Gamble
4. Abbott laboratories
5. GlaxoSmithKline
6. Cipla
7. Sun Pharmaceuticals Limited
8. Johnson & Johnson¹⁰

3.2. Safety of OTC drugs: need for separate Pharmacovigilance system

OTC drugs are relatively safe. However, inappropriate use can lead to complications and adverse events that affect public health. The consumption of these medicines can be unsafe, as incorrect self-diagnosis or the ingestion of inappropriate doses can lead to side effects and the occurrence of adverse reactions and drug-drug interactions. Measures should be implemented to optimize the safe use of OTC drugs to avoid the occurrence of secondary events associated with the lack of knowledge related to their usage. Recently, an increase has been observed in the use of pharmaceutical drugs by the general population. However, this increase has not been associated with health improvement.

According to the World Health Organization (WHO), more than 50% of the drugs consumed worldwide are prescribed or dispensed inappropriately, and almost 50% of patients misuse these drugs, resulting in increased morbidity and mortality. This self-management of health encompasses the concept of self-medication, defined as the selection and use of drugs by individuals and caregivers to treat self-recognized or self-diagnosed conditions or symptoms. This self-medication can be an unsafe practice due to inaccurate self-diagnosis or an inappropriate dosage intake that can result in side effects, adverse reactions, and pharmacological interactions. Improper self-medication increases the costs associated with health care in the number of patients taking OTC. Increased access to medicines without improved health literacy increases the risk of misuse.¹²

Inappropriate self-medication with OTC drugs can have serious repercussions (including death), especially in pregnant and nursing mothers, paediatric and geriatric populations, and patients with co-morbidities.¹³ National health policies concerning the use of OTC drugs should be targeted at these populations and drug groups to optimize their use and avoid the occurrence of side effects associated with the lack of knowledge of the use of these drugs. In addition, these policies should improve e-health literacy, considering the increase in the number of people who use the internet or social networks as health resources to search for information.¹²

Incorrect use of over-the-counter drugs might result in health and other drug-related issues. A drug-related problem (DRP) is an incident or scenario involving drug therapy that interferes with anticipated health results, either directly or indirectly. Pharmacists are highly trained professionals obligated to provide effective patient counselling to guarantee the safe use of pharmaceuticals. They play a vital and proactive role in preventing and resolving DRPs, thus preventing adverse events, avoiding extra costs resulting from inappropriate use of medications, and adding value to patient safety.

Pharmacists are the most accessible healthcare professionals on the front lines for the general population and, seemingly, the most equipped professionals with formal knowledge and training on self-treatment and over-the-counter pharmacotherapy. As a result, pharmacists in community settings have momentous responsibility and opportunity to respond to patients' minor complaints and safeguard them from the risks associated with self-medication. Pharmaceutical counselling provided by community pharmacies is particularly crucial when medications are purchased over-the-counter (OTC) without advice given by a physician.

Easily accessible OTC medications are considered harmless by consumers and thus often underestimate the potential risks. They have an incomplete awareness of several risk areas of OTC medications, such as those relating to drug interactions and misuse/abuse¹³

Consumers think that OTC medicines are safe since pharmacists dispense them without a prescription from a registered medical practitioner. However, OTC has adverse effects and could be misused, abused, or interact with prescription drugs. The patient must assess the safe use of these products without the practitioner's intervention. Therefore, people must acquire knowledge about the safety of OTC medicines. Failure to comply with directions may lead to profound side effects (i.e., the correct dose, correct schedule, and for the intended disease). For example, an overdose of Acetaminophen has been associated with liver damage. Analgesics increase gastrointestinal tract bleeding even when taken at appropriate doses. Cough products such as Dextromethorphan and Diphenhydramine may be abused due to their euphoric and alcohol-like effects.¹⁴

4. Over-the-counter Drugs Market in India

The market for OTC products in India can be categorized as (1) frank OTC products that are advertised on public media and construed as actual OTC products, (2) prescription brands that are not advertised but are promoted to physicians and also purchased by consumers without prescription called OTC brands.

The value of the Indian OTC drugs market is estimated to be US\$ 2.7 billion (Rs 188.6 billion) at a compounded annual growth rate of 9% to reach around \$6.5 billion (Rs

441.1 billion).¹⁰

The significant players for OTC products in India are Cipla, Abbott India Limited, Amrutanjan Health Care Limited, Boehringer Ingelheim Limited, Mankind, Dabur India Limited, Pfizer,

Emami, GlaxoSmithKline, Sanofi, Himalaya Herbal Health Care, Novartis, Marico, Merck, Piramal Enterprises, Procter & Gamble, and Lupin.¹⁵

