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A STUDY OF OTC DRUGS IN INDIA AND REGULATIONS GOVERNING THEM

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ABSTRACT

To convert a Rx to an Over-the-counter version, the drug must have some intrinsic characteristics that make it suitable for self-medication. Although definitions vary by country, the prescription to Over the counter-switch refers to the conversion of established Rx to OTC classification and done in scenario where the drug must have an extremely high safety limit, it is used in clearly defined circumstances, simple to use, the drug's use potentially hazardous conditions are not be concealed. The pandemic of COVID-19 had a vital effect on the market. India's manufacturers depend largely on Chinese imports of active pharmaceutical ingredients (APIs). The lockdown slowed API output, resulting in less accessibility and more material prices for the products. Due to the huge demand for necessary OTC medications, the government limited the export of some essential medicines. Aside from OTC pain relievers and fever reducer paracetamol, medicines restricted for export include metronidazole and other components containing vitamin B1 and B12 as well as antibiotics used to treat bacterial and other diseases. On the other side, online purchases of over-the-counter medications have increased. For example, in April 2020, the Andhra Pradesh Medical and Health Department introduced 'Covid Pharma,' a mobile application to monitor people who buy medicines Over the counter (OTC). This study focused on OTC drug products, their present status and regulations.

Keywords: Switching, OTC, Rx, DNCE, DNRD, Medications

INTRODUCTION:

Historical background

- In 1860s the preparations of remedies at home were replaced by purchasing of medicines.
- 1905s the market of the patent drugs was at its peak.
- 1920s due to intense economic and political struggle changed preferences care, resulted in decline in public demand and use of patient medicines.
- The Food, Drug, and Cosmetic Act (FD&C) of 1938 granted the FDA some regulatory authority, but it did not specify which medications could only be purchased with a prescription and which could be purchased without one.
- In 1951, FD&C Act was amended to explain the distinction between Over the counter and Rx drugs and to address drug concerns about safety.

Over the counter medications were required to be both effective and safe, according to a 1962 amendment to the FD&C Act. What works for one person may not work for the other, and any medication may produce unwanted side effects (also called adverse effects, adverse events, or adverse drug reactions). Until 2007, when a new law was enacted requiring companies to report significant adverse events associated with OTC Drugs, In the United States, there was no formal mechanism in place for reporting Over the counter medication side effects.

Over the counter products are regularly available to consumers without the requirement of a doctor's prescription. Most OTC Drugs are approved by the regulatory body and contain ingredients that are safe and effective when used without the guidance of a medical professional. Common disorders such as frequent headaches, allergies, the common cold, constipation, backache, acidity, and chronic fatigue can be treated without observation of physician in everyday life **[1]**.

In general, OTC medications fall into two groups:

I. Since their introduction, the first group of OTC medicines has always been categorized as non-prescription drugs.

II. The second group of OTC medicines began as RX medications but were later converted to OTC medications.

WHO states that a product must be sold as a prescription drug for at least five years before it can be considered an OTC medicine. Every country has a different time frame for switching from Rx to OTC drugs.

Table 1: classification of OTC products

OTC Drug Classes	**Acne medications, analgesics** **Bronchodilators & antihistamines** **Cold remedies, contraceptives & vaginal products** **Dandruff & athlete's feet, dentifrices & dental products** **Emetics & antiemetics** **Laxatives** **Ophthalmic** **Stimulants, sleep aids, sunburn treatments & sunscreens** **Vitamins & minerals**

https://www4.uwsp.edu/psych/s/290/drug-OTC.doc

India

- The Drug Consultative Committee of India declared in November 2016 that it was setting up a drug definition that could be dispensed without a prescription. Prior to this, it was widely assumed that any drug that did not fit into a prescription schedule could be acquired without a prescription. However, by early 2018, the relevant definition had not been passed. Due to the lack of a legal definition for OTC Drugs, this $4 billion market segment is unregulated.
- Rural and modern India places a greater emphasis on self-medication in treating minor ailments, whereas Europeans rely on the advice of their local pharmacist, and North Americans rely more on the advice of physicians. Opportunities exist in countries with growing healthcare infrastructures and economies to reduce the significant strain on doctors while also assisting governments in reducing their healthcare expenditure **[2]**.

