

APRIL 2019 • Vol. 5 • Issue 1

**MONTHLY** • Pages 64

₹ 200

RNI No.: DELENG/2015/67140; Published on: Every month; Posted at Lodi Road HPO, New Delhi on 9-10th of every month

# THE AWARE CONSUMER

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## IN FOCUS

Medication Misuse  
In India:  
A Major Public  
Health Issue

## HORIZONS

30 Top OTC  
Health Products  
Of 2018

## CONSUMERS BE AWARE

OTC Drug  
Addiction, Abuse  
And Treatment

**NEED FOR A  
COMPREHENSIVE POLICY ON  
OVER THE COUNTER  
MEDICINES**



**PLUS**

**ROUND UP • MY MARKET • THE PRESCRIPTION**



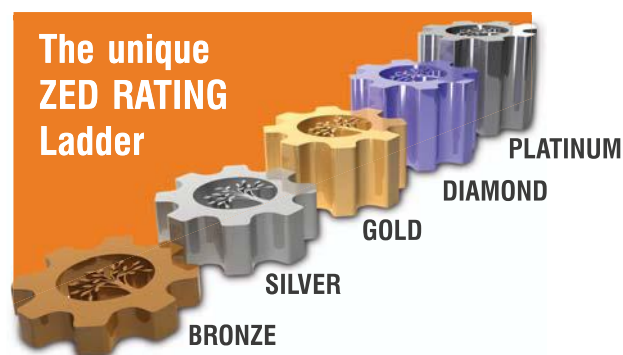
“Let's think about making our product which has 'Zero Defect'; so that it does not come back (get rejected) from the world market and 'Zero Effect' so that the manufacturing does not have an adverse effect on our environment”

**SHRI NARENDRA MODI**  
Hon'ble Prime Minister



## Certification Scheme

A roadmap to  
World-class manufacturing



### HIGHLIGHTS

- ⚙️ A scheme by Ministry of MSME, Govt. of India
- ⚙️ Certification on the systems and processes of MSMEs
- ⚙️ Handholding MSMEs towards world class manufacturing
- ⚙️ Special emphasis on MSMEs supplying to Defence Sector
- ⚙️ Direct subsidy to participating MSMEs
- ⚙️ Creating a credible database of MSMEs for OEMS/CPSUs/Foreign Investors under "Make in India initiative"
- ⚙️ Quality Council of India (QCI) to function as the NMIU (National Monitoring and Implementing Unit) of the scheme

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# VIEWPOINT



BEJON KUMAR MISRA | [bejonmisra@consumerconexion.org](mailto:bejonmisra@consumerconexion.org)

## OTC Drugs Tread With Care

**FOUR OUT OF** five adults commonly take over-the-counter medications, most often to treat ailments like aches and pains, coughs and colds, fever, allergies, skin disorders, and heartburn and other digestive problems. The reasons are easy to understand.

O.T.C.s are convenient, readily available in groceries and big stores as well as pharmacies, and they are less expensive than going to the doctor and perhaps paying for a costly prescription.

In addition to saving consumers time and money, O.T.C.s give many people a sense of self-control over their health and well-being.

That's all to the good if OTC drugs are used appropriately, for an indicated condition in the proper dosage and for no longer than the recommended time. However, one in five adults who self-medicate admit to taking more than the recommended dose or using the medication more frequently than the label indicates.

Globally, self-medication has been reported as being on the rise. People around the world tend to treat the disease,

almost 50% either wait for the problem to run its course or use a home remedy. About 25% visit doctor or use prescription medicine previously obtained for the same condition. The remaining 25% turn to the OTC medicines.

In many countries, OTC drugs are selected by a regulatory agency to ensure that they are safe and effective when used without physician's care. Taking over-the-counter medicines still has risk. Some interact with other medicines, supplements, food and drinks and some causes problem for people with certain medical conditions. OTC drugs have drug interactions with prescriptions and other drugs, it can cause various adverse reactions and even lead to death as well. More medicines doesn't necessarily mean better. Tread with care.

OTC Drugs' means drugs legally allowed to be sold 'Over The Counter', i.e. without the prescription of a Registered Medical Practitioner.



Message from the Editor-in-Chief

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## **REGULATION** **Need Of The Hour**

**REGULATION OF OVER** the counter drugs in India is especially difficult. According to the Organization of Pharmaceutical Producers of India, "There is at present no system of national chains of supermarkets or drugstores / pharmacies, and retailing is dominated by small independent shops. Chain pharmacies haven't been able to make any significant gains in garnering share of market. "Because there are no chain supermarkets and drugstores, most drugs are acquired through private drug dealers and "pharmacist."

The OTC segment in India is not identified separately. Instead, anything that does not fall in the prescription drugs category is classified as being Over The Counter. The growth of the Indian OTC market has outpaced the other OTC markets in the world. Currently, the Indian OTC market ranks 11th in terms of market size globally. The Indian OTC market is extremely competitive at present. The pharmaceutical companies are fighting it out with the leading FMCG companies for a share of the consumer's wallet. Awareness is a major problem when dealing with OTC products in rural and semi-urban India and consumers prefer to self-medicate themselves using herbal options.

In the extreme condition of a serious illness, a doctor is consulted. A paradigm shift has been observed in the lifestyle of the urban consumer though. Buoyed by the zeal to remain fit and active, the urban consumer has shifted to the adoption of vitamins and dietary supplements. As a result, sports nutrition is expected to be the highest driver of value over the next five years. Long working hours, sedentary jobs and fast-paced lives have further accentuated the usage of supplements.

Modern retailing of OTC products is still in its infancy and its presence is limited to urban areas. Chemists and pharmacists lead the OTC retail channel with their penetration being extremely high, especially in tier II and III cities and in rural areas.

The process of prescription of medications requires long years of learning. A pharmacist does not know the microbiology, physiology and medical history of a patient as well as the full potential of a certain drug. Thus, by prescribing OTCs, not only will he be causing harm but also adding on further problems to a patient. Regulation is the need of the hour.



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**Self-medication is on the rise across the world as empowered consumers want the primary care benefits that OTC medicines offer and India is no different.**

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OTC Drugs' means drugs legally allowed to be sold 'Over The Counter', i.e. without the prescription of a Registered Medical Practitioner. In India, though the phrase has no legal recognition, all the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). Prescription Drugs are those that fall under two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X.

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The pharma regulatory body is considering introducing provisions in Drugs and Cosmetics rules to allow for more over the counter medicines for minor ailments without doctor's prescription.



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Kanchana TK is the Director General of the Organisation of Pharmaceutical Producers of India (OPPI) that represents research-based pharmaceutical companies in India. Here she speaks about OPPI and its role as an advocacy body in working towards shaping the Indian healthcare system.

## MY MARKET

### 35 | INDIA OVER THE COUNTER DRUGS (OTC) MARKET-GROWTH, TRENDS, AND FORECAST (2019-2024)



India is the 11th largest market for OTC drugs in the world. Government and different pharmaceuticals companies are taking up various initiatives to create awareness about different drugs and shift Rx to OTC.



## OUT OF THE BOX

### 39 | WHAT ARE THE TIPS TO FIND THE SUITABLE MEDICAL SUPPLY STORE

Since most of the people do not have the time to go to the shop, hence there is a home delivery facility for many stores.

## IN FOCUS

### 45 | MEDICATION MISUSE IN INDIA: A MAJOR PUBLIC HEALTH ISSUE IN INDIA

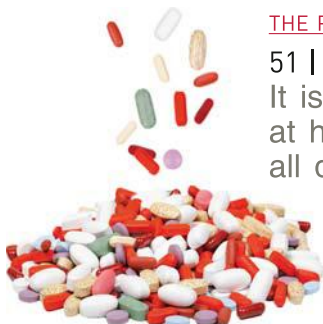


Due to poor or non-existent regulations, it has been estimated that at least 50% of the average family spending on medicines in the country is incurred on irrational or unnecessary drugs and diagnostic tests.

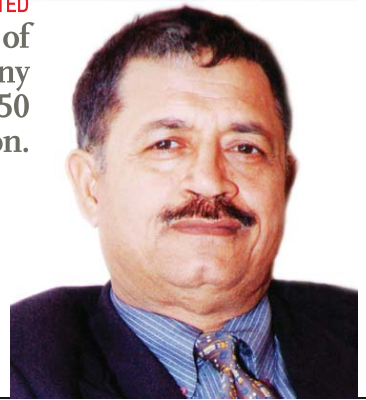
## THE PRESCRIPTION

### 51 | MOST COMMONLY USED OTC MEDICATION

It is good to keep several medications at home for various illnesses as long as all directions are followed and all expiration dates are monitored. You can buy many medicines for minor problems at the store without a prescription (over-the-counter).



Drugmaker Mankind Pharma is looking at achieving a turnover of USD 1 billion by 2021 from the present Rs 5,200 crore. The company is also looking at increasing its exports substantially to USD 100-150 USD million in the next three years from the present USD 10 million.



# ROUNDUP

India's OTC market grew 8 per cent to US\$ 2.7 billion with a five-year Compounded Annual Growth Rate of 9 per cent.



## Call For Separate Regulations For Medical Devices And OTC Drugs

**THE 4TH INTERNATIONAL** Conference on Pharmaceuticals and Medical Devices held in Bengaluru on 18th & 19th February witnessed the participation of drug regulators from over

30 countries including Russia, Kenya, the UK, Malaysia, Indonesia, Saudi Arabia and Uzbekistan, along with participation of Indian drug regulators from 15 states.

### DATA BRIEFING

About **40%** of O.T.C. drugs are used by people older than 65, who are most likely to have health issues that may contraindicate the use of certain OTC medications.





(L-R) - Dr Vivek Ahuja, Debashish Banerjee, Navdeep Rinwa, Dr Subrahmanyam Gutina, Dileep Mangsuli and Rahul Shingrani in a joint session, at the Medical Devices and Indian Pharma Conference, 2019

The conference was organised by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers and Government of India jointly with the Federation of Indian Chambers of Commerce & Industry (FICCI).

Some of the issues discussed at the CEOs roundtable included development of separate medical device and over-the-counter (OTC) drug regulations act, early decision on implementation of trade margin rationalization, addressing the issue of Active Pharmaceutical Ingredients (APIs) price escalation imported from China, incentivisation for innovation in the pharmaceutical and medical device sector, greater transparency in the functioning of National Pharmaceutical Pricing Authority (NPPA) and lastly, amendments by the Ministry of Consumer Affairs for allowing companies to utilise the mandatory CSR spending towards medicine donations into Jan Aushadhi or Ayushman Bharat scheme.

Knowledge sessions were focused towards promoting



innovative ecosystem in India for pharmaceutical industry, interaction with State Drug Controllers and CDSCO for facilitating ease of doing business, initiatives for import registration procedure to enable faster access to global market for the industry, WHO activities and plans related to the regulation of health

technologies and enabling the industry to gear up for Ayushman Bharat, the most aspirational health scheme rolled out by the government.

In his concluding remarks, Navdeep Rinwa, Joint Secretary, Department of Pharmaceutical, Government of India, mentioned how the government was prioritising the pharma and medical device sector in AI applications by bringing in task forces and other policies in place. Regulations for Over the Counter medications was also of prime importance during the discussions and various stakeholders expressed their views on the same. ▶



# SARIDON

## A Widely Used OTC Medicine, Exempted From List Of Banned Drugs By Supreme Court

**SARIDON IS SAFE.** If you go by the latest Supreme Court ruling, that is. The formulation of the analgesic tablet, manufactured by Piramal Enterprises Limited (PEL), has been exempted from the list of over 300 banned fixed dose combination drugs (FDCs).

The controversy over Saridon began in September last year when the SC banned 328 FDCs, including a combination of paracetamol, propyphenazone and caffeine (Saridon). That same month, PEL, however, managed to get a stay order for Saridon allowing it to continue manufacturing, distributing and selling the tablet.

The combination, however, was declared unsafe by an expert committee report under the chairmanship of Dr Nilima Kshirsagar, chair of clinical pharmacology at the Indian Council of Medical Research. According to the 700-page report by the expert committee appointed under the Drugs Technical Advisory Board, the combination of paracetamol, propyphenazone and caffeine, or, Saridon, was one among the 300-odd combinations for which the makers could offer no “convincing scientific/clinical/justification” for the indications that the drug claimed to address.

In the case of Saridon, the problem lies in the ingredient propyphenazone that poses a risk of “adverse reactions such as skin rashes, erythema (skin redness), leukopenia (low count of white blood cells), asthma precipitation”, among other serious conditions. Although uncommon, the committee concluded that these reactions can be “severe and potentially fatal”. “It is also why the ingredient has been

withdrawn from other countries,” they wrote in the report.

Propyphenazone is also understood to cause serious side-effects to the bone marrow, Dr Anurag Bhargava, professor, department of medicine, Yenepoya Medical College, Mangaluru had told The WEEK after the drug ban in September 2018.

According to Bhargava, the original Saridon, manufactured by Roche pharmaceuticals, contained phenacetin. This ingredient, he says, was dropped later because it was found to be carcinogenic, and with side-effects to the kidney. “The current ingredient in Saridon, propyphenazone, also figures on the WHO's

‘Consolidated List of Products Whose Consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments,” he said.

On February 21, after the SC exemption for Saridon, Nandini Piramal, Executive Director, Piramal Enterprises Limited said, “We are pleased with the Supreme Court ruling, as it is an affirmation to our commitment to provide effective and safe healthcare solutions that address unique needs of Indian consumers. We were confident that the law would prevail in our favour... This exemption from the banned list of FDCs validates our intent to serve our customers with the highest levels of integrity. We continue to expand our healthcare product portfolio with an aim to be among the top three OTC (over the-counter) product companies in India by 2020.”

In its press statement, PEL claimed that according to a recent study by A.C. Neilson, the addressable analgesic market is Rs 6,450 crores, of which the analgesic tablet market is Rs 2,050 crores (as of December, 2018). Saridon is amongst India's most widely distributed analgesic tablets with a strong distribution network across 9 lakh outlets in India, the statement said. ▀



Based on the deliberations of 52nd meeting of drugs consultative committee (DCC), the government formed a sub-committee comprising of five state drug controllers to recommend the list of OTC drugs to be sold in pharmacies.

The term of reference of the panel is to look into the drugs marketed in country vis-a-vis conditions for sale stipulated under various Schedules like H, H1, G, X, K and suggest list of drugs which may be considered for marketing as OTC along with conditions to be followed.

Currently, Drugs & Cosmetics Act and Rules thereunder which regulates prescription drugs (Rx drugs) divided in Schedule H, H1, X has no provision to regulate the distribution, marketing, promotion and consumption of OTC drugs. Hence, the drugs which do not fall under prescription drugs category are generally considered as OTC drugs.

The panel had written to all stakeholders seeking suggestions from them.

## OPPI Seeks A Robust Framework For OTC Drugs In The Country

**THE ORGANISATION OF** Pharmaceutical Producers of India (OPPI) through its Special Task Force on OTC along with a few members from the domestic pharmaceutical industry and consumer industry, has come out with a slew of suggestions to be considered by the expert committee while framing over-the-counter (OTC) drugs regulation. The suggestions include keeping OTC medicines out of price control, allowing their advertisement & labelling as well as defining a clear process for switching from prescription (Rx)-to-OTC and pharmacovigilance, among other things.

The pharma advocacy group proposed that a separate Rule and a separate Schedule on OTC (proposed nomenclature Schedule "O") should be included in the Drugs & Cosmetics Act 1940 and Rules 1945 to regulate OTCs which will improve timely access to medicines and to curb under the sales of Rx drugs.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955 which controls the advertisement of drugs to treat a total of 54 ailments including fever, also puts a restriction on advertisement of OTC drugs. Due to ban on advertising and promotion of OTCs, consumers are deprived of important information on usage and side-effects of these drugs which abets risky behaviour among consumers, the industry body added. Hence, it suggested a re-look of this Act, against this evolving landscape of empowered consumerism.

Self-medication is on the rise across the world as empowered consumers seek primary care benefits that OTC medicines offer and India is no different. Acidity, constipation and headache are some of the popular categories of

self-medication in the country.

Said Kanchana TK, director general, OPPI, OTC medicines are a critical component in advancing consumer health because they allow people to treat or manage many health conditions with responsibility and more conveniently. Because they enable people to responsibly self-medicate, OTC medicines save health systems valuable resources and in turn save consumers' time and money. Globally, OTC medicines have played a significant role in expanding access to safe and effective treatments.

In 2016, India's OTC market grew 8 per cent to US\$ 2.7 billion with a five-year Compounded Annual Growth Rate of 9 per cent, according to Nicholas Hall's global OTC sales database DB6 2017.

However, lack of OTC drug regulation has boosted unchecked self-medication which poses a danger to patient safety and can negatively impact health outcomes. For instance, the easy availability of antibiotics without a valid prescription has contributed to rising antimicrobial resistance in the country.

Its high time, India brings out a with well-defined OTC regulation that fosters a favourable environment for responsible self-medication thereby improving standards of public health and driving value on healthcare, said

Nicholas Hall, chairman & CEO, Nicholas Hall Group of Companies.