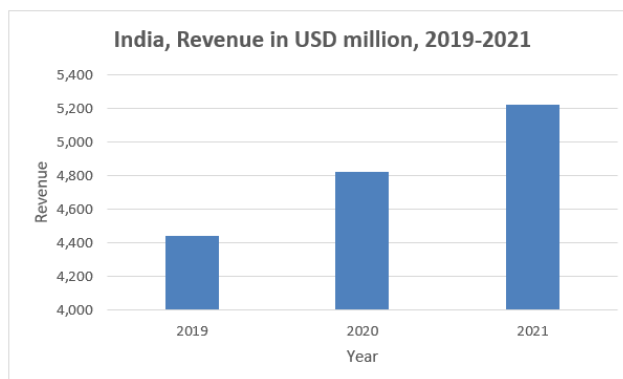


Figure 3: India, revenue in USD million, 2019-2021¹⁰

Table 2: Approved drugs in India¹⁶

Active Ingredient	Brand Name	Therapeutic Indication	Approval Date
Polyethylene Glycol	MiraLAX	Laxative	10 June, 2006
Terbinafine	Lamisil Derma Gel	Topical Antifungal	24 July, 2006
Cetirizine HCl	Zyrtec	Anti-Histamine	16 Nov, 2007
Omeprazole	Zegerid	Acid reducer / PPI	12 Jan, 2009
Lansoprazole	Prevacid	Acid reducer / PPI	18 May, 2009
Fexofenadine HCl	Allegra	Anti-Histamine	25 Jan, 2011
Triamcinolone acetonide	Nasacort (nasal spray)	Allergic Rhinitis	11 Oct, 2013
Oxybutynin	Oxytrol	Overactive Bladder	25 Jan, 2013

4.1. Labeling of OTC drugs

Labeling criteria: Labeling is crucial for over-the-counter medicines. It provides consumers with important drug information, and the content should be easy to understand. According to Rule 95 of the D&C Act, labels must adhere to the requirements. The essential characteristics of over-the-counter medications will also be modified, and they will be classified as OTC-1 and OTC-2 based on safety, therapeutic index, patient accessibility requirements, availability, non-

addictive nature, supply chain mechanism, and socio-demographic conditions of the nation. These changes will be made along with the definition and rules for advertising.¹⁵

Section 96 of DCR stipulates the labeling instructions. There are no specific labeling conditions or requirements for OTC drugs in India. In contrast, it is mandatory for all medicines except Ayurvedic, Siddha, and Unani drugs to put the following information on their labels:

1. Generic name and brand name
2. Contents of ingredients and total contents
3. Details of the manufacturer, including name, address, and manufacturing license number
4. The batch details, dates of manufacturing, and expiry dates
5. The maximum retail prices
6. Rule 161 states the labeling provisions of all Ayurvedic, Siddha, and Unani drugs¹⁰

5. Indian Pharmaceutical Association Recommendations

The word OTC (over-the-counter) Medicines must be defined under the Act, giving it legal status.

We need a clear-cut list of OTC medicines. A separate list for:

1. (a) Single ingredient OTCs
- (b) Fixed Dose Combination (FDC) OTCs

In addition, we need to have two sub-categories of OTC medications:

	Suggested category	Brief description	Example
A	OTC Medicine-(Pharmacy)-(Non-prescription medicine)	OTC Medicines- to be sold only through pharmacies	Paracetamol, Aspirin, Antacids, Topical preparations of specific NSAIDs, Cetirizine, Albendazole, povidone-iodine preparations, and average saline nasal drops. In addition, all drugs which are currently under Schedule K
B	OTC-General sales	Which could also be sold through outlets other than pharmacies.	Dettol, Savlon, Band aids

5.1. Non-prescription or otc medicines

5.1.1. Labelling

The medicine label should specify that it is an OTC Category Medicine, a green.

Vertical line of 1 mm thickness, and have the written box as below (and a symbol):

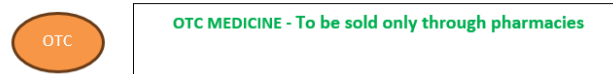


Figure 4: Labelling of OTC category drugs

In addition to the above messages, the package should include one of the following:

1. The medicine package should compulsorily contain a PPI (Patient Product Information/Patient Package Insert/s) or a PIL (Patient Information Leaflet) (in a readable font) -in English and at least two local languages prevailing in the locality/state in which the medicine is sold. The drug control authority must approve this PPI or PIL, and the manufacturer must insert it.
2. The medicine carton/label should bear the “Drug Facts.” The below-stated example is from the USA.

The information provided in these should cover the following:

1. Any warnings/contra-indications for use.
2. Indications, dosage, frequency of dose, maximum daily dose.
3. Potential adverse effects (those which can be ignored, and those, if seen by the patient, should stop taking the medicine).
4. DO NOT use for more than three days/week without consulting your doctor or pharmacist.”
5. Please read the enclosed PPI (Patient Package Insert) before using the medicine.