DEFINITION OF RX TO OTC SWITCH

To convert a Rx to an Over-the-counter version, the drug must have some intrinsic characteristics that make it suitable for self-medication. Although definitions vary by country, the prescription to Over-the-counter switch refers to the conversion of established Rx to OTC classification. These are, in general, as follows:

1. The drug must have an extremely high safety limit.
2. The drug must only be used for clearly defined circumstances.
3. The medication must be simple to use.
4. The drug's use potentially hazardous conditions must not be concealed.

- The USFDA has clearly outlined the regulations for converting the condition of a drug from prescription to nonprescription. The drug's status is modified based on the drug's safety and information on the label detailing the pros and cons of the drug product when used without a prescription from a health

professional. The sponsor conducts labelling comprehension tests, with the main study endpoint being self-recognition of the condition. The FDA's Division of Non-prescription Regulation Development **(DNRD)** and Division of Non-prescription Clinical Development **(DNCE)** are responsible for updating monographs and handling NDAs regarding OTC Drug products, respectively.

- Finally, OTC has no legal recognition in India, drugs that are not part of Rx-only drugs are considered OTC drugs. There is no well-documented procedure or specific regulation in India for switching from Rx to OTC products. Many countries around the world have a formal procedure for transforming Rx to OTC status. Indian authorities will eventually need to formally list the Over the counter as a category, as switching will be one of the most common strategies used by global players to join OTC.
- A new investigational product's clinical trial period noticed a rise in the number of individuals being evaluated is far lower than the actual population that will be subjected to after marketing begins. Consequently, following a new product's initial registration, whereas Clinical evidence currently available may confirm the product's safety and efficacy, it is always prudent to carefully monitor the drug's usage in the actual patient community. Therefore, regulatory authorities generally prefer to be extra cautious when it comes to making a new product available only by prescription.
- Self-administration of treatment with OTC medications depends on the patient's judgement, including details on the label, for accurate diagnosis of disorder or symptom. An over-the-counter medication may be used because of a false diagnosis even though it is ineffective at addressing the underlying problem. In general, the risks associated with a misdiagnosis include both the possible negative effects of the medication when used inappropriately and the risks related to not treating the true cause of the symptoms.
- Although the **Pharmaceutical company** benefits the most from an OTC transition, independent health insurance providers are also permitted to drive the switch in some countries. Patients are reimbursed for medication costs by private insurers in nations such as the United States. Thus, when a popular, secure, and efficient Rx drug becomes OTC, the insurance is no longer responsible. Therefore, Rx to OTC modifications have been supported by several insurers **[3] [4]**.

INDIA OTC MARKET SCENARIO

- The pandemic of COVID-19 had a vital

effect on the market. For example, India's manufacturers depend largely on Chinese imports of active Pharmaceutical ingredients (APIs). The lockdown slowed API output, resulting in less accessibility and more material prices for the products. Due to the huge demand for necessary OTC medications, the government limited the export of some essential medicines. Aside from OTC pain relievers and fever reducer paracetamol, medicines restricted for export include metronidazole and other components containing vitamin B1 and B12 as well as antibiotics used to treat bacterial and other diseases.

- On the other side, online purchases of over-the-counter medications have increased. For example, in April 2020, the Andhra Pradesh Medical and Health Department introduced 'Covid Pharma,' a mobile application to monitor people who buy medicines Over the counter (OTC).
- According to the MDPI report 2022, the incidence of self-medication in India is approximately 44.9**%**. Self-medication is most common in middle-lower-class families, with an incidence rate of 26.31**%**.
- **Hamdard Laboratories** released 12 OTC boosting immunity products in January 2021. Antacids, cough and cold remedies, laxatives, analgesics, vitamins, and allergy products are frequently used as medicinal products in India.
- Menstrual cramps and musculoskeletal injuries, as well as other musculoskeletal problems, are frequently treated and managed with over-the-counter painkillers. As reported by the Interventional Pain and Spine Centre (IPSC), 19**%** of the Indian adult community suffers from chronic pain in some form, with females having a 25**%** prevalence. Nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen such as aspirin, naproxen, and ibuprofen are the mostly used Over the counter analgesics in India **[5]**.