Pharmaceutical industry seeks support from government to bring the clear advantages of responsible self-medication to the growing population in India. A robust OTC guideline could be the success formula to expand access to medicines in the country. ■



# Consumers, Beware



## OTC Drug Addiction, Abuse And Treatment

**OTC DRUGS HAVE** various medical uses and effects, treating mild pain to motion sickness. Some abuse OTC drugs to self-medicate for mental illnesses like anxiety and depression. Abusing these medications can also give users a euphoric “high” or hallucinations. Any use outside of what's recommended is considered abuse.

**“Someone abusing OTC drugs might move on to more dangerous or illicit drugs in search of a better high.”**

### OTC Drug Addiction

Recreational OTC drug use can also change the brain's chemistry over time. Eventually the user builds a tolerance to the drugs, needing more of the substance to get the previous effects. Those addicted to OTC drugs maybe also develop withdrawal symptoms when they stop using.

Common symptoms of OTC drug withdrawal include:

- Confusion
- Irritability
- Agitation
- Anxiety
- Mood changes

Learning to spot an OTC drug addiction can be difficult. OTC drugs like Tylenol and various cough medicines don't carry the same dangerous image as illicit drugs like heroin. People don't always see them as addictive, so many loved ones of people addicted to OTC drugs don't know to look for signs of a growing problem.

Some of the signs of an OTC drug addiction include continuing to use the drugs despite known consequences and spending an excessive amount of time or money using or getting them.

### OTC Drug Abuse Statistics

**3.1**  
million

Approximately 3.1 million young people aged 12 to 25 have used a nonprescription cough and cold medication to get high.

**4**  
percent

About 4 percent of 12th graders have abused some form of cough medicine.

### OTC Drug Addiction Treatment

Those suffering from OTC drug addiction have many treatment options. Individual and group therapies, mental health counseling and psychotherapies like Cognitive Behavioral Therapy (CBT) are all effective treatment methods.

Inpatient and outpatient rehab programs allow those recovering from OTC drug addiction the resources to get and stay sober. Enrolling in a drug rehab program can significantly reduce the odds of relapse.

### Get the Resources to Beat Addiction

Overcoming an OTC drug addiction can be difficult, but it is far from impossible. Inpatient drug treatment programs give recovering addicts 24-hour medical care, while those in outpatient programs can visit specified medical centers while keeping their home lives intact. If you or someone you care about is struggling with an addiction to OTC drugs like dextromethorphan, contact a recovery professional for available treatment options. ▶





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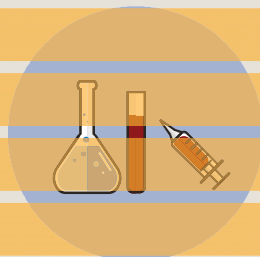


# National Accreditation Board for Testing and Calibration Laboratories (NABL)

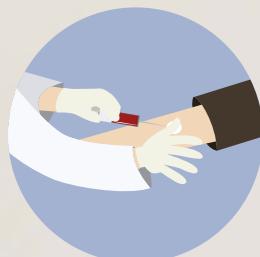
*(A Constituent Board of Quality Council of India)*



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**QUALITY IN PATIENT CARE**



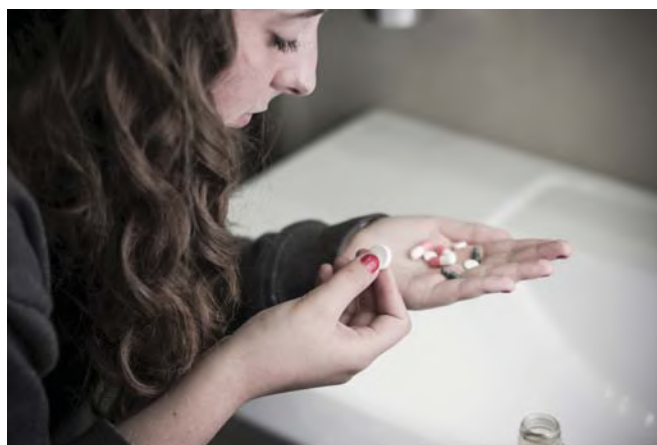
## INDIA'S OVER THE COUNTER PROBLEM

### INTRODUCTION

**OTC Drugs'** means drugs legally allowed to be sold 'Over The Counter', i.e. **without the prescription of a Registered Medical Practitioner.** In India, though the phrase has no legal recognition, all the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). Prescription

Drugs are those that fall under two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X. Drugs falling under Schedule G require the following mandatory text on the label: "Caution: It is dangerous to take this preparation except under medical supervision" and hence are not advertised to the public voluntarily by the industry. In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the Drugs and Cosmetics Act (DCA) and its subordinate legislation, the Drugs and Cosmetics Rules (DCR).

**Over-the-counter (OTC) drugs** are medicines that may be sold directly to a consumer without a prescription from a healthcare professional, as compared to prescription drugs, which may be sold only to consumers possessing a valid prescription. In many countries, OTC drugs are selected by a regulatory agency to ensure that they are ingredients that are safe and effective when used without a physician's care. OTC drugs are usually



Teenage girl using over-the-counter drugs

regulated by active pharmaceutical ingredients (APIs), not final products. By regulating APIs instead of specific drug formulations, governments allow manufacturers freedom to formulate ingredients, or combinations of ingredients, into proprietary mixtures. [1, 2]

OTC drugs are typically safe if used at recommended doses. Like illegal and prescription

drugs, they can also be abused. Although less potent than other substances, OTC drugs still pose a risk for developing an addiction.

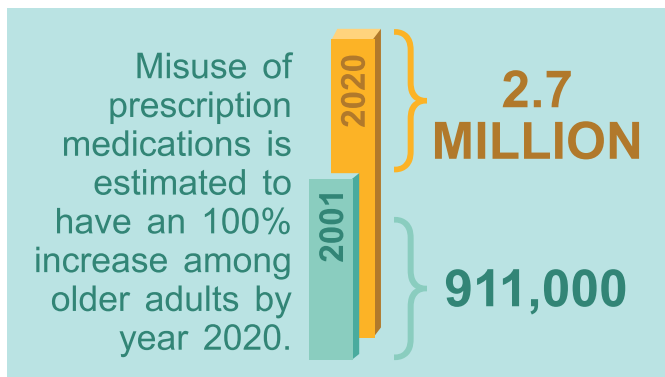
**Abusing OTC drugs can lead to health problems including memory loss, kidney failure, heart problems and death.**

Some commonly abused OTC medications include:

- Cough medicines (Dextromethorphan, or DXM)
- Cold medicines (Pseudoephedrine)
- Motion sickness pills (Dimenhydrinate)

### What defines an over-the-counter drug?

India has decided to rethink which medicines can and can't be sold without prescriptions. These measures will finally create a definition for over the counter (OTC) drugs and possibly curb the sale of some dangerous medicines. So what separates OTC drugs from



prescription-only and why is this categorisation so important?

In November 2016, India's drug regulator announced it was creating a definition for OTC medicines. This change created some much-needed clarity around which medicines are safe for general purchase.

Although India already has a definition for drugs that require a prescription, the existing regulations do not lay out which drugs can be sold without one.

"Generally, people presumed drugs not in Schedule H, H1, X, etc., do not require a prescription. Now, the regulator will list separately which drugs can be sold without a prescription.

It is thought the new category will include drugs for fevers, colds, emergency contraception and certain types of allergies. Through creating a legal demarcation for these drugs, the government will be better able to regulate the sector. The move will also help them curb the unlicensed sales of prescription-only drugs, like antibiotics.

## The need for OTC drugs

Globally, OTC drugs are an important class of medicines. Referring to any drug that can be sold directly to the general consumer, the term can be further subdivided into various categories, with the specifics varying widely from place to place.

Rather counterintuitively, the name does not indicate that the drugs are literally sold over a counter. Oftentimes, they can simply be taken off a shelf, and paid for with your other shopping.

According to the Consumer Healthcare Products Association (CHPA), 81% of US adults use OTC medicines as a first-line treatment for minor illnesses. The average consumer makes 26 trips a year to purchase OTC drugs, compared with just three visits to their doctor. And there are more than 750,000 retail outlets that sell OTC products, compared to 54,000 pharmacies.

As the CHPA website explains: "Without affordable and accessible OTCs, underserved populations would depend more heavily on the highest cost medical care for minor ailments."

## Varying definitions

Typically, OTC drugs are defined in distinction to prescription-only. In the UK, for example, medicines fall into three categories: prescription-only (available from a pharmacist to a specific patient); pharmacy medicines (which can be sold by a pharmacist without prescription); and general sales list (which can be sold anywhere, including supermarkets). The latter group includes painkillers like paracetamol, as well as skin creams and anti-allergy drugs.

It is easy to see the purpose of this kind of categorisation. Since OTC drugs are safe for the vast majority of people, and are used to treat minor ailments, it wouldn't make commercial or medical sense to restrict their availability. Conversely, since prescription drugs are generally quite powerful, and suited only to specific patients, they are not appropriate for retail sale.

However, this is not to say the division is set in stone. It is not unusual for a prescription medicine to be reclassified as OTC or vice versa, in light of new evidence, and laws do not entirely line up around the world.

## India's OTC problem

Despite the classifications in place elsewhere, India has never given OTC drugs legal recognition. Its OTC drug market, estimated to be worth around \$4bn, is a somewhat murky category. It is also growing fast, as new chemists open up in rural areas and an influx of new products hit the shelves.

The lack of regulation is troubling, in that it heightens the risk of OTC drugs being taken inappropriately. A 2016 study by the India Pharmacopoeia Commission found a growing incidence of adverse reactions, concluding: "The present study reveals that safety of OTC drugs is a matter of grave concern. Therefore stringent safety monitoring and regulations are needed."

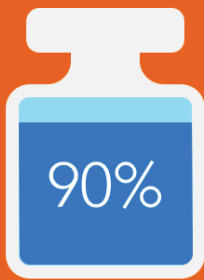
On top of this, a number of 'prescription-only' drugs are easily available over the counter. Many of these drugs, like paracetamol, are low-risk, and will likely be recategorised as OTC. But it also includes some higher-risk products that should never be administered in this manner.

For example, antibiotics are often acquired without prescription, contributing to the growing problem of antibiotic resistance. The government has lately been pressing for more cautious use of antibiotics.

When illegal drug sales proliferate, this is likely to hit poorer communities the hardest. According to a recent cross-sectional Indian study: "When there is a perceived poor access to health care, OTC medication use becomes a low-cost alternative...People who are economically weak are less likely to consult a medical practitioner for a medical condition."

It has also created a market for drugs tourism, demonstrated most chillingly by the young English couple

# PRESCRIPTION & OTC DRUG ABUSE THE NEW EPIDEMIC



**1 IN 6 TEENS**  
has used a  
prescription drug in  
order to get high or  
change their mood.



**90% OF**  
**ADDICTIONS**  
start in the  
teenage years.



Americans die more  
from **DRUG**  
**OVERDOSES** than in  
car crashes which is  
driven by painkillers.

found dead in their Agra hotel in 2014. The couple, who had overdosed on prescription medication, had earlier tweeted: 'Codeine under the counter here. With Valium, Xanax and Lyrica. Winning'.

Such incidents, of course, are mercifully rare, but they do point towards a greater need for oversight.

## **BENEFITS AND RISKS OF SWITCHING FROM PRESCRIPTION ONLY TO O.T.C.**

### **POSSIBLE BENEFITS**

1. Increased access
2. Decreased frequency of visits to physicians, leading to lower healthcare costs
3. Improved education of consumers
4. Increased autonomy of patients
5. Decreased cost to third party players

Even if O.T.C.s are used correctly, there can be problems. Some drugs should not be taken by people with certain health conditions, or be combined with other drugs — prescribed or over the counter — because of the possibility of adverse interactions.

About 40 percent of O.T.C. drugs are used by people older than 65, who are most likely to have health issues

that may contraindicate the use of certain over-the-counter medications. Because of chronic health problems, age-related changes in how well the body processes drugs, and the sheer number of prescription medications many older people tend to take, they face the greatest risk of adverse side effects and drug interactions.

Among drug-related hazards disproportionately faced by older patients are falls, depression, confusion, hallucinations and malnutrition.

Just because a drug is sold over the counter does not mean it's harmless. Laxatives, for example, are said to be among the most misused over-the-counter remedies, and I don't mean by people who abuse them in an effort to lose weight. Over-the-counter sleeping pills that contain antihistamines can lose their effectiveness over time, which can result in people taking more than the recommended dose. They should not be used for more than two weeks. Even if taken as directed, they can result in daytime sleepiness, dizziness and a thickening of bronchial secretions.

Some people with chronic heartburn take antacids that counter the effects of stomach acid. But these can also cause diarrhea or constipation, and block the absorption of certain prescription medications. Better choices now available over the counter are H2 blockers (like Pepcid





**A 2016 study by the India Pharmacopoeia Commission found a growing incidence of adverse reactions, concluding: “The present study reveals that safety of OTC drugs is a matter of grave concern. Therefore stringent safety monitoring and regulations are needed.”**

and Zantac) and proton-pump inhibitors (like Nexium, Prilosec and Prevacid) that stop the production of stomach acid. But these drugs may also pose dangers when taken long term, including bone fractures and magnesium deficiencies that can lead to seizures.

When Nsaids, or nonsteroidal anti-inflammatory drugs, like aspirin, ibuprofen and naproxen are taken too long, they can likewise pose dangers, including bleeding ulcers, kidney or liver damage and an increased risk of a heart attack or stroke. And so on....

#### **POSSIBLE RISKS**

1. Inaccurate diagnosis
2. Delay in obtaining needed therapy
3. Use of suboptimal therapy
4. Drug resistance
5. Increased costs to patients
6. Failure to follow label instructions (Adverse effects, Drug interactions)
7. Perceived loss of control by physicians

People who have underlying health problems or who routinely take one or more prescription drugs would be wise to consult their doctors before taking an O.T.C. drug. At the very least, check with the pharmacist. If you fill all your prescriptions at the same pharmacy, potential adverse drug interactions are easier to pick up. Failing that, carry with you a list of all the prescription and O.T.C. medications you take to show the pharmacist.

Among other sensible precautions when using an O.T.C. drug: Read the entire label, including ingredients,

dosages, time limits and warnings; note whether the drug should be taken with food or on an empty stomach; don't mix medicines with alcohol; avoid taking vitamin-mineral supplements at the same time; and, if you experience an allergic or adverse reaction, write down the likely cause so you can avoid that ingredient in the future.

#### **Changes ahead**

At the time of writing, around February 2018, India's Drugs Consultative Committee, which is part of the health ministry, was drawing up a legal framework for OTC drugs, using international models for reference. Not only will it define which medications truly are OTC, but it will also make it a prosecutable offence to sell drugs that aren't on the list.

Once we have a notified list of OTC drugs, it will be easier to track those selling 'prescription-only' drugs without a prescription from registered medical practitioner. This will also help create more awareness among consumers.

The move is thought to be related to the recent wave of OTC product launches. At present, it is not clear which of these new drugs are appropriate for retail sale.

The move to define OTC drugs will have important ramifications for India's pharma sector. We are also waiting to see a clearer spelling out of the definition as currently India does not have one. It is a largely catch all term for any consumer health care product, vitamins, cough, colds and the like. It would certainly be a step in right direction to define OTC as distinct from prescription. This would be great both for customers and companies planning their strategies in this very important segment. ▶



# Labeling Of OTC Drugs In India:

## Dilemma Whether Pharmacy Centred or Patient Centred

– Ravi Shanker, Monika Joshi, Kamla Pathak

**CONTEXT: OTC MEDICINES** are an important component in healthcare, allowing the freedom to the patient to self-medicate for treating minor, common health problems, at lower costs and with higher time saving. It is very important that the patients have access to sufficient information to make an informed choice for the proper use of these medicines. The label of OTC medicines plays an important role in conveying valuable information to the patient for safe and effective use of OTC.

**Objective:** The study was conducted to evaluate the labelling of OTC drugs in India as per the guidelines of US FDA. Result: The result was not positive as it was found that 59% of the labels did not disclose even the therapeutic category. There are 87% labels which do not have any information related to the contraindications and 90% labels do not enumerate the adverse effects of the medicine. The legibility was very poor comprising only 33% of total. Conclusion and Practice Implication: The labels were not able to withstand the guidelines of US FDA that may be compromising with the health and safety issues of the patients. The labels should provide all important information and instructions to patient.

### INTRODUCTION

The promotion of consumer involvement in their healthcare is the core principal of health promotion and well being of the society. The best way which is in use in the present scenario is the increased use of OTC drugs rather than prescription drugs. Over the counter (OTC)

drugs is one of the self care activities undertaken by individual, family and community intended to promote health and minimize illness. OTC Drugs' means drugs legally allowed to be sold 'Over the Counter', i.e. without the prescription of a Registered Medical Practitioner. OTC drugs play a vital role in healthcare system.

A huge part of population rely on OTC for the treatment of common ailments like headache, cold, fever, and cough, indigestion, flu and dermatitis. Therefore, wide safety margin must be established for the OTC drugs. OTC product benefits must outweigh the risk and the chances of misuse of it should be below. Individuals can directly be involved in their healthcare by increasing purchase of OTC rather than prescribed drugs. The switching of drugs from prescription to OTC has increased worldwide.

Moving trend from prescription to non prescription medications saves the time and also reduces cost as it is cheaper for patients to purchase OTC rather than file a prescription. In 1996 Food and drug administration (FDA) approved the Rx to OTC switch of Nicotine patch and gum for the one who want to get out of cigarette addiction but don't want to visit a doctor. There have been a number of prescriptions to OTC switches in the recent past which is documented in table 1. Non-steroidal anti-inflammatory drugs (NSAIDs) like aspirin and paracetamol are the most commonly used OTC medications. Popularity of OTC drugs in India had risen promptly. As per OTC market size, India ranks 11th as result of high growth rate of OTC market over past eight years.