5.2. Otc - General Sales Medicines

These medicines can be sold at shops/general stores besides pharmacies. The medicine

label should specify that it is an OTC - General Sales medicine has a specific symbol designating it, a green vertical line of 2 mm thickness, and the written box as below.

These medicines can be advertised to the public without making tall claims or misleading the public. All advertisements should also contain warning messages in

Drug facts	
Active ingredient (in each tablet)	Purpose
Chlorpheniramine maleate 2mg	Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies;	
<ul style="list-style-type: none"> Sneezing Runny nose Itchy watery eyes Itchy throat 	
Warnings	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> Glaucoma A breathing problem such as emphysema or chronic bronchitis Trouble urinating due to an enlarged prostate gland 	
Ask a doctor or a pharmacist before use if you are taking tranquilizers or sedatives	
When using this product	
<ul style="list-style-type: none"> You may get drowsy alcohol, sedatives, and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery avoid alcoholic drinks excitability may occur, especially in children 	
If pregnant or breast – feeding, ask a health professional before use.	
Keep out of reach of children. In case of overdose, get medical help or contact a poison control centre right away.	
Directions	
Adults and children 12 years and over	take 2 tablets every 4 to 6 hours; Not more than 12 tablets in 24 hours
Children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; Not more than 6 tablets in 24 hours
Children under 6 years	ask a doctor
Other information	
<ul style="list-style-type: none"> Store at 20-25° c (68-77 ° F) Protect from excessive moisture 	
Inactive ingredients D&C yellow no.10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Figure 5: Model of OTC drugs label as per USA guidelines.



Figure 6: Labelling of general sales OTC medicines

bold and be easy to locate and read in English and at least two local languages.

Examples: Dettol, Savlon, Band-aids¹⁷

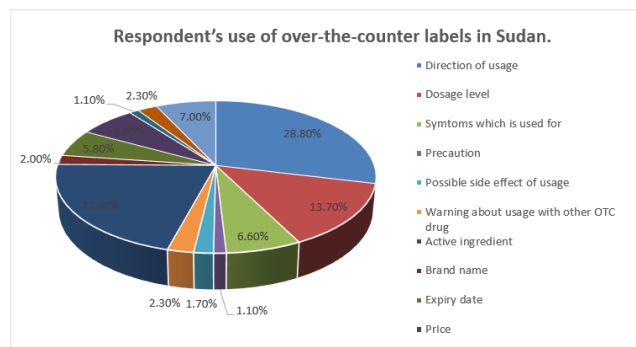


Figure 7: Respondent's use of over-the-counter labels in Sudan.¹

6. Conclusion

The consumption of OTC drugs has increased worldwide. Consumers are buying OTC drugs without considering their side effects. The public widely practices self-medication.

Significant problems and malpractices are associated with sharing OTC medications, using expired medicines, doubling the dose of drugs when they are ineffective, storing OTC medications, and not reading labels and expiry dates.

As the selection and use of over-the-counter medications are continuously increasing, pharmaceutical counseling should be readily available and actively provided for consumers to achieve safer self-medication. Improved pharmacists' practices about OTC can improve the rational use of non-prescription (OTC) drugs. Pharmacists must remain updated in their knowledge to make such practice safe and valuable.

There are no guidelines for OTC medications in India regarding labeling specific OTC categories. There is a critical need to improve and organize the labeling of OTC medicines so they are simple, straightforward, and easy to read. Drug regulatory authorities in India should enforce stringent policies in respective states so that practicing community pharmacists only dispense safe medications such as OTC drugs.

There is a need to create awareness about OTC drugs among various categories of communities, especially in rural areas. Orientation programs are needed to conduct, which can help reduce misuse and abuse and elicit proper use of medications.

A legally recognized class of OTC pharmaceuticals, patient awareness programs, and the support of pharmacists and pharmaceutical companies are required to maximize the rational usage of OTC medications in India. The Ministry of Health in India should control regulations governing the manufacture of patient information booklets in a local language for easy comprehension. National health policies concerning the use of OTC drugs should be targeted at these populations and drug groups to optimize their use and avoid the occurrence of side effects associated with the lack of knowledge of the use of these drugs. In addition, these policies should improve e-health literacy, considering the increase in the number of people who use the internet or social networks as health resources to search for information.

It is recommended that more information about the risks of self-medication, drug adverse reactions, antibiotic stewardship, more supervision of the prohibition of over-the-counter drugs and selling practices, and adequate facilities for people's access to medical services be provided at the policy level.

Hence, a separate pharmacovigilance system should be implemented to optimize the safe use of OTC drugs and avoid secondary events associated with a lack of knowledge about their usage.

7. Source of Funding

None.


8. Conflict of Interest

None.

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