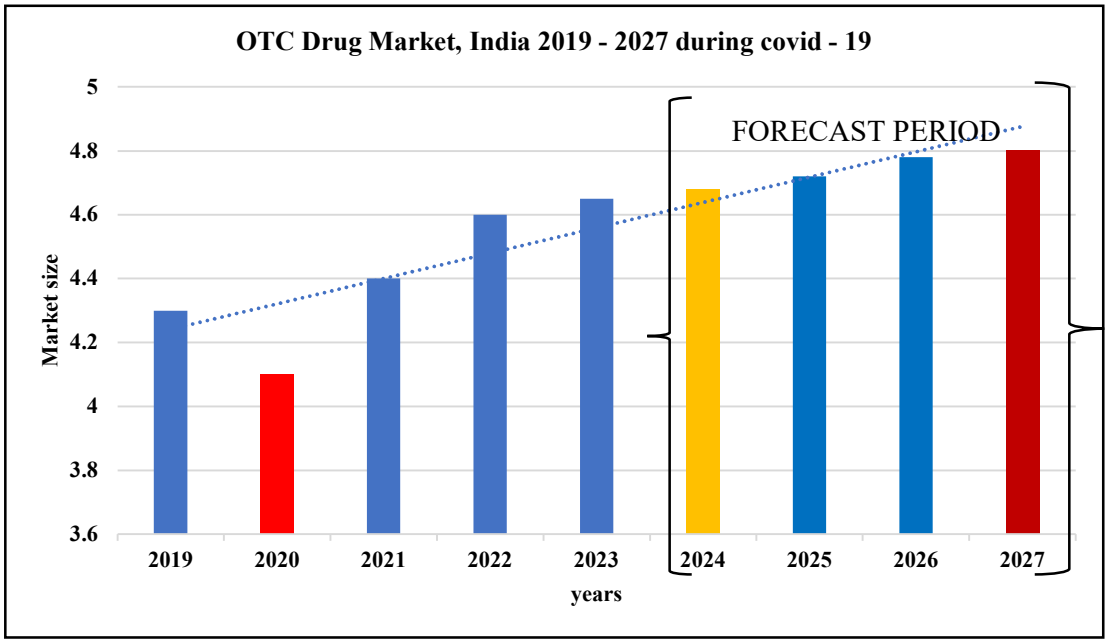

Figure 1
Source: Mordor intelligence

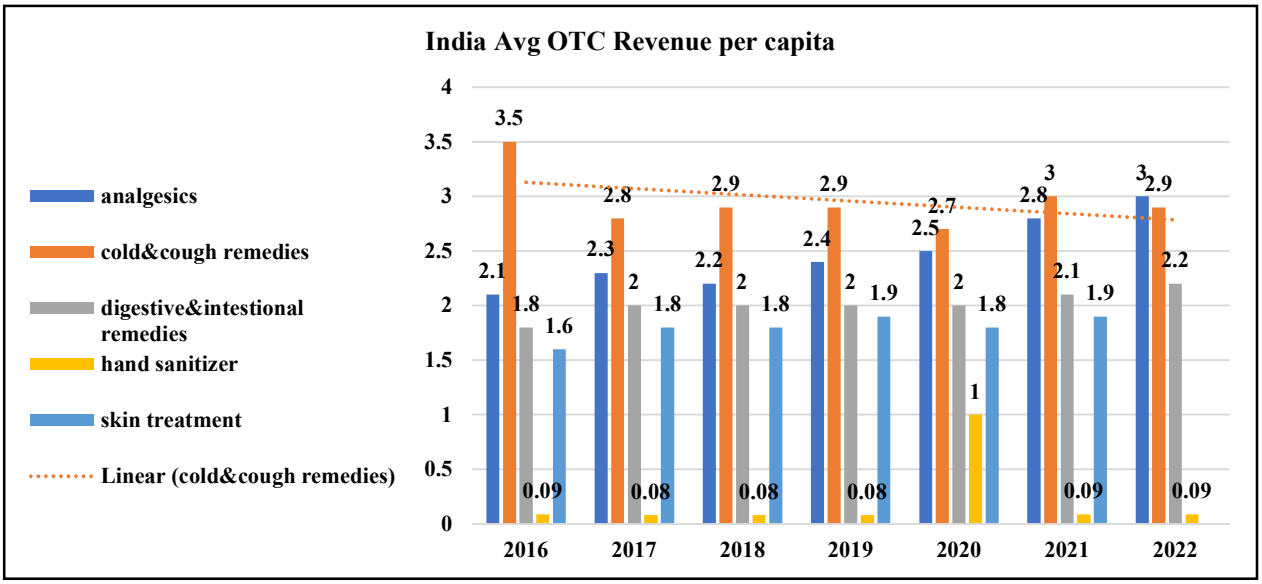

Figure 2
https://www.statista.com/outlook/cmo/otc-Pharmaceuticals/India

Market Dynamics

In accordance with an article named "Prevalence and Pattern of Antibiotic Self-Medication Practice in an Urban Population of Kerala, India: A Cross Sectional Study" that was published by NCBI in 2019.

- 3.8% of graduates and 8.5% of skilled employees used antibiotics for self-medication.