**Table 1: List of drugs switched from Rx to OTC switch in the recent past years**

Name of drug	Active ingredient	Therapeutic indication	Approval date
Oxytrol for women	Oxybutynin	Overactive bladder	25 Jan, 2013
Nasacort Allergy 24HR (nasal spray)	Triamcinolone acetonide	Allergic rhinitis	11 Oct, 2013
Allegra	Fexofenadine HCl	Antihistamine	25 Jan, 2011
Prevacid 24 HR	Lansoprazole	Acid reducer/PPI	18 May, 2009
Zegerid OTC	Omeprazole	Acid reducer/PPI	12 Jan, 2009
Zyrtec allergy and Zyrtec hives relief syrup and chewable tablet for children	Cetirizine HCl	Antihistamine	16 Nov, 2007
Lamisil Derm gel	Terbinafine	Topical Antifungal	24 July, 2006
Miralax	Polyethylene glycol 3350	Laxative	10 June, 2006

**Table 2: Labeling requirements of OTC medications as per FDA and Drug and Cosmetics Act 1940 of India**

As per FDA	As per drug and cosmetic rules (1945)
Active ingredient in each dosage unit	Generic and trade name
Appropriate precaution for use and special warning	Net contents and content of active ingredient
Dosage instructions	Batch number
Interactions	
Warnings	Name and address of manufacturer including manufacturer license number.
Adverse effects	Manufacture and expiry date.
Directions for use	Maximum retail price

Current data indicates Indian OTC market to represent \$1,773 million with a share of 23% as demonstrated by figure 1. In India manufacture, purchase, sale of drug is regulated by Drug and cosmetic act 1940 and rules 1945. In India there is no judicial recognition for OTC drugs. The drug included in the schedule H and X of drug and cosmetic act are termed as prescription drugs. For the drug listed in schedule G of drug and cosmetic act (1940) no prescription is require but the following mandatory text must be mentioned in the label: “caution: It is dangerous to take this medicine except under medical supervision. In India and most of the underdeveloped countries all the drugs which are non-prescription are easily available for over the counter sale. The commonly used OTC drugs mainly belong to classes of NSAIDS, anti-allergic, vitamins and supplements, gastrointestinal and medicated dermatological products (Figure 2). The drugs whose stocks are maintained at home, most of the times include antacids, anti flatulent, drugs for headache and loose motion.

OTC drugs are easily accessible and are used for the treatment of minor illness. Although OTC medicines are supposed to be relatively safe, readily available and consumed by patients without physicians consent, it is very important that the patients have the access to clear and broad information to make an informed choice of proper selection of medicine and their fruitful use. It is

very important to recognize that even OTC medicines can cause unwanted side effects if not properly used.

The information provided by the label and patient package insert act as a major source of knowledge for the patients regarding various issues for safe and effective use of the medication. The label should provide all the information as the patient has to take it without the consult of the physician. Therefore label is of primary importance as it conveys important drug information to the consumers. The label provides basic information about the drug to the patient like drug name, use, dosage, directions, etc. Additional information of the drug like its pharmaco-kinetics, pharmacodynamics, adverse effect, indications, risk and benefits are provided through package insert, a FDA approved document dispensed with some drugs. The information given to the consumers using labels and patient package inserts helps in gaining information regarding safe use of medicine and preventing medication errors and drug abuse. The label must be clear, properly readable by patients and should provide sufficient information to the patients. A standard format to make drug information clear, simple and readable on label of OTC drugs was proposed by FDA in 1997. The label of a drug in India should confirm the specifications as per drug and cosmetic rule 95 of drug and cosmetic act. The labeling requirement as per drug and cosmetic act are listed in Table 2 that are product oriented while labeling requirement are patient oriented

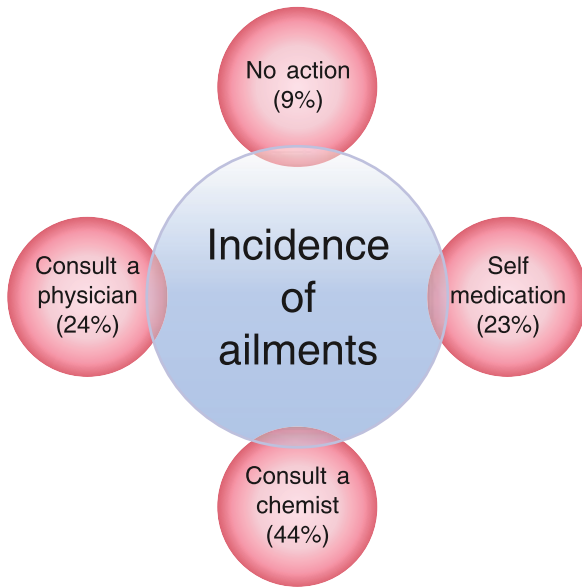


Figure 1: Current status of OTC drugs in the Indian market

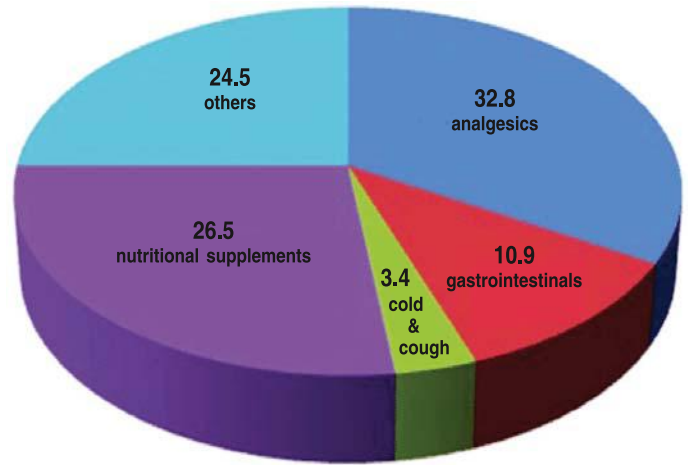


Figure 2: Categorization of OTC drugs as per the general indication

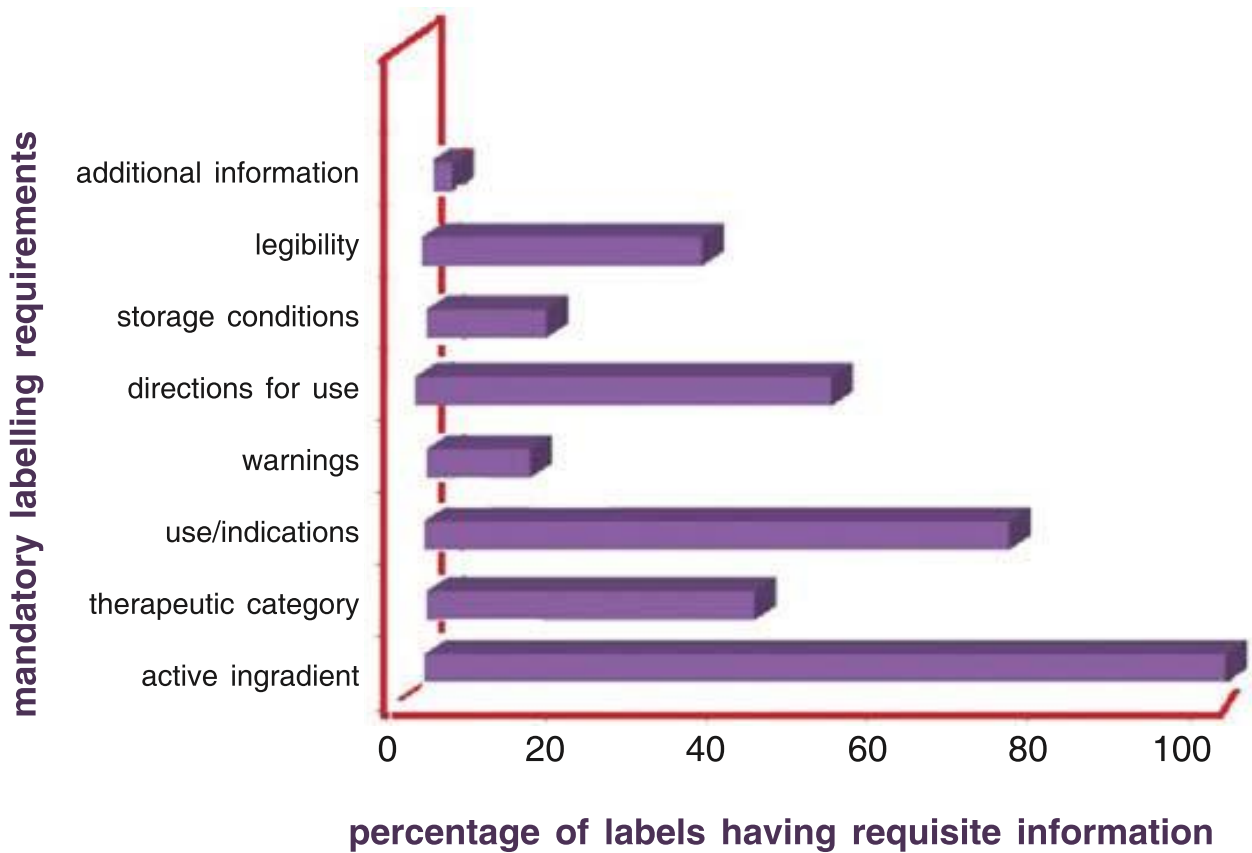


Figure 3: Percentage of labels having mandatory labelling requirements as per USFDA

as per FDA guidelines. So the study was carried out with a objective to evaluate whether:

1. The labels of OTC medications have adequate information for the patients to make the proper self-medication.
2. Additional information is present or not on the patient package inserts wherever applicable.
3. The information provided is legible and can be clearly understood.

## EXPERIMENTAL METHODS

A total of 100 OTC medicines were randomly collected from a pharmacy, covering various categories of medicines and various dosage forms like tablets, capsules, liquid orals and external preparations. The labels of these medicines were then assessed based on the "21 CFR 201.66" label guidelines provided by the United States Food and Drug Administration (US FDA) for OTC medicine labelling. The proposed labelling includes various components, and was studied as specified by Drug Facts standard labelling format, with the following results:

- (a) Label to include- Active ingredient along with its strength

All the 100 labels evaluated fulfilled the given criteria as the name of active ingredients along with their potency/ strength was clearly marked on the packages.

- (b) Label to include-Therapeutic category/purpose

The most common concern was the failure of the labels to identify the therapeutic class of drug. Almost 59 % of the labels did not disclose the therapeutic category and some medications possessing the class didn't have any information regarding the pharmacokinetic parameters (e.g. Half life of drugs in case of long acting drugs should be mentioned otherwise may lead to toxicity).

- (c) Label to include-Uses /indications for which medicine can be utilized

Although a significant percentage (73%) mentioned the indications for the medicine. The topical medications and the nutritional supplements have been found to have better complied with the mandatory requirements (85%) as compared to analgesics and gastrointestinal drugs (63%). The indications were very broad, vague and almost 18% labels lack the information regarding specific indications (first line treatment).

- d) Label to include-Warnings

It includes the important aspects regarding safety issue of the product and the conditions which must be reported immediately. The labels should have

proper information regarding common adverse effects, contra-indications, precautions, over dosage, when it is appropriate to seek medical advice and special conditions like pregnancy & breast-feeding.

## RESULTS

1. 75 % of the labels have been provided with a general warning.
2. 90% of the labels failed to enumerate the adverse effects of the medicine.
3. There was maximum percentage of labels (86%) which did not state what is to be done in case of overdose
4. There was scarcely any label which provided information regarding usage in pregnancy and breast-feeding (4%)
5. 87% of the labels didn't provide any information regarding contraindications of medicines.
6. 73% labels did not even advise to seek medical guidance.

- (e) Label to include-Directions for use

This includes the dose that has to be given; the dosing interval and the dosage regimen for children. Almost half of the medicines (48%) did not mention the amount to be used, while 34% did not mention the dosing interval. Over 85% of the medicines did not state the maximum dose allowed. It was also observed that 64% of the medicines failed to specify the dose for children. Only one label included instructions for use in Devanagiri script.

- (f) Label to include -The product's inactive ingredients

This makes the consumers avoid the ingredients that may cause an allergic reaction as it varies from person to person. A specific example is the failure of formulation to clearly mention the concentration of the alcohol in liquid formulations for children where small amount can cause severe damage. None of the labels included the inactive ingredients (other than saying in some cases, the solvent/base used).

- (g) Label to include -Storage conditions

Even though a large percentage (89%) of the labels provided the storage conditions, maximum out of them were imprecise and difficult to understand. Nearly 85% of the labels were found without a specific temperature mention. Furthermore, the storage conditions and the terms used to describe them are not common and are not easily understood by a common man leading to huge confusion. E.g. It was mentioned to store the formulation at cool place, but no specific temperature range was indicated.

- (h) Label to include - Legibility to find out whether the label is easily readable



Only 35% of the medicine labels were clearly legible as the font size was appropriate. 28% of drug labels could be read with much effort on the eyes while the remaining labels had a font size so small that they could be seen with the aid of magnifying glass.

## CONCLUSION AND PRACTISE IMPLICATIONS

There are no specific guidelines for OTC medications in India as laid by any regulating authority asking for an immediate need for a specific OTC category of medicines in India, with clear-cut laid down guidelines for their complete labelling. The label of OTC medicines should contain sufficient information, so that the patient gets sufficient information for the safe and effective use of OTC medications. There is an important need to considerably improve

and organize the labelling of OTC medicines, so that they are simple, straight forward, and easy to read. The patient or the consumer can easily decide what the product is used for and what circumstances or medical conditions it should and should not be used.

## SUGGESTIONS

There should be specific standards and provisions regarding the labels of the medications. There should be provision of minimum font size of the text for proper legibility to the patients. The labels should be designed and printed while considering the requirement of geriatric patients and the patients having somewhat impaired vision. The labels should also be printed in languages patients will comprehend. Patient leaflets should be used to give all details required in case the primary label is not having sufficient space. In case of developing nations like India the rural areas govern the maximum parameters, so it should be well kept in mind of the manufacturers and the packagers to design the package and label as per the local consumers. The labels have to become more patient and community oriented then to be product oriented. If critical information cannot be included on the primary label, suitable patient package inserts should be included with the medicine or on the secondary packages for the most efficient, safe, rational and ethical use of OTC medications. The study proves that the labelling of OTC medications till date in India is very much industry centred instead of patient centred and it should be corrected immediately in profit and service of the society. ▶



**It is very important to recognize that even OTC medicines can cause unwanted side effects if not properly used.**

- (i) Label to include- Additional information through patient package inserts:

Patient package inserts are useful for providing additional information to the patient. Out of the 100 medicines examined, only 3 included a patient package insert. Many a times, secondary packaging of medicines is also given to the patient as additional protection for their medicines or as attractive packs. These secondary packages can also be used to convey valuable information to the patient. In 46% of the cases, a secondary package was found to be available to the patient, yet only 34% of them gave more information on its label than the primary package. On the positive side, all the 100 labels did provide required details of manufacture and expiry of the medicines. These are also crucial requirements for medicine safety.

## DISCUSSION

The study thus clearly revealed that there is limited space available on the primary package of the OTC medications to carry all the required information. In cases where there was a secondary package and a scope for providing additional information was available, yet the information was not provided. The use of primary package inserts was also not entertained at all, ignoring a very useful and easily accessible method to give all the necessary details to the patients for safe and efficacious use of the OTC medicines. The study also revealed that the required information provided on OTC medicine labels in India is usually quite insufficient for the patient to make a "responsible" decision for self-medication as it even not have the therapeutic category details and the dose that has to be taken (Figure 3). This causes a great concern regarding safe and effective use of OTC medications.

# SUPPORT THE CAMPAIGN



**LOOK OUT FOR THE RED LINE**

**BE RESPONSIBLE**

Medicines such as Antibiotics have a Red Vertical Line on their pack to indicate that these should be consumed only on doctor's prescription. Always complete the full course as prescribed by the doctor.

## SIGN THE PLEDGE.

[HTTP://WWW.CAUSES.COM/CAMPAIGNS/106670-RAISE-AWARENESS-FOR-SALE-USE-OF-ANTIBIOTICS-TO-COMBAT-AMR](http://www.causes.com/campaigns/106670-RAISE-AWARENESS-FOR-SALE-USE-OF-ANTIBIOTICS-TO-COMBAT-AMR)

**Campaign Partners**



## Pharmacist Recommended: 30 Top OTC Health Products Of 2018

**Alia Paavola**

*U.S. News & World Report and Pharmacy Times,*  
released their annual list of top recommended health products.



**THE LIST COLLECTS** recommendations from thousands of pharmacists for more than 1,100 over-the-counter brands in 154 product categories. Here are the No.1 pharmacist-recommended OTC products in 30 categories:

1. **Acid reducer:** Prilosec OTC (winning 40 percent of pharmacists' votes)
2. **Acne treatment:** Differin gel (winning 27 percent of pharmacists' votes)
3. **Adhesive bandage:** Band-Aid (winning 74 percent of pharmacists' votes)
4. **Antihistamine:** Claritin (winning 39 percent of pharmacists' votes)
5. **Athlete's foot treatment:** Lamisil (winning 45 percent of pharmacists' votes)
6. **Blood glucose monitor:** OneTouch (winning 32 percent of pharmacists' votes)
7. **Children's pain reliever:** Children's Tylenol (winning 58 percent of pharmacists' votes)
8. **Children's allergy medicine:** Children's Zyrtec allergy syrup (winning 38 percent of pharmacists' votes)
9. **Cough, cold and flu-daytime:** DayQuil (winning 28 percent of pharmacists' votes)
10. **Cough, cold and flu-nighttime:** NyQuil (winning 43 percent of pharmacists' votes)
11. **Cough suppressant:** Delsym (winning 50 percent of pharmacists' votes)
12. **Dandruff shampoo:** Head & Shoulders (winning 31 percent of pharmacists' votes)
13. **Digital thermometer:** Braun ThermoScan (winning 30 percent of pharmacists' votes)
14. **First aid topical antibiotic/antiseptic:** Neosporin (winning 75 percent of pharmacists' votes)
15. **Headache relief:** Advil (winning 26 percent of pharmacists' votes)
16. **Immune system support:** Emergen-C (winning 39 percent of pharmacists' votes)
17. **Lactose intolerance remedy:** Lactaid (winning 92 percent of pharmacists' votes)
18. **Menstrual pain relief:** Midol Complete (winning 31 percent of pharmacists' votes)
19. **Migraine relief:** Excedrin Migraine (winning 74 percent of pharmacists' votes)
20. **Mouthwash:** Listerine (winning 34 percent of pharmacists' votes)
21. **Nausea remedy:** Emetrol (winning 82 percent of pharmacists' votes)
22. **Oral decongestant:** Sudafed (winning 49 percent of pharmacists' votes)
23. **Oral glucose:** Insta-Glucose (winning 57 percent of pharmacists' votes)
24. **Pregnancy test:** First Response (winning 72 percent of pharmacists' votes)
25. **Sleep aid:** Tylenol PM (winning 71 percent of pharmacists' votes)
26. **Smoking cessation aid:** NicoDerm CQ Patch (winning 69 percent of pharmacists' votes)
27. **Sunburn relief:** (winning 63 percent of pharmacists' votes)
28. **Sunscreen:** Neutrogena (winning 32 percent of pharmacists' votes)
29. **Toothpaste:** Crest (winning 36 percent of pharmacists' votes)
30. **Topical cough suppressant, lozenge:** Cepacol (winning 37 percent of pharmacists' votes). ▶



## Pharmacies May Sell More Over The Counter Medicines Soon

– Teena Thacker



Pharma officials have already shortlisted over the counter (OTC) medicines to be put under a separate schedule which can be dispensed without a doctor's prescription. Photo: Mint



**IN A MOVE** that could save patients the bother of having to visit their doctor for every common ailment, the Central Drugs Standard Control Organization (CDSCO), the regulatory body for pharmaceuticals and medical devices, is considering introducing provisions in the Drugs and Cosmetics rules to allow pharmacists to dispense drugs for minor conditions and adjust dosages without a doctors' prescription.

The drug regulator has proposed the introduction of a new category of over the counter (OTC) medicines consisting of anti-allergies, antipyretic (for fever), antiemetic (for vomiting and nausea), muscle relaxants, decongestants (for cough and cold), anti-inflammatory drugs, antacids, external preparations for skin and hormonal contraceptives, which pharmacists will be empowered to dispense without a doctor's prescription.

The proposed provision, which is expected to shorten waiting periods at clinics, will be discussed at the drugs consultative committee (DCC) meeting. Chaired by the Drug Controller General of India (DCGI), the DCC meeting will be attended by state drug controllers from all across India.

According to the DCC agenda, reviewed by Mint, a special provision to include OTC medicines in the Drugs and Cosmetics rules has been proposed. If approved by DCC, the matter will be taken up by the government's

Kailash Gupta, president, All India Chemists and Distributors Federation, said that the expanded powers will have several advantages, "including increased convenience and accessibility for those who need refills or have a minor condition. The patients will be able to cut down on doctors consultations fees and the improved ability of the pharmacist to help manage a patient's long-term care will help alleviate pressure on hospital emergency rooms and doctor's offices."

"Other benefits include the ability of pharmacists to prescribe drugs in times of emergency and assist patients who don't have a family doctor," he added.

Officials believe that the move will boost Prime Minister Narendra Modi's vision of improving accessibility and affordability of drugs. "Pharmacists play a crucial role in the healthcare system due to their easy accessibility. International practices show that there is a separate category of drugs which are harmless and safe enough to be dispensed without any prescription. We want to bring this concept in India too which will help people skip doctor's visit for common ailments. This will make access to drugs easier for not only those living in urban areas but those living in rural areas and mostly dependent on quacks. The pharmacists are qualified to provide these services and have been underutilized," said the official cited above.

## The pharma regulatory body is considering introducing provisions in Drugs and Cosmetics rules to allow for more over the counter medicines for minor ailments without doctor's prescription.

chief advisory body on drugs—the Drugs Technical Advisory Board (DTAB)—next month and will then be sent to the Union health ministry for final notification.

Over-the-counter drugs are common in many countries. Currently, in India allopathic drugs which are safe to be dispensed mostly fall under Schedule H and H1 and require a prescription. "As per D&C Act 1940 and thereunder Rules 1945, these drugs should be sold against prescription only. The new proposal therefore will make it easier for people to get these drugs hassle free," said a senior official, privy to the development requesting anonymity.

Officials at the drug controller office have already shortlisted OTC medicines to be put under a separate schedule which can be dispensed without a prescription. There are some restrictions though— pharmacists will not be allowed to prescribe habit-forming drugs or strong antibiotics.

Doctors, however, raised questions over potential conflict of interests because the pharmacists would be both prescribing and selling drugs.

"The process of prescription of medications requires long years of learning. A pharmacist does not know the microbiology, physiology and medical history of a patient as well as the full potential of a certain drug. Thus, by prescribing, not only will he be causing harm but also adding on further problems to a patient," said Rahul Pandit, director, intensive care, Fortis Hospital, Mulund, Mumbai.

According to figures available with the Union health ministry, currently, India ranks 11th in the global OTC market size. Revenue from OTC medicines in India makes up 21% of the total market revenue of \$20 billion. ▀

5 million preventable  
deaths occur every  
year



**Helpline**  
**1800-11-0456**

Reach out to us before  
you are one of them



## Kanchana TK

is the **Director General** of the **Organisation of Pharmaceutical Producers of India (OPPI)** that represents research-based pharmaceutical companies in India. Here she speaks about OPPI and its role as an advocacy body in working towards shaping the Indian healthcare system.





**OPPI IS AN** advocacy body representing research-based pharma companies in India. We have been in existence from 1965 and for more than 50 years our focus area has been to collaborate and drive an ecosystem that is patient-centric.

To this end, we have four key areas: IPR and the need to promote an environment that respects innovation and research as today's innovation is tomorrow's medicines. The second area is to collaborate and work towards improving healthcare access in the country through mechanisms and patient-centric policies. Thirdly the stringent Code of Pharmaceutical Marketing Practices establishes our focus on ethics and patient safety. All OPPI members adhere to this stringent code that is based on the international IFPMA Code. Finally Pricing is our fourth area of focus. We believe that a transparent business environment will help in bringing investments and improve ease of doing business for our members in India.



**“A drug policy that enhances access to healthcare, encourages innovation and enables ease of doing business can be the only sustainable way to address the unique healthcare challenges that India faces.”**

**Q Can you give us an overview of your current member base?**

We have around 30 multinational pharma companies from Europe, the US, Japan, the UK. In fact, some of our members have been present in India for over 100 years and have been part of India's pharmaceutical growth story. While, some are here in a smaller capacity depending on the market and in areas they are active, some others believe India is the right market for only certain therapeutic areas.

**Q What has been the impact of the growth of the Indian market on your member companies?**

Our companies operate in two markets: branded generics and patented medicines. India is complex for both. Both these markets have seen decreased levels of growth in recent years but we believe that India has a potential for growth if futuristic and progressive policies are rolled out that lead to economic and healthcare prosperity.

China today is investing in regulatory reforms; this means that at some point they will be ready for a sophisticated healthcare system. However, India appears to have knee-jerk fixes. We believe that these policies and broad guidelines are the first baby steps towards creating something more robust. The government needs to focus on strengthening regulatory systems; increasing healthcare budgets; exploring innovative healthcare financing models; and collaborating with drug makers to allow newer treatments to reach the patient.

**Q What is the future for multinational companies coming to the Indian market?**

Most big players are already here, whether with a small or a large presence. However, for an organization to have a sustained presence here, they must be allowed to operate in an environment that is conducive to business with a robust policy framework that supports the ease of doing business in our country.

Again, a quick comparison with China. Recently enacted changes in the China Food and Drug Administration (CFDA)'s regulatory policy is expediting drug approval pathways and it permits research-based companies to defray huge capital expenditures by allowing the outsourcing of manufacturing. In 2010, the CFDA revised its GMP standards, and at the beginning of 2017, the regulatory body also announced plans to replace current GMP certification of every five years with a dynamic unannounced inspection system. These policy moves are intended to bring China's GMP code in line with that of EU and U.S.

The Chinese biopharma industry is also making significant investment in bioprocessing, including adopting more advanced technological platforms (SUT, modular factory, mammalian-cell-based bio-manufacturing systems, etc.).

**Q What has been keeping you busy at OPPI?**

Over the last 18 months, there has been a renewed focus on health and it appears that India has developed a new and much-deserved consciousness of these



issues. In the past, the political conversation were centered around topics such as infrastructure, employment or industrialization, but today healthcare is an important ask of the Indian people.

With the current government's focus on health, our role as an advocacy body becomes more crucial. Drawing on our members' experiences in both developing and developed markets, we are able to collaborate with the stakeholders towards bringing global best practices and developing comprehensive solution to healthcare challenges in our country.

The fact that the government is more engaged and open than ever before to non-traditional solutions such as partnerships and alternative sources of financing has enabled us to explore innovative suggestions that are patient-centred and futuristic in their approach.

It is important to remember that India is a big country and therefore finding solutions to healthcare issues is far more complex than in smaller countries. The process might be slow, but a dialogue has begun.

**Q Earlier the Government had announced a new draft Pharma Policy. What do you make of the proposal and do you think it is actionable in its current form?**

I think the time is right to have a new National Pharma Policy and that this is a welcome move in the right direction. However, we believe this policy cannot be implemented without meaningful stakeholder consultations; including not just pharma companies, but patient groups, regulatory experts and so on. Pharma policy covers an enormous range of issues; from regulatory issues such as promoting Good Manufacturing & Laboratory Practices in the manufacture of drugs, quality control, and streamlining of drug approval process to encouraging R&D for drug discovery; and working towards global best practices; not just pricing.

The government must make sure that all stakeholders are involved and have been consulted thoroughly. This is a disruptive process that will hopefully lead to better access and affordability. The concern we have as an industry is, while we support the focus on quality which is crucial, and all our member companies adhere to good manufacturing practices and comply to stringent globally

accepted quality standards, there needs to be a uniform manufacturing standard for India and the government is working towards it. Additionally, we believe the proposal in the new draft on bioavailability and bioequivalence (BA/BE) studies is very important because that was previously not there for many medicines and is important for the patient.

We are in discussion on many issues and the government itself is having inter-Ministry stakeholder meetings; highlighting their more concentrated, collaborative approach for the best interests of the patient.

**Q Many stakeholders have raised concerns on the Policy. What is the OPPI take on this?**

A drug policy that enhances access to healthcare, encourages innovation and enables ease of doing business can be the only sustainable way to address the unique healthcare challenges that India faces.

OPPI is cognizant of the Government's measures to promote the use of generic medicines however, prior to any decision being taken in said regard, we urge that adequate steps are taken so as to ensure uniform quality & standard of drugs across states in India and all drug manufacturers mandatorily follow WHO GMP manufacturing practices.

What the government is trying to fix is what they believe to be unethical practices. However, this can be fixed through better implementation of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) which is currently voluntary.

**Q In your article 'The Power of Innovation,' you mention that there is much more that can be done in terms of drug development in India. What could help drug development and innovation in India?**

India is great at re-engineering; however, we are not great at innovation. Looking outside of medicine, I cannot recollect the last great car, device, or phone we created.

One thing that I think that the government should do – especially for illnesses that are “Indian” such as dengue, elephantiasis, and encephalitis – is come forth and invest in developing a vaccine, medicine or pill, along with industry. To collaborate and innovate something, this has not happened yet but there is a lot that we could do, purely for the Indian population. Those are areas where the State is responsible for its people.

The problem is not the lack of intellectual talent, but a lack of infrastructure. Where do we go? There are few national labs and national R&D centers. In fact, according to an article in Scroll.in (May 2016), over the last ten years, 332 out of the 579 medical teaching institutions in the country have not produced a single research paper. There is no intellectual sophistication. A world class center, bringing together a university with a couple of companies to create a consortium would be a great initiative, but we have not seen anything of this sort.

Fostering innovation is not limited to adapting counterfeit, trademark or piracy laws, it's beyond that. We are diluting innovation, rather than creating it. There is an opportunity there.



**Q Public awareness for health is an effective tool for dissemination. Can you give our readers any examples of how OPPI work in building awareness of health issues in India?**

Anti-Microbial Resistance (AMR) is a huge public health hazard both globally as well as in India. OPPI's 'Red Line Campaign,' launched in collaboration with the Ministry of Health (MoH) and other patient groups and healthcare stakeholders was aimed at creating awareness on the rational use of antibiotics. Launched in English and Hindi the campaign seeks to educate consumers on the proper use of antibiotics and the ill-effects of its misuse. This campaign has been selected for being one of the most effective language campaigns to create awareness on AMR and was displayed at the National Science Museum in London as part of their Superbugs initiative in 2018.

**Q As you represent the research-based pharma companies, what is your take on India setting an example for its neighboring countries in terms of healthcare development?**

I wish it did. India continues to be one of the poorest performers in its region in terms of quality and accessibility of healthcare, ranking at 154, far below China, Sri Lanka and even Bangladesh, according to the Global Burden of Disease study published in the Lancet in 2017.

In India, the total expenditure on healthcare as a percentage of GDP is just 4 percent, while in the US it is 17 percent (World Bank Report). According to World Health Organization (WHO) data, for countries performing best in the healthcare sector, the US ranks 37, while India stands at 112. We have neither the wrong nor right model in India and the opportunity exists in this huge space between wrong and right. We can become the

country that leads the way in regulatory, financing, insurance, expansion and innovation.

**Q Against this, how is OPPI shaping the Indian healthcare system?**

It is a collaborative effort between OPPI, our member companies, patients, and the media. The media has been very fair in reporting. OPPI, the government, the media, and the patients are all learning because we are shaping something new. We are not taking any global model and implanting it in India. India cannot replicate any model of any country. We need to come up with something new, taking something good from China, the UK, the US, or even from Bangladesh. There is no single model or solution as in smaller Asian countries such as Malaysia or Indonesia.

Solutions therefore must come from multi-stakeholder engagement; sometimes from the government, sometimes from the industry, sometimes from patient groups, sometimes from the media. We are all responsible for shaping healthcare for India and that is why it is exciting.

**Q What is your final message to our international readers?**

Everything you hear about India is both true and contradictory. When I say India is modern, it is traditional; when I say India is poor, it is rich. India is a land of paradoxes but also of opportunity. India is bidding to lead G20 in 2019, will also include healthcare on the agenda.

I think India needs to be indulged – I know that this is a strange choice of a word – because the opportunities here and the scale of influence that the country has is so large.

This is because we influence the rest of the world, and if do not have the right policies, half the world will probably not have the right health policies. ▀





**Pyush Misra**  
Director,  
Consumer Online Foundation

Many would be surprised that the term OTC doesn't exist as per Indian law. Neither the Drugs & Cosmetics Act, 1940 nor the Drugs & Cosmetics Rules, 1945 define OTC.



## Why India Needs A Comprehensive Policy On OTC Drugs

### **OVER-THE-COUNTER (OTC)**

medications that don't require a doctor's prescription to buy them have become a mainstay of Indian healthcare as most people self-medicate.

A survey in 2015, participated by 20,000 people in 10 Indian cities, by online doctor consulting platform,

Lybrate found that 52 percent of those polled practised self-medication citing lack of time to visit a doctor, wanting to save on consultation fees and reliance on the internet for solutions as key reasons.

Patients generally rely on their friendly neighbourhood chemist to prescribe them appropriate medicines

for ailments such as cough, cold, nasal congestion, allergies, pain, fevers, acidity, diarrhoea, dry eyes and most skin-related conditions.

A paracetamol is a classic OTC medication globally, it is an age old antipyretic, or fever reducing drug, with proven safety and efficacy.

In 2016, India's over-the-counter

(OTC) market grew 8 percent to \$2.7 billion, with a five-year compounded annual growth rate (CAGR) of 9 percent, according to Nicholas Hall's global OTC sales database DB6 2017.

### Perils of self-medication

But the problem in India is that OTC drugs don't come with labels telling the consumer the purpose of the medicine, the active and inactive ingredients used in it, who should take the medicine and how to take it safely.

A lot of times the chemist who is prescribing the medicine isn't qualified to do so and has no understanding of the patient's medical condition. While an OTC drug should be used temporarily, many patients end up taking them for long periods of time.

Also, it is an open secret that practically any drug, even those that require a doctor's prescription, are available over the counter. Drugs like antibiotics were sold freely for a long time without prescription, before government tightened the screws in the face of anti-microbial resistance.

In 2016, the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) alerted the Drug Controller General of India (DCGI) to the rampant misuse of creams containing steroids with antibiotics and anti-fungal agents causing serious side-effects such as extensive ringworm infection.

### Lack of regulation

Unlike countries like the US, UK and China, we don't have a well-defined legal and policy framework to either support or regulate distribution, marketing and consumption of OTC drugs. There is no defined list of OTC drugs.

Many would be surprised that the term OTC doesn't exist as per Indian law. Neither the Drugs & Cosmetics Act, 1940 nor the Drugs & Cosmetics Rules, 1945 (D&C) define OTC.

At its core, the Drugs & Cosmetics Act - which governs all products classified as drugs - is a series of Schedules containing specific drugs. Which Schedule a drug is listed under decides its regulatory status. Drugs under Schedule H, H1 and X cannot



**OPPI along with a few members released a study titled: Shaping India's OTC Policy 2018. The study calls for a well-regulated OTC framework that helps improve access to medicines and also supports responsible self-medication to achieve multiple health and economic objectives.**

be sold without a doctor's prescription. Therefore, from an OTC marketer's perspective, drugs that fall outside these Schedules are considered to be non-prescription and by inference, free to be made available over the counter. However, the law does not explicitly state this.

This leaves a huge grey area, compounded by lack of labelling and drug monitoring.

### Demand for OTC policy

To be sure self-medication is nothing new in India. If regulated properly - armed by more patient education - OTC medications can be a useful tool to deal with the problems of rising out-of-pocket healthcare costs, inadequate doctor-patient ratio and weak and overburdened public healthcare system.

The Organisation of Pharmaceutical Producers of India (OPPI) along with a few members from the domestic pharmaceutical industry and consumer industry released a study titled: Shaping India's OTC Policy 2018. The study calls for a well-regulated OTC framework that helps improve access to medicines and also supports responsible self-medication to achieve multiple health and economic objectives.

The study's important recommendations include suggestion to include a separate Rule and a separate Schedule to classify OTC products in the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945.

The study asks for government to clearly define a pathway for prescription (Rx) to OTC switches, strengthen labelling and patient information, mandatory clinical trials and bioequivalence studies for OTCs, restrict distribution of prescription drugs as OTC, removal of OTC products from price controls and allow the market to determine prices.

The most evolved are the US and UK that have a substantial OTC market and allow OTC drugs to be advertised in the mass media and to be made available in non-pharmacy outlets such as general stores. They also have clearly defined requirements for switching drugs from prescription to non-prescription status, and clear guidelines on labelling and advertising claims. Regulatory implementation in these countries is rigorous. ■

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4<sup>TH</sup> EDITION

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on the occasion of

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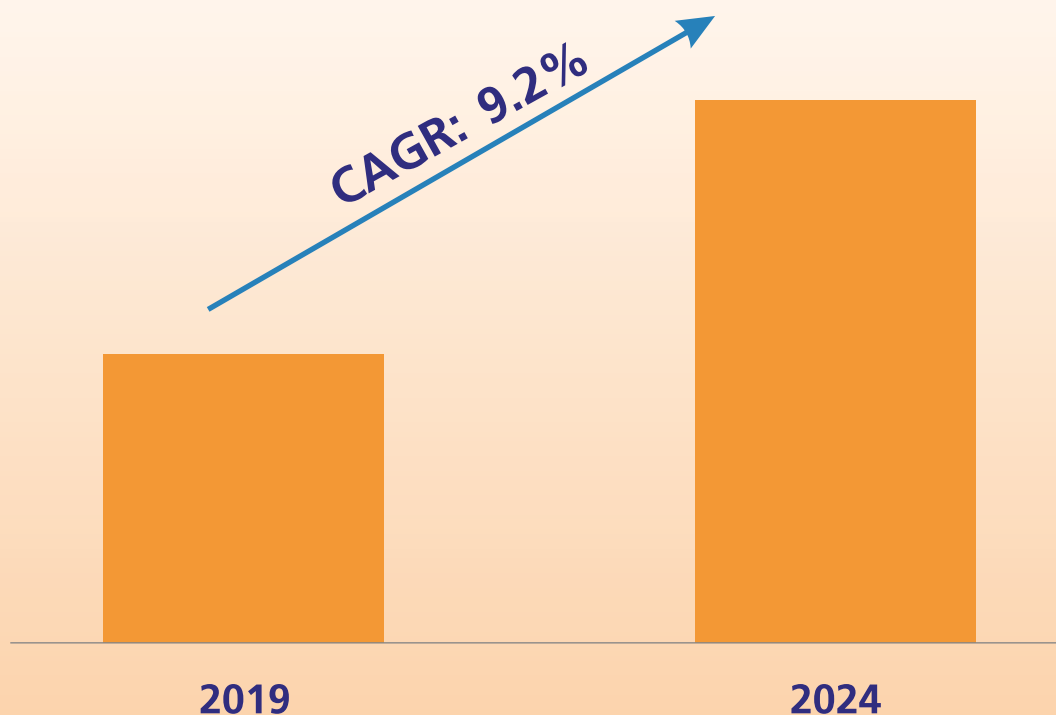
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## INDIA OVER THE COUNTER DRUGS (OTC) MARKET- GROWTH, TRENDS, AND FORECAST (2019 - 2024)

### India Over the Counter Drugs (OTC) Market Summary



Source: Mordor Intelligence



**INDIA IS THE** 11th largest market for OTC drugs in the world. Government and different pharmaceuticals companies are taking up various initiatives to create awareness about different drugs and shift Rx to OTC. Urban India is catching up with the notion of OTC drugs due to the advent of technology and advertisements, high work stress levels and increasing health awareness.

### Market Overview

The key factors propelling the growth of the Indian over-the-counter drugs market are the shift in consumer attitude toward self-medication, product innovations, and inclination of pharmaceutical companies toward OTC drugs from RX drugs.

India is one of the emerging markets for OTC drugs and offers significant growth potential for the industry. The market is growing in India due to the increasing healthcare expenditure, unhealthy dietary habits, expanding population, and growing healthcare awareness.

The increasing disposable income of people, along with a shift in the consumer attitude toward self-medication and increasing geriatric population are the two major factors driving the overall market in the region. Thus, the increasing awareness about the cost-effectiveness of self-medication and OTC medicines is also a crucial factor fueling the market growth.

There is also the rapidly growing population, which is coupled with the fact that the middle class in these regions is expanding on a large scale, which may add critical mass to the population available to access OTC

#### By Product

Cough, Cold, and Flu Products  
Analgesics  
Dermatology Products  
Gastrointestinal Products  
Vitamins, Minerals, and Supplements (VMS)  
Other Products

#### By Distribution Channel

Retail Pharmacies  
Online Pharmacy  
Other Distribution Channels

medication. Thus, the increasing investments of market giants in the emerging market are expected to drive the growth of the overall market.

India Over the Counter Drugs market is broadly categorized into Formulation, Product Type and Distribution Channel. On the Basis of formulation, the market is segmented into Liquids, Tablets, Ointments, Sprays and others. Based on Product Type the market is analysed as Analgesics, Cough & Cold preparations, Vitamins and Minerals, Traditional Medicines, Indigestion

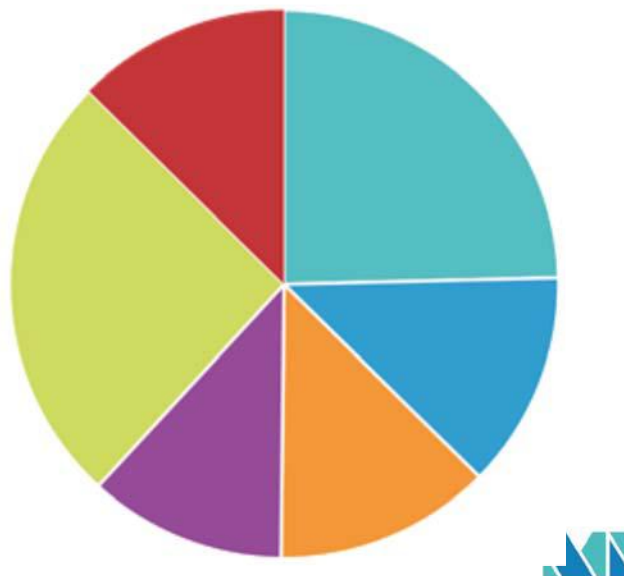
**Figure 5.11: The Indian Respiratory Drugs Market: Revenue (\$bn) and AGR (%), 2018-2028**





## Over the Counter Drugs Market: Revenue Share (%), by Product Type, India, 2018

- Cold, Cough, and Flu Products
- Analgesics
- Dermatology Products
- Gastrointestinal Products
- Vitamins, Minerals and Supplements (VMS)
- Others



Source: Mordor Intelligence

Preparations and others. Vitamins and minerals is the largest product type accounting for a share of approximately 27% of the total market value followed by Cough and cold medications with a share of around 21%. By distribution channels market is segmented into pharmacies, supermarkets/hypermarkets, Hospital pharmacies and others.

### Scope of the Report

As per the scope of the report, over-the-counter drugs are referred to as the non-prescription drugs. These medicines can be bought by individuals without a doctor's prescription and are safe for consumption without the doctor's consent. There are a wide number of therapeutic applications for OTC drugs ranging from weight control drugs to analgesic drugs, and many more.

### Key Market Trends

Analgesics is the Segment by Product that is Expected to Grow the Largest During the Forecast Period.

Analgesics accounted for a significant value share of the over-the-counter (OTC) drugs market. OTC analgesics are found to have several applications in the treatment of fever, headache, musculoskeletal injuries and disorders, arthritis, and menstrual cramps that have spurred the overall demand in the market. Other factors, such as obesity, stress, and lifestyle disorders lead to chronic pain and different kinds of aches. The population is widespread in the developed markets, as well as in high economic growth countries, such as India, China. Therefore, in these countries, the population contributes to the increasing demand and growth of analgesics in the market.

Increasing disposable income of the people along with a shift in the consumer attitude towards self-medication and increasing Geriatric population with new social diseases in the region are the two major factors driving the market in the region. Increasing awareness about the cost effectiveness of self-medication and OTC medicines is also a crucial factor fuelling the market growth. However, doctor's willingness to prescribe OTC and prohibition of advertising for common ailments are the major restraints hindering the growth of the market.

### Market Dynamics

What issues will affect the Indian pharmaceutical industry?

#### Market Drivers

- Shift In Consumer Attitude Towards Self-Medication
- Rise In Geriatric Population
- Rapid Shift From Rx To OTC
- Liberalization Of OTC Drugs Sales
- Affordability Of OTC Drugs

#### Market Restraints

- Drug Abuse
- Restrictions In Distribution
- Therapeutic Errors
- Restrictions Against Over The Counter Antibiotics Usage

#### Current Opportunities

- Companies Willing To Shift To Otc
- Widespread Use Of Media Venue Choices To Boost Awareness

**Key Challenges**

- Trade-Offs For Lower Cost Generic Prescription Drugs
- Continued Openness Towards Private-Label Alternatives

**Major Players**

- GlaxoSmithKline
- Johnson and Johnson
- Dabur India Limited
- Sun Pharmaceuticals Limited
- Reckitt Benckiser
- Bayer Healthcare AG
- Emami Limited
- Piramal Enterprises
- Abbott
- Cipla Limited

**Competitive Landscape**

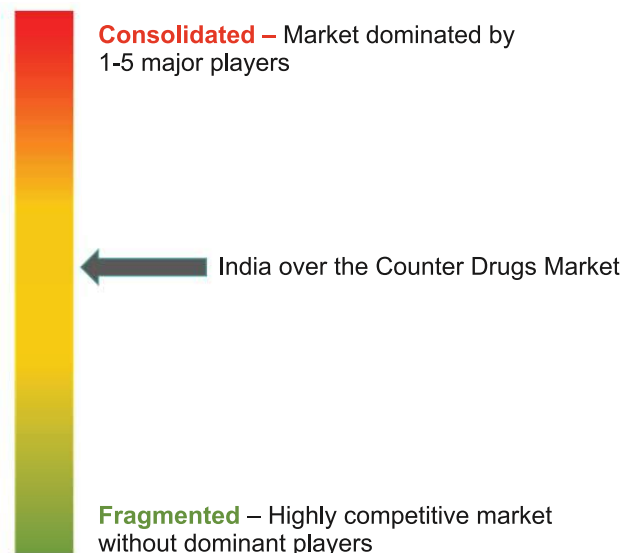
The industry players are found focusing on new product development and acquisition strategies to gain market share. The developing countries have also opened new growth avenues for pharmaceutical companies. Thus the market has different challenges and requires innovative products facilitating new innovative OTC drugs.

Overall revenue for the Indian Pharmaceutical market will reach over \$28.7bn in 2018, our work forecasts. We predict strong revenue growth through to 2028. An ageing population, increasing access to healthcare and increasing incidence of chronic diseases, especially diabetes and cardiovascular disease, will drive sales to 2028.

How will leading therapeutic areas perform to 2028? Our study forecasts revenues in therapeutic areas including:

- Infectious disease drugs
- Cardiovascular disease drugs
- Gastro-intestinal drugs
- Respiratory disease
- Pain relief / analgesics
- Diabetes
- Vitamins / Minerals / Nutrients
- Dermatology
- Central Nervous System (CNS)
- Gynaecology

## India Over The Counter Drugs (OTC) Market Concentration



Source: Mordor Intelligence



The strong growth is expected in healthcare industries due to increase in the health expenditure of government to develop healthcare industries. Factors driving over-the-counter drugs market are changes in cultural attitudes regarding self-medications required for minor health problems, increasing patent expiration rates results in switching from medical prescriptions to OTC by companies. Convenience of direct purchase, affordability of over-the-counter drugs, high adoption and acceptance in developing markets, and price of OTC's drug as compared to prescribed drugs are expected to drive the growth of global OTC market. ▶



## WHAT ARE THE TIPS TO FIND THE SUITABLE MEDICAL SUPPLY STORE



**THERE ARE SEVERAL** local stores, where you will find the necessary medicines which can cure your disease. With the medical pharmacy supply store, you are sure to get some good drugs. Since most of the people do not have the time to go to the shop, hence there is a home delivery facility for many stores. It will guarantee that the medicine store will supply good and effective drugs. Compared to other, there is good loyalty, which you will receive from the store representatives.

From the health industry, drug manufacturers earn good benefits. Rather than quality services, most of the stores aim to earn the profit. But there are some

reputable medical supply shops which cater to the needs of the customers in a better way. There are some of the vital points to understand before one comes to the medicinal supply to buy drugs. There are some of the qualities which the medical supplier needs to show.

### Getting Close To Buyers

While being reputed for years, some of the medical stores try to get close to the buyers. This can be done, only if the shop representative develops a good relationship with the customers. With a good quality supply, the representative of the medical shop often try to convince



the customer and ensure the buyer to return back to the store. With good behavior and providing the buyers with information about the medicines, the drug shop tries to keep the customers.

### Being A Brand Name

Not just an associate marketer, the best medical supply in Kolkata should possess the own identity as a part of the brand. From the branded and renounced distributor, it is a simple and common thing to achieve the supplies. This refers that the customer can get great loyalty from the store representative and authorization is one the line. From a trustworthy store, you will be given the most reputable and respectable services.

### Great Return Policy

Before buying the medicines, one needs to understand the return policy for the store. You should check that the return policy is reasonable and sound. Instead of credit points towards the future buys, you need to develop that whether the medicine suppliers provide the refund as well.

### Whether Costly Drugs Are Available in Discount Prices

Before going to the medicine store, you need to check whether the shop is providing discounts on the costly drugs. These medicines are often very critical for severe illness. ▶

# Useful Tips For Buying Medicines From The Top Medicine Store India

**WHEN YOU ARE** suffering from any medical conditions, then it can be temporary or permanent. Hence, in such circumstances, you will need to select the topmedicine store India for buying the drugs. Medical supplies can include all types of drugs like the tablets, pills and syrups and ointments. To recover in a rapid manner, you need to get a suitable drug so that disease can be treated in time. The store should be equipped with all kinds of medicines so that the buyers can get the drugs easily. If you are aiming for some of the essential drugs, then one needs to understand the tips for buying the medicines.

### # Take A Look At The Location Of The Shop

If you desire to buy the store, then you need to look at the location of the medical store. Usually, it is seen that the pharmacy medical supply store is located in the heart of the locality. This makes it easy for the buyers when you go to purchase the drugs. Moreover, if the location of the store is at a convenient place, then one can come to the shop in an easy manner. Moreover, while buying the drugs at the time of emergency can help you, if the store is at an easy location.



### # Take A Look At Other Facilities Of The Store

It is very important for you to check the timing of the store. On the hind side, it is very necessary for the drug shop to provide twenty-four-hour service. Suppose, you need to get medicines at the dead hours of the night and you will find the store open. Moreover, the store needs to have all kinds of medicines for adults and young children. It is also necessary to check the behavior of the store representative. It is seen the store representative is very knowledgeable and can impart knowledge about a particular drug. The representative will

tell all the essential things about a particular medicine.

### # Developing A Relationship With The Seller

It is essential for the buyers to develop a strong relationship with the medicine sellers. This will help you to buy the drugs in an easy manner. Moreover, it will make it easy for the buyer to get the drug which is not easily available in the market. Moreover, a good relationship can yield great discounts on the price of medicines, if the drug is priced high. ▶

# What Are The Advantages Of Top Pharmacy Store In India



**ARE YOU LOOKING** for some medicines? You might be searching for a suitable pharmacy to get the medicines, but not getting it. Under such circumstances, you need to select the top medical store in India, which can provide a lot of benefits for the buyers. There are a lot of good things which comes with the medical shop and these can be termed as an advantage for the medicine store. There are more benefits of the store which are as follows:

## # Reliability And Trust Over The Shop

If you are regularly visiting the medical store, then at one point in time you will develop a relationship with the medical store person. This is how the store owner will know you and you will get to know the store owner. After the development of the relationship, the purchaser can ask any sort of questions to the drug seller regarding the medicines. This is where the relationship has developed. There is an obvious sense of reliability over the drug owners. The main goal of the medical pharmacy stores in India is to make sure that you visit the store to gain positive experience.

## # Just Spend The Right Amount Of Time In The Pharmacy

It is often understood that you are in the rush and go off

after buying the medicines. The store can often make the drugs ready if you make a phone call to the shop. The pharmacists will often answer the questions over the phone. But this is not enough. You need to come to a medical shop and spend time with the pharmacists. This will help you to develop knowledge regarding the drugs while talking with the pharmacists.

## # Providing the Individual Attention

For these top medical stores, the customer is the priority. The shop will put the attention towards individual customers, which is one of the hallmarks. The seller will tell you, whether the price of the generic and branded is high or low. Not only that the medicine seller will tell you how many doses you need to take for how many days and the side – effects of the medicines. This is especially important for you when you are buying the drugs over the counter.

## # Availability Of Variety Of Drugs

It is necessary for the best pharmacy to have a variety of drugs in stock. This will help you to buy any kind of medicine from the store. There should be the presence of both generic and branded drugs in the store. The store should have enough stock of children medicines. ▶

# What The Uncommon Advantages Of Best Indian Medicine Store



**IT IS TIME** for you to give a second thought with the Best Indian Medicine Store if you think that the advantages you are currently availing with the drug store are not sufficient. Well, the advantage which you will get from the best medical shop in your locality will never be available from any online or other stores.

From the top medical shop, one can expect more things. For the valued and generalized customers, the medical shop leaves no stone unturned in delivering good service. Over the years, it is these efforts which have helped them in developing thousands of customers. The customer-centric service makes the shop unique in nature.

## # Attending The Customer Individually

It is the nature of 'Indias Best Pharmacy Store' to provide importance to the customers. Along with affordability, the medical stores provide a lot of things. For effective treatment, the trained staff will provide good advice.

## # Providing Commendable Service

With a local presence, you will be able to enjoy some of the good benefits from the medical shop. The shop offers rapid services through free home delivery, keeping in mind the convenience of the patients. The customers

have the options of buying nonprescription and prescription drugs directly from the store.

## # Facilities Provide By The Store

- Assistance In Procuring Imported Medicines
- Conduct Free Health Check Up Camp
- Twenty four hours serviceable outlet
- Incredible discounts
- Special schemes for physically challenged people

## # Affordable Price Range

For the general buyers, the local store can provide the medicines at an affordable cost. For both over the counter medicines, the shop offers better rates for all the drugs. This can be a good choice for all the buyers, who are buying drugs on a regular basis. The prices of drugs are less from the local store.

## # Ease Of Buying The Drugs

This is often a critical part of the local store. Suppose you have gone to the medical shop by estimating a certain price for a particular medicine. The cost of the medicine is too high often. This is done if the person is known. ■



# Look At The Advantages Of Purchasing Drugs From the Indian Medical Shop

- Pharmacies can have an online presence and increase their customer base
- They can attract new customers and reach new geographical locations
- Search medicines and look for generic alternatives
- Stores can manage their inventory digitally and get helpful reminders and notifications on expiry dates
- Offer different schemes and marketing campaigns to customers
- Provide a superior level of customer service
- Advantage or refill orders from repeat customers



**BY LEAP AND** bounds, the sale of medicines is increasing rapidly. Be it a simple medicine or a drug for the critical disease, Indian Pharmacy Store will provide you everything. There are certain shops which provide you with all types of drugs. When you go to certain shops, you will get the advantages of buying drugs. Let's check out some of the facts. There are many stores, which are selling brand medicines. But often you will find both branded and generic drugs.

## # Cheap Price Of The Drugs

For most of the customers, the price of the medicines is very important. There can be the advantage of getting a good amount of discounts when you buy the drugs from The Medical Shop. On the cheap rates, pharmacies usually provide the drugs. There is a number of discount schemes which are being implemented when you buy the medicine from the reputed store. From the ordinary shop, don't waste your time buying high priced drugs.

## # Get The Genuine Products

Then the bulk pharmacist, retail sellers of drugs are more experienced. The authenticity of the drugs can be clarified in a better way by the retail pharmacists. They have a better connection with the pharmaceutical companies since these stores handle large amounts of medicines. There are certain stores which you need to prefer while

buying medicines. There will less scope of getting the low-quality medicines. You should always prefer the retail chain of medicine store, for buying the original drugs.

## # Knowledgeable Pharmacists At The Your Service

When you go to the medicine store without a prescription, you can get some great help from the pharmacists. These persons are very knowledgeable and can make you understand about the drugs. These people will tell you about the dosage, usage and side effects of the drugs. Not only that, they will even tell you that how quickly you can get cured after taking the drugs.

## # Home Delivery On A Rapid Basis

Suppose, you are alone and sick and cannot move out of the house to buy the medicines. Then what can you do? You can call up the store and order the medicines. The store consists of delivery boys, who can deliver the medicines to the home. This process is very rapid and you will get the medicines within a certain period of time.

## # Maintaining The Privacy

The customer details are being kept secret by the pharmacy. They will never disclose the medicines sold to one customer to another. ▶



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Due to poor or non-existent regulations, it has been estimated that at least 50% of the average family spending on medicines in the country is incurred on irrational or unnecessary drugs and diagnostic tests.

## Medication Misuse In India:

# A Major Public Health Issue In India

**IN INDIA, IT** has been estimated that 50% of family spending on healthcare is on unnecessary medications or investigations. This, combined with the wide availability of medications, has seemingly contributed to increasing rates of antibiotic resistance and further impoverishment.

### Background

Failures in the pharmaceutical regulatory environment in India have contributed to oversupply and ease of access to various medications including many with little evidence to support their safe use. This, combined with poor community literacy about medication safety and usage, potentiates misuse and overuse of medications in India. This, in turn, can contribute to ill-health, public health predicaments such as antibiotic resistance and further impoverishment of the community. Indeed, Sengupta in his assessment of universal health care in India, reports that:

Due to poor or non-existent regulations, it has been estimated that at least 50% of the average family spending on medicines in the country is incurred on irrational or unnecessary drugs and diagnostic tests.

This is a complex ethical issue as at the other extreme excessive restrictions on access to medications could also result in poor outcomes for the community. This is especially the case in rural areas where there is non-availability of trained practitioners to prescribe and dispense medicines. For example, restricting antibiotics in isolated areas where trained practitioners are not available might mean treatable infections go untreated.

However, the scale of misuse, and in particular overuse, of medications in India is an issue of increasing concern amongst both government and non-government public health organizations. The World Health Organisation (WHO) considers essential those medicines that should be available and affordable in order to



When it came to antibiotic misuse, while practitioners in rural areas tend to prescribe more antibiotics than urban practitioners.



address priority healthcare needs and promote the health of the community. There are only 348 drugs on India's essential medicine list yet there are known to be 60 000–80 000 brands of drugs available on the market within India, 2 even accounting for different preparations of drugs this is an extraordinary number. This results in an overwhelming workload for the already stretched regulators and feeds into what has been reported as a growing culture of irrational and unnecessary prescribing and consuming practices.

We hypothesize that there is extensive medication misuse throughout India and that the causes are multifactorial including supply-side factors (government policy, corporate interests and provider features) and demand-side consumer influences. In order to further understand the extent of the issue and inform policy decisions by health organizations, a literature review was conducted. This aims to characterize the extent of medication misuse in India and to understand the underlying factors involved. In particular we seek to understand, in relation to medication usage, the knowledge, attitudes and behaviours of medical practitioners, pharmaceutical providers and consumers.

### Factors relating to misuse

The factors related to medication misuse and overuse can be considered based on the various parties involved in the distribution of pharmaceuticals, namely the healthcare providers, the pharmacists, the consumers and patients. A number of underlying health system factors were also found to be facilitating medication misuse in the community.

### Health system factors relating to supply, regulation and enforcement

The literature revealed a number of health system and regulatory failures that have been found to influence the

misuse of medications in India. On a health system level, providers expressed that poor script regulation, the ability for unqualified practitioners to write prescriptions, unregulated dispensing of medications and weak drug policy all serve as primary causes of medication misuse. They noted that lack of political will, and an inadequate regulatory framework, was facilitating an oversupply and usage of inappropriate medications.

Many of the studies in this review found that high availability of a wide range of medications influenced medication use. The oversupply of some medications to public dispensaries was a concern raised by some doctors and pharmacists due to supply becoming more important in medication choice than evidence-based guidelines. Furthermore, in evaluating the available cold and flu medications in India, Roy et al. found that banned drugs were still available, and there was a high availability of medications with no evidence of efficacy. A high rate of self-medication was influenced by a lack of regulation of available medications in India. Additionally, a lack of enforcement of regulations, meant that pharmacists could dispense medications despite incomplete or out of date prescriptions.

### Factors related to health care providers

A number of factors were found to influence healthcare providers to misuse medications in their prescribing practices. Multiple prescription audits demonstrated poor prescribing practices on the part of physicians. Common infractions included not including frequency of dosage on the script, not recording duration and using only brand names on prescriptions. Furthermore, it was found that prescribers were poor at educating patients around the appropriate use of prescribed medications. However, healthcare providers were amenable to education around appropriate medication selection and appropriate prescription practices with interventions being shown to

make a difference in prescribing practices. Patient preferences also influenced the prescribing practices of health professionals, this is further explored below.

Other factors noted by doctors that increase their misuse of medications included time constraints, diagnostic uncertainty and poor availability of diagnostic laboratories to confirm diagnosis prior to treatment. A more insidious finding was that doctors often prescribed higher cost medications because it would result in a higher profit. In these cases, the more expensive medications would be given despite them not necessarily being the most appropriate choice. In other cases, the high costs of medication restricted the use of appropriate medication and as a result patients were prescribed less appropriate medications.

When it came to antibiotic misuse, it was noted that private practitioners tend to use more expensive, broad spectrum antibiotics; while practitioners in rural areas tend to prescribe more antibiotics than urban practitioners. A strong theme that emerged from the literature was that a lack of good education for healthcare providers around appropriate antibiotic use was an important factor influencing inappropriate

prescribing practices. This was evidenced in practitioners lacking knowledge about medicines, receiving inadequate continuing medical education and being influenced by pharmaceutical representatives. Junior medical practitioners tended to prescribe more antibiotics than senior medical practitioners. A lack of knowledge was found to result in misdiagnosis, inadequate antibiotic treatment and indiscriminate use of antibiotics.

### Factors related to pharmacists

As noted above, a recurrent theme in the literature was the ease of access to medications from pharmacists without requiring a prescription. In one study, community pharmacists were noted to have between 10 and 20 visits per day of people requesting self-medication. Despite a lack of training in diagnosis and prescribing medications, pharmacists demonstrated a willingness to dispense medications to consumers based on the patient's symptoms or request for particular medications. In these instances, the pharmacist's choice of medication was often based either on availability or on perceived prescribing practices of doctors<sup>8</sup> rather than on current guidelines. Pharmacists interviewed in focus groups attributed much of the blame for antibiotic misuse to the consumers (see below) and healthcare providers (see above) and explained that they felt powerless to challenge doctors if they saw inappropriate scripts.<sup>8</sup> However, other evidence demonstrated that pharmacists themselves fail to educate patients about the appropriate

use of antibiotics and when dispensing medications without a script, they will often choose the incorrect dose or duration of treatment. Other factors which pharmacists cited for their failure to fully inform patients about the appropriate use of prescribed medications included time constraints and inadequate knowledge.

### Factors related to consumers

Finally, it was clear throughout the literature that there were a number of factors relating to consumers that influence medication misuse in the community. There were found to be high levels of non-compliance amongst consumers. Factors influencing non-compliance included lack of education about their medication, marital disharmony, superstitious beliefs about the underlying disease and financial constraint. For example, 90% of patients who discontinued their epilepsy treatment in Das' longitudinal study expressed their inability to afford ongoing treatment.

Self-medication was seen multiple times as a contributing factor to medication misuse, with patients utilizing old prescriptions, requesting specific medications directly from pharmacists and using unfinished courses of medication for new complaints. Self-medication was influenced by poor knowledge of the risks involved, lack of time and money to visit a doctor for perceived mild complaints, and a lack of awareness of the dangers.


Additionally, patients placed pressure on health providers to prescribe medications such as antibiotics for inappropriate indications as many consumers demanded fast symptom relief. Patients preferred to avoid expensive diagnostic investigations and simply be prescribed medicines. This

stems from both an inability to pay for investigations, and an unwillingness to return to the healthcare provider for further management<sup>27</sup> with a preference for seeing multiple doctors instead of allowing one to coordinate care. While some studies noted that antibiotics were overused in poorer populations, other studies noted overuse of antibiotics in higher socio-economic populations. In both cases, however, a lack of education about the appropriate antibiotic use was evident in the populations who utilized more antibiotics.

### Prevalence of medication misuse

The literature demonstrated that the overuse and misuse of medications in India is widespread. Antibiotic use was of particular concern. Chandy et al. in their examination of outpatients in Vellore found an overuse of antibiotics among all service providers in all geographical locations.

BE NICE TO  
PHARMACISTS  
BECAUSE  
WE CAN KILL U  
WITH ONE  
mistake





## 90% of patients who discontinued their epilepsy treatment in Das' longitudinal study expressed their inability to afford ongoing treatment.

Similarly, in Erode City (Tamil Nadu), Moorthi found widespread inappropriate use of antibiotics with 65.67% antibiotic scripts for children in community pharmacies being for simple colds. Even in those cases where the condition warranted an antibiotic, there was an inappropriate selection of antibiotics. Basu et al. in their study of paediatric outpatients in Darjeeling found 36.8% of prescribed antibiotics were irrational—what is more, all medical officers surveyed acknowledged that they overused and misused antibiotics.

In a number of studies across India, pharmacists were shown to be dispensing antibiotics without a script. In Salunkhe et al.'s study, 94.65% of pharmacies dispensed antibiotics for a sore throat or diarrhoea without a script<sup>35</sup> while Rathnakar et al. found that 51.7% pharmacies would dispense antibiotics upon request without a script.<sup>34</sup> Freely available antibiotics without the gatekeeper effect of a required prescription creates an opportunity for overuse and inappropriate use of antibiotics.

Multiple studies audited prescribing patterns compared with WHO medication usage indicators.<sup>42</sup> In both outpatient and household studies, there was a high level of polypharmacy, i.e. 'the use of multiple medications and/or the administration of more medications than are clinically indicated.' WHO notes that such irrational use of medications commonly results in unnecessary side effects. In studies of inpatients, the number of drugs prescribed per patient ranged from 4.5 to 9.5, whilst outpatient surveys ranged from 1.56 to 4.54 drugs prescribed per patient.

Prescribing tended to be by brand name (rather than generic name) with Patel finding 96.6% scripts at the pharmacy audited contained only brand name.<sup>16</sup> In the household surveys reviewed, many scripts were found to be irrational: including 63.51% in one West Bengal study.

### Adverse drug reactions

In addition to various articles detailing high prevalence of medication misuse, there were also 18 articles specifically relating to ADRs, which all examined inpatient

populations. ADRs may be an indicator of medication misuse due to poor prescribing practices and lack of compliance. In the studies examined, the most common factors related to ADRs were older age, multiple comorbidities, polypharmacy, longer length of stay for inpatients and non-compliance for outpatients. Two studies found a low reporting rate of ADRs by medical staff and this was shown to be as a result of lack of knowledge about how to report, lack of time, the non-availability of reporting forms, diagnostic uncertainty and fear of legal implications around reporting.

### Discussion

#### Main findings of this study and what this study adds

This review has attempted to understand the extent of and reasons behind the misuse of pharmaceuticals in India. Medication misuse was found to be very common in India. By examining the underlying influences on healthcare providers, pharmacists and consumers, this literature review provides a unique insight into the determinants of medication misuse. These were multifactorial, stemming from each level of the health system: policy, health providers, medication dispensers and consumers. Some of the primary themes that have emerged from the data include a lack of effective





regulation, a lack of education at all levels around appropriate medication use and the risks associated with inappropriate use, as well as an uncoordinated response from the different levels of the health system. Many of the studies noted a culture of blame-shifting emerging, for example pharmacists blaming poor prescribing of doctors<sup>8</sup> and doctors blaming the pharmacists for dispensing without a prescription.

### What is already known on this topic

These findings are consistent with data found in other nations. Preventable adverse events due to medications have been shown to be a leading cause of death in the USA.<sup>64</sup> Numerous studies in the USA demonstrated medication-related errors in prescribing, dispensing and non-intentional non-adherence. Likewise, Australian studies have demonstrated a high rate of polypharmacy and self-directed medication use. Furthermore, a UK literature review in 2002 found that 4 of every 100 hospital bed days were related to ADRs. The nature of errors in high-income countries will be different to those in India. For example, dispensing errors at a pharmacy in the UK will be different to the pharmacy factors described in this paper. However, these findings in developed countries demonstrate that the issue of medication misuse is not isolated to India, but an issue that needs to be

addressed in any context where pharmaceuticals are widely available.

### Limitations of this study

Limitations of this review include that although there were over 100 articles reviewed, the majority of publications simply audited medication usage rather than analysing how appropriate it was. India is a very diverse country and there is a vast diversity in the population between geographic and demographic contexts. Although the review showed that medication misuse was common throughout India, the factors involved may vary between different contexts. In particular, the appropriate use of medications in rural areas and urban areas will be quite different with the variation in accessibility of healthcare and disease prevalence patterns. This review has considered studies from all of these contexts and as a result may not be easily applicable to one context.

While medication misuse is thought to be common in inpatient and outpatient settings, the majority of these studies examined hospital inpatient populations with few examining the general community and population. This restricts the generalizability of the results with limited data about medication usage practices and their appropriateness in the general community.

These limitations suggest that further research is warranted. In particular research should seek to provide a richer understanding of the attitudes and behaviours of various populations towards medication use and misuse. It would be helpful to have further research with community populations exploring in greater depth their perceptions around appropriate and inappropriate medication use. Further qualitative and ethnographic research could usefully explore strategies to address the problems identified. For example, it was noted that one issue is a lack of implementation of regulations around drug dispensing and prescription monitoring. Further research with key stakeholders including government, health practitioners, non-registered health providers, pharmacists and consumers may help to provide insight into useful strategies, which could be implemented to address this particular aspect of the problem. Ethically it may be difficult, or even impermissible to restrict access to life-saving medications, especially in areas where access to health services is limited. In a country of socio-economic extremes, the challenge of determining appropriate strategies to limit the misuse of medications is difficult.

Nevertheless, it is clear that the extent of medication misuse needs to be addressed at all levels of the Indian health system with collaboration between all players in order to improve the outcomes. Policy-makers need to consider the interplay between systemic, provider, dispenser and consumer factors in order to address the serious concern. An education campaign for health providers, pharmacists and the public around the risks of inappropriate use of antibiotics is warranted, and further research could be done to explore effective strategies to address the social factors underlying a culture of medication misuse and overuse. ▀

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BUSINESS  
is PATIENT  
SAFETY.

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## MOST COMMONLY USED OTC MEDICATION



**ACETAMINOPHEN.** Acetaminophen is the most commonly recommended OTC medication for fever. It works well for minor aches and pains, especially for people who cannot tolerate antiinflammatory medications such as ibuprofen or aspirin.

### Over-the-counter medicines

You can buy many medicines for minor problems at the store without a prescription (over-the-counter).

#### Important tips for using over-the-counter medicines:

- Always follow the printed directions and warnings. Talk to your health care provider before starting a new medicine.



It is good to keep several medications at home for various illnesses as long as all directions are followed and all expiration dates are monitored

ADAM.

- Know what you are taking. Look at the list of ingredients and choose products that have fewer items listed.
- All medicines become less effective over time and should be replaced. Check the expiration date before using any product.
- Store medicines in a cool, dry area. Keep all medicines out of the reach of children.

Women who are pregnant or breastfeeding should talk to their provider before taking any new medicine.

Medicines affect children and older adults differently. People in these age groups should take special care when taking over-the-counter medicines.

Check with your provider before taking an over-the-counter medicine if:

- Your symptoms are very bad.
- You are not sure what is wrong with you.
- You have a long-term medical problem or you are taking prescription medicines.

### ACHES, PAINS, AND HEADACHES

Over-the-counter pain medicines can help with headache, arthritis pain, sprains, and other minor joint and muscle problems.

- Acetaminophen -- Try this medicine first for your pain. DO NOT take more than 3 grams (3,000 mg) on any one day. Large amounts can harm your liver. Remember



that 3 grams is about the same as 6 extra-strength pills or 9 regular pills.

- Nonsteroidal anti-inflammatory drugs (NSAIDs) -- You can buy some NSAIDs, such as ibuprofen and naproxen, without a prescription.

Both of these medicines can have serious side effects if you take them in high doses or for a long time. Tell your provider if you are taking these medicines many times a week. You may need to be checked for side effects.

## FEVER

Acetaminophen (Tylenol) and ibuprofen (Advil, Motrin) help reduce fever in children and adults.

- Take acetaminophen every 4 to 6 hours.
- Take ibuprofen every 6 to 8 hours. DO NOT use ibuprofen in children younger than 6 months.
- Know how much you or your child weighs before giving these medicines.

Aspirin works very well for treating fever in adults. DO NOT give aspirin to a child unless your child's provider tells you it is OK.

## COLD, SORE THROAT, COUGH

Cold medicines can treat symptoms to make you feel better, but they do not shorten a cold. Taking zinc supplements within 24 hours of the start of a cold may reduce the symptoms and duration of a cold.

**NOTE:** Talk to your provider before giving your child any type of over-the-counter cold medicine, even if it is labeled for children.

### Cough medicines:

- Guaifenesin -- Helps break up mucus. Drink lots of fluids if you take this medicine.
- Menthol throat lozenges -- Soothe "tickle" in the throat (Halls, Robitussin, and Vicks).
- Liquid cough medicines with dextromethorphan -- Suppress the urge to cough (Benylin, Delsym, Robitussin DM, Simply Cough, Vicks 44, and store brands).

### Decongestants:

- Decongestants help clear a runny nose and relieve postnasal drip.
- Decongestant nasal sprays may work more quickly, but they can have a rebound effect if you use them for more than 3 to 5 days. Your symptoms may get worse if you keep using these sprays.
- Check with your provider before taking decongestants if you have high blood pressure or prostate problems.
- Oral decongestants: Pseudoephedrine (Contac Non-Drowsy, Sudafed, and store brands); phenylephrine (Sudafed PE and store brands).
- Decongestant nasal sprays: Oxymetazoline (Afrin, Neo-Synephrine Nighttime, Sinex Spray); phenylephrine (Neo-Synephrine, Sinex Capsules).

### Sore throat medicines:

- Sprays to numb pain -- Dyclonine (Cepacol); phenol (Chloraseptic).
- Painkillers -- Acetaminophen (Tylenol), ibuprofen (Advil, Motrin), naproxen (Aleve).
- Hard candies that coat throat -- Sucking on candy or throat lozenges can be soothing. Be careful in young children because of the choking risk.

## ALLERGIES

Antihistamine pills and liquids work well for treating allergy symptoms.

- Antihistamines that may cause sleepiness -- Diphenhydramine (Benadryl); chlorpheniramine (Chlor-Trimeton); brompheniramine (Dimetapp), or clemastine (Tavist)
- Antihistamines that cause little or no sleepiness -- Loratadine (Alavert, Claritin, Dimetapp ND); fexofenadine (Allegra); cetirizine (Zyrtec)

Talk to your provider before giving medicines that cause sleepiness to a child, because they can affect learning. They can also affect alertness in adults.

### You can also try:

- Eye drops -- Soothe or moisten the eyes
- Preventive nasal spray -- Cromolyn sodium (Nasalcrom), fluticasone (Flonase)

## STOMACH UPSET

### Medicines for diarrhea:

- Antidiarrhea medicines such as loperamide (Imodium) -- These medicines slow down action of intestine and reduce number of bowel movements. Talk to your provider before taking them because they can worsen diarrhea caused by infection.
- Medicines that contain bismuth -- May be taken for mild diarrhea (Kaopectate, Pepto-Bismol).
- Rehydration fluids -- May be used for moderate and severe diarrhea (Analytes or Pedialyte).

### Medicines for nausea and vomiting:

- Liquids and pills for stomach upset -- May help with mild nausea and vomiting (Emetrol; Pepto-Bismol)
- Rehydration fluids -- May be used to replace fluids from vomiting (Enfalyte or Pedialyte)
- Medicines for motion sickness -- Dimenhydrinate (Dramamine); meclizine (Bonine, Antivert, Postafen, and Sea Legs)

## SKIN RASHES AND ITCHING

- Antihistamines taken by mouth -- May help with itching or if you have allergies
- Hydrocortisone cream -- May help with mild rashes (Cortaid, Cortizone 10)
- Antifungal creams and ointments -- May help with diaper rashes and rashes caused by yeast (nystatin, miconazole, clotrimazole, and ketoconazole). ▶

# 10 Medicine Cabinet Essentials

**WHEN IT COMES** to first aid in the home, be prepared with a well-stocked medicine cabinet. If you need to treat an illness or injury, you will have all the basics on hand to help yourself or others.

Before you head to the drugstore, take an inventory of your medicine cabinet and what's currently on your shelves. This is a good opportunity to clear your medicine cabinet of old prescriptions and expired products. Make this a habit and try to do this every three months. Find a local center near you that can properly dispose of old medication. Some grocery stores or community centers offer this service annually. By doing this, you won't have to worry about how long that bottle of pink liquid

has been sitting on your shelf the next time you have a sudden stomach ache.

**Remember:** Always follow dosage instructions as indicated on medication packaging.

## Medications and first aid supplies to have on hand at all times

The following medicine cabinet supplies can treat a range of illnesses and minor injuries, from allergies and stomach aches to cut, bruises, aches and pains.

### 1. Emergency instructions

Tape a list of important phone numbers (doctors, Poison Control), medication instructions and allergy alerts inside the cabinet door.

### 2. Acetaminophen and an NSAID

Acetaminophen is a pain reliever and fever reducer. Non-steroidal anti-inflammatory drugs (NSAIDs) can reduce inflammation related to conditions like backaches and toothaches. Be aware of NSAID sensitivity in your family, especially in young children.

### 3. Aspirin

Aspirin works as a pain reliever for adults, but it's also important to have on hand in case of emergencies. According to the American Heart Association, taking aspirin also helps during a heart attack. In fact, people having a heart attack are often given an aspirin by emergency medical services. However, it's wise to be aware of aspirin sensitivity in your family, and it should never be given to children under 18.

### 4. Antihistamine

Antihistamines treat hives, itching and allergic reactions from a wide range of causes. Stock both oral antihistamines (the liquid or pill form that may be helpful during a serious allergic reaction) and hydrocortisone cream.

### 5. Decongestant, cough suppressant and flu relief medicine

You won't want to leave home to go to the drugstore when you're feeling lousy, so keep cold and flu relief medication on hand.

### 6. Antacids

If you are suffering from heartburn, these are your best bet for quick relief.

### 7. Antibiotic ointment

Apply this after you've washed cuts and scrapes with warm water and soap, then cover the wound with clean bandages.

### 8. Bandages

Stock up on adhesive bandages of all sizes, plus plenty of gauze and sterile tape.

### 9. Thermometer

Feeling someone's forehead may be a good first step, but a thermometer is necessary for an accurate temperature reading.

### 10. Heat and ice packs

Keep several of these on hand, as they can provide relief for everything from headaches and sprains to injuries and sore muscles. ▶

**“Consumer  
Rights Are Our  
Fundamental  
Rights, IT is our  
Duty to ensure  
we are not  
shortchanged”**



## Consumer Selection And Buying Behaviour Towards Over The Counter (OTC) Medicine In **JAIPUR CITY**



**OVER THE PAST** 50 years or so the Indian pharmaceutical sector witnessed rapid growth and transformation. The Indian pharmaceutical industry is expected to grow with 15 per cent per annum between time periods 2015-20 and with annual growth rate of 5 percent it will be outperform globally. The expected market growth rate will be US\$ 55 billion by 2020 which shows that Indian Pharmaceutical market emerging as the sixth largest pharmaceutical market globally by absolute size. The 70 percent of Indian pharmaceutical market share in terms of revenue is majorly dominated by Branded generic drugs. Similarly, the other patented drug contributes 21 percent market share whereas over the counter (OTC) drug market contribute 9 percent of total USD 20 billion revenue of the Indian pharmaceutical market.

The World Health Organization estimates that India accounts for 21% of the world's global burden of disease and due to these health issues India is losing more than 6% of its GDP annually. These healthcare issues include lack of medical facility, counterfeit and spurious drugs in market and unqualified medical practitioners in rural areas. The cost involves in physician consultancy as well as transportation are also a major problem faced by population which lies under poverty line. To come out from above these problems majority of the population now a day's practices self-medication with OTC medicines for treating minor ailments.

On the other side, the growing world of fast technology and scientific advancement life become stressful due to Changing lifestyle with smaller living space, less exercise (sedentary jobs), taking junk food, consuming addictive products to stay awake on the job for longer hours and eating on the run put more stress on the body which get expressed in the form of psychosomatic disorders like frequent headache, allergy, common cold, constipation, backache, acidity, chronic fatigue etc. which they are trying to manage with over the

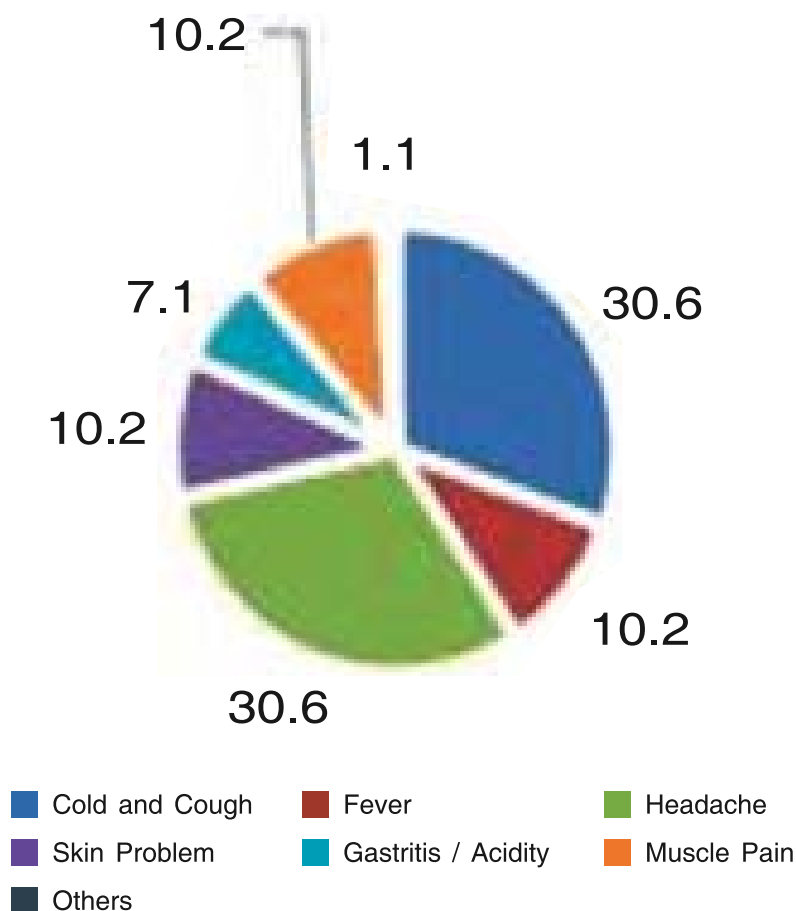
counter (OTC) medicine. This has led to steady increase in self-medication for the past many years.

Over the last decades, the Indian pharmaceutical industry has been facing multiple pressures arising from increasing R&D costs, the implementation of product patent regime, issues related to regulatory requirement, and the absence of a strong product pipeline. To compete with this volatile, uncertain, complex and ambiguous (VUCA) world the Indian pharmaceutical industry has to revisit their traditional growth strategies with special emphasis to marketing and promotional strategies. Hence in promoting OTC products among consumer the pharmaceutical industry also considers safety in using OTC medicines. The main motive behind this promotional

strategy is to make consumers learn about the effect of drugs depending on their physical well-being after they have taken it due to remedy a certain ailment. Increase in health awareness among urban and rural population and easily assessable of OTC products turn into increase in demand and significant growth in OTC market sector. For rational use of OTC medicines among consumer the pharmaceutical companies, pharmacist and other healthcare stake holders should play a proactive role in balancing safety and patient autonomy.

### Type of common ailments for preferring self-medication

The respondents were asked that in which type of common ailments or symptoms they preferred self-



**Figure 2:** Common ailments for preferring self-medication (N=100)

medication. The 30.6% respondents showed that they prefer self-medication in headache, 30.6% respondents prefer self-medication in cold and cough. 10.2% of respondents take self-medication in fever, muscle pain and skin problem. Rest of 7.1% of respondents use self-medication in gastritis or acidity problem. Some of respondents use self-medication in allergies and rhinitis.

### Pharmacist advice to consult doctor for long time medical problem

Respondents were also asked that does pharmacist advise them to consult the doctor if they have long term medical problem. The 81% of respondents replied yes that pharmacist advise them to consult with doctor whereas 19% respondents replied no.

5.4 Consumer opinion regarding use of more than one OTC product in more than one common ailments.

46% of respondents opined that



Information on internet, rising doctors fees lead to self-medication

they were rarely use more than one OTC product if there is more than one common ailment in same time whereas 33% opined that they were more likely to use more than one OTC medicine at the same time. The rest of 21% never use more than one OTC medicine in same time if they have more than one common ailments or symptoms.

### Source of information regarding branded OTC product.

The above fig. 3 represents the various advertisement and promotional strategy for OTC brand medicine performed by the pharmaceutical industry and its impact on consumer. 23.32% of

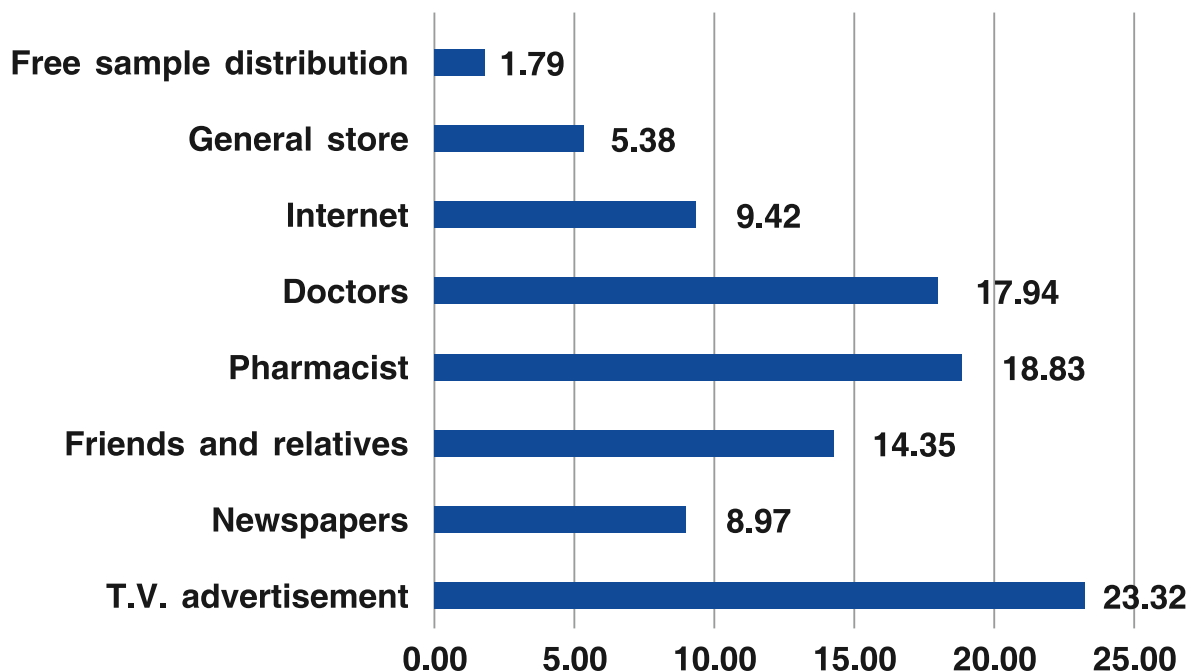


Figure 3: Source of information regarding OTC brand



respondents shows that they came to know about new OTC medicine brand through television advertisement. 18.83% respondents showed that pharmacist provide them information about OTC medicine. 17.94% respondents represent that doctors make them aware about OTC medicine whereas 14.35% respondents opined that they get the OTC medicine information from friends and relatives. 9.42% respondent receive information through internet and web portal. 8.97% respondent opined that newspaper is another source of information about OTC medicine. Rest of respondents 5.83% and 1.79% opined that general store and free sample distribution was used by pharmaceutical company to promote their OTC medicine. Thus the maximum source of information regarding OTC medicine information used by consumer is television advertisement, pharmacist, doctors, friends and relatives, internet, newspaper and general store respectively.

### Consideration for selecting an OTC medicine

In the above fig. 4, factors considering by consumer for choosing OTC medicine products is presented. 28.8% respondents opined that brand name was considered while selecting the OTC product. 25.6% respondents showed that they consider symptoms for which OTC medicine will be used. 16.9% respondent opined that dosage of OTC medicine was important criteria for selecting OTC product whereas 11.9% and 10.6% responded towards price and packaging of OTC medicine. Only 6.3% of respondent opined that advertisement was an important factor for selecting OTC brand product.

### Reason behind consuming same OTC brand

It was found that from the total survey consumers 54 % of consumers opined that they were use

same OTC brand for minor ailments. The reason behind consuming same OTC brand is 22 consumers opined that brand is effective, 17 consumers showed that quality was maintained in branded OTC. whereas 9 consumers opted for brand values and 6 consumers showed that brand familiarity was the reasons for selecting same OTC brand product.

### DISCUSSIONS

The present study revealed that consumer preferred to use OTC medicine for treating common ailments which also presented that people are aware regarding use of OTC medicine. The pharmacist play an important role in pushing and providing information about new OTC brand product. The majority of consumers shows that they rarely use more than one OTC medicine in more than more common ailments this also reflects that there should be effective measures should be made for proper use of OTC medicine. T.V.

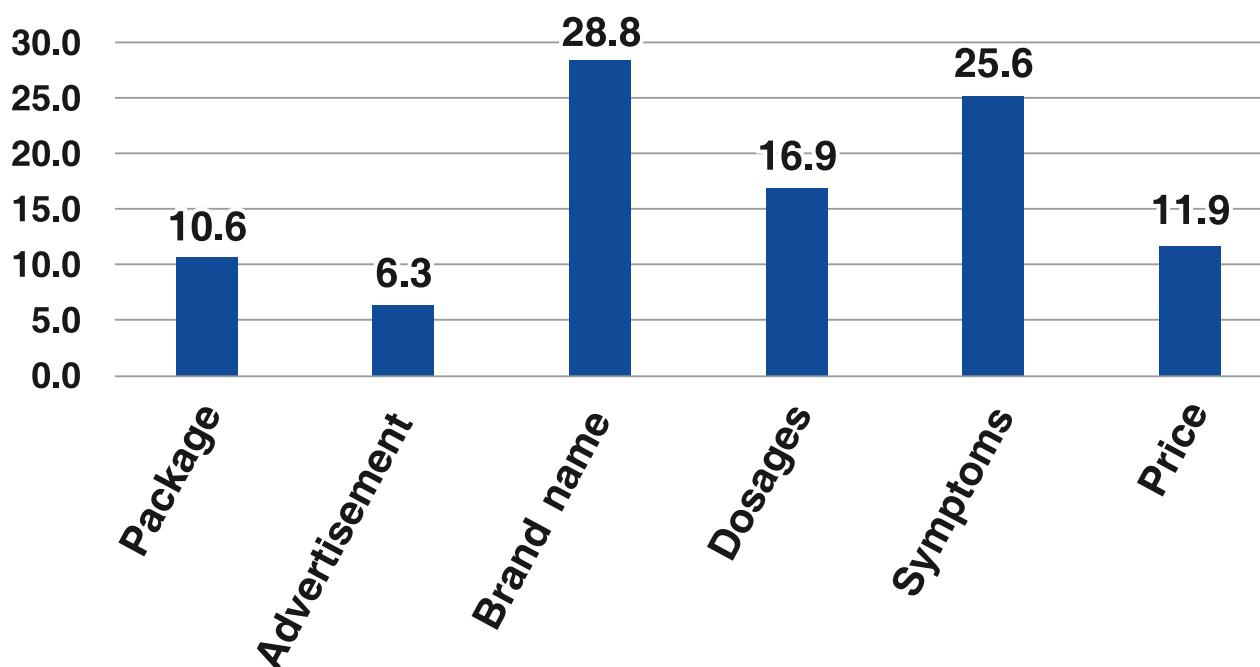


Figure 4: Factors considered for selecting OTC medicine product

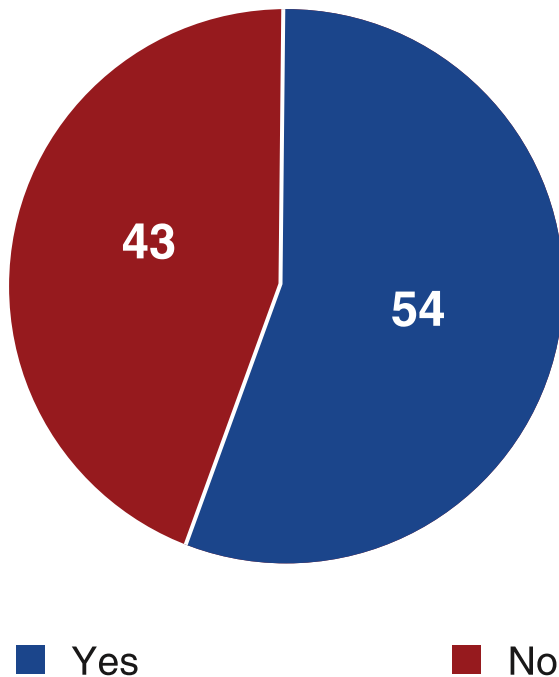


Figure 5a: Do you usually consume the same OTC brands?

advertisement, pharmacist was the major source of information regarding branded OTC product from where consumers get the information.

The consumer considers brandnames and symptoms for selecting the new OTC brand product so it is necessary for pharmaceutical companies to work intensively on brand building as well as the label and the advertisement should include information about symptoms and indication for which OTC medicine were used, in other words it means that the role of advertising is expected to be mostly instructive and suggestive of application specifics which make aware to the consumer before it is to be used. The study also presents that consumer buy same branded drug because they believe that branded OTC medicines are effective and hence the pharmaceutical companies has to also work on quality of OTC product to retained the loyal customer with their branded OTC medicine.

## CONCLUSION

The results reveal that consumer in Jaipur city are aware regarding use OTC medicine for common ailments and there is responsibility of pharmaceutical companies, government and other health stake holders to promote knowledge and awareness among consumer for safe and effective use of OTC medicine. For making OTC brand awareness the pharma companies should use proper promotional and advertisement channels, they can also take help of pharmacist and other health service provider to promote their OTC brand among mass population. The study also reflects that familiarity with the OTC brand is the key factor in determining the repetitive purchase of OTC product so the OTC brand building and positioning are the most important part of OTC marketing strategy which should be consider by pharmaceutical industry. ▶

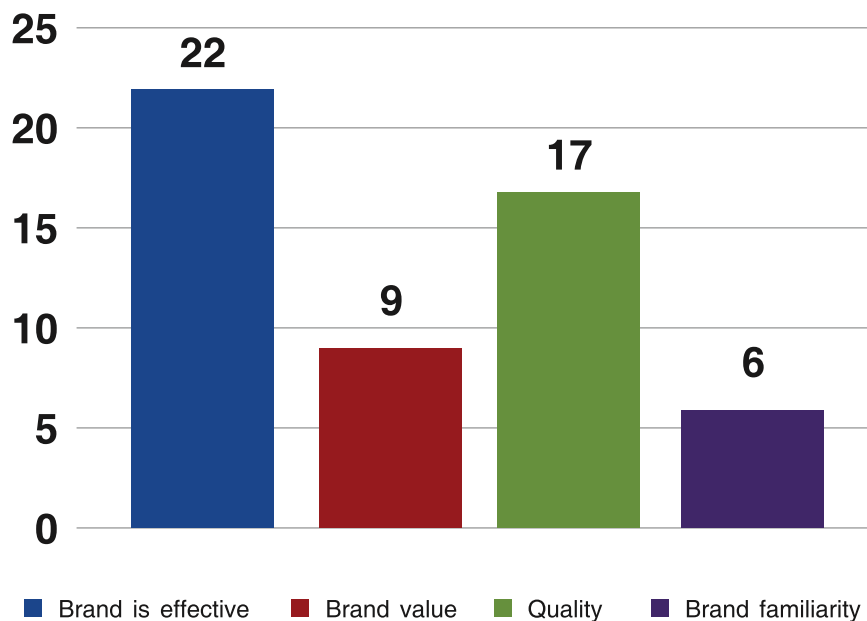


Figure 5b: If yes, then why?

1 OUT OF  
4



consumers is a *family health influencer*, often **sought by others for advice** on treating minor ailments.

**This knowledgeable consumer:**



**Understands**  
what OTC  
ingredients do



**Knows**  
what OTC  
to take



**Goes online**  
to diagnose  
symptoms



**Avoids**  
going to the doctor  
unless they have to





## Nicholas Hall

**Executive Chairman & Creative Solutions Director  
at Nicholas Hall Group of Companies**

**NICHOLAS HALL HAS** more than three decades of experience in the healthcare industry. He has chaired and moderated over 300 OTC conferences and seminars in 58 countries. The Nicholas Hall Group provides a complete marketing and business intelligence support service for consumer healthcare professionals, offering data and analysis on a truly global basis. He manages the Nicholas Hall Group's consulting business, which has among its clients many blue-chip OTC companies, as well as some of the leading local laboratories in Asia, Middle East and Latin America.

The global consumer healthcare market in the mainstream retail sector had a difficult year in 2018, with value growth of around 4%, a little below its historical 4.5%. Volume accounts for about half of this growth and the rest was made up of price increases. With the world's high population boom-- skewed though it is to an ageing demographic-- our industry is in fact failing to keep up with the population in real terms. This lack of growth has turned the eyes of the industry from seeking organic growth through improved new products and more consumer-focused marketing to M&A. Some companies are in a perpetual state of integration and reorganisation, and this is unsustainable. It is no surprise that the top 7 companies globally, which account for about a quarter of the world market by value, are in fact failing to exceed the global growth rate.

At the moment there are three main drivers of consumer healthcare. First, prescription-to-OTC switch, which has been significant in the past; but the massive up-front costs are a deterrent to investment, so we have seen little switch activity in the past 3 years. Secondly, a strong cough and cold season is a very basic sales booster, but was notably absent in 2018. And thirdly, the

strength of the Emerging Markets, all of which are down from their previous peaks for reasons of politics, economics or lack of appreciation of the benefits of self-care on the part of the regulators. In the future, we hope for a radical restructuring of public health as governments try to increase provision at a lower cost, and in doing so accept the need to empower the consumer healthcare industry with more beneficial regulations, but the New Paradigm, as I call it, seems some way off.

In all of this discussion of sales growth, I exclude the much more productive non-retail sectors. E-commerce currently accounts for 12% of all consumer healthcare purchases, and by 2025 this percentage will be closer to 20%. The data is insufficiently granular at the moment, which is why we exclude it from our DB6 database, but we hope to rectify this omission in the next two years. The same is true for the other big non-retail sector, the multi-level marketing of companies like Amway, which we must never forget is the world's largest marketer of packaged vitamins.

Of the 64 countries in which I work, none is more important than India, which is why I look forward so much to my annual visit. For me, India is at the same time a source of inspiration and frustration. The courage and diversity of its people and the ambitions of its political and industrial leaders are a source of true inspiration. I never cease to remind my global audience that India will soon have the world's largest population and, despite the checks and balances from being the world's largest democracy, which undoubtedly slows the pace of change compared with a command economy like China, progress is being made in social policy and infrastructure.

But frustrations are there too, and India knows it could be so much more and do so much better. Nowhere is

that more evident than in consumer healthcare, where the industry needs more support from government to bring the clear advantages of responsible self-medication to an eager population.

Every day we talk to empowered consumers all over the world who want the primary care benefits that OTC medicines offer, but don't want to lose precious time. That is why self-medication is on the rise across the world, and India is no different. Our Mirror study clearly endorses this with data showing that the practice of self-medication has almost doubled over the past 10 years. But this growth could be better channeled in the context of creating a greater economic value for the country, if regulations were better defined.

I travel extensively and what I see in markets such as Brazil, Mexico and Indonesia is proof positive that deregulation works. Mexico is a beacon for prescription-to-OTC switch -- a comparative rarity in India -- and as a result there is a thriving responsible self-medication sector, with carefully-controlled claims on packaging and in advertising.

Brazil is going through dark times at present, with political uncertainty and economic gloom, but OTC has benefitted from deregulation of ingredients, pricing and chain pharmacies. With a flatlining economy, OTC sales were up nevertheless by 10.5% CAGR over the past 5 years, testament to the power of consumers and innovative marketers.

These countries and others have benefitted from well-defined OTC regulations, creating a more favourable environment for responsible self-medication. Standards of public health improve, there are fewer sales of the so-called "under-the-counter" medicines, jobs are created in factories and pharmacies, and the cost to the economy in lost production through minor illnesses is reduced.

In summary, India could easily generate double-digit growth in consumer healthcare, to the advantage of the

economy and, more importantly, the Indian consumer who needs the benefits of self-care. But a mixture of restrictive practices on the part of the retail pharmacy sector, which has limited the growth of chemist chains and e-commerce; a Ministry of Health that has held back almost all the switches that crowned other Asian markets; the fragmented nature of distribution; India's complexity; and a certain timidity on the part of marketers, has kept the growth rates below 10%. India's extremely low prices are also a disincentive for local and foreign players to invest in the market.

It has been my privilege to work in the OTC industry for over 45 years, and to visit India for the past quarter century. It is with the greatest satisfaction that the co-operation with my friends at CubeX and Havas Life Sorento continues to grow each year. Between us we have so many years of observing and influencing the trends in consumer healthcare in global and local markets.

I am passionate about the need for India to embrace the concept of responsible self-medication fully. There is nothing stopping India from maximising this value with a more favourable regulatory regime. I live in hopes! ▶

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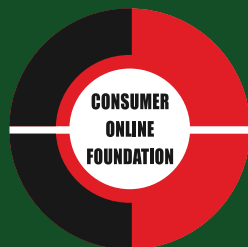
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