- 25% of participants consumed sore tongue medication, 22% fever medication, and 14% cough medication.

Self-medication is prevalent rate in India was 53.5%, according to research titled "prevalence and predictors of self-medication practices in India: a systematic and meta-analysis" that was released in an open access journal in August 2020 **[5]**.

Drivers and Restraints India

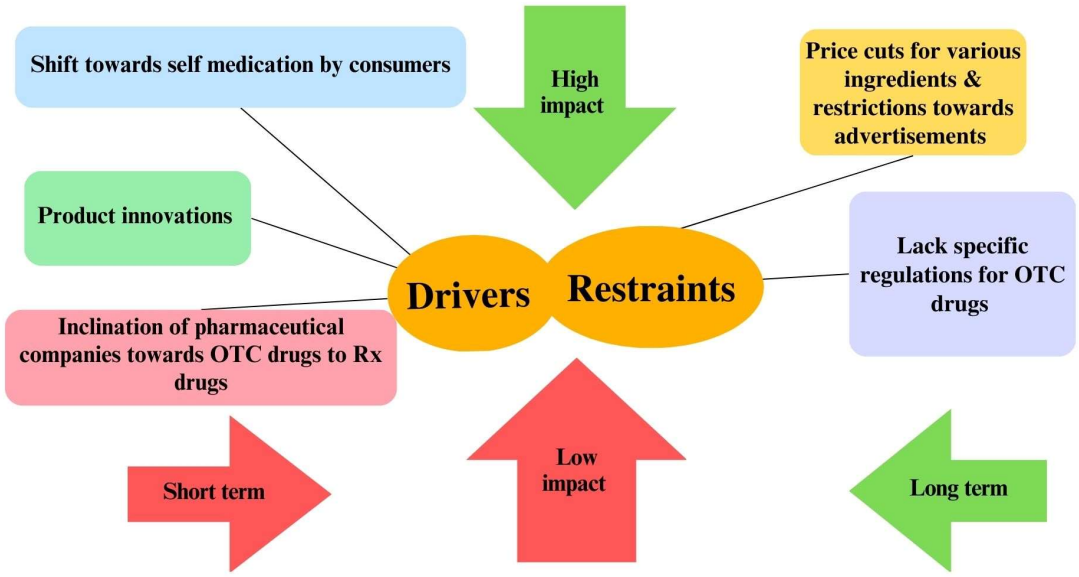

Figure 3: India OTC Market Analysis - Industry Report - Trends, Size & Share (mordorintelligence.com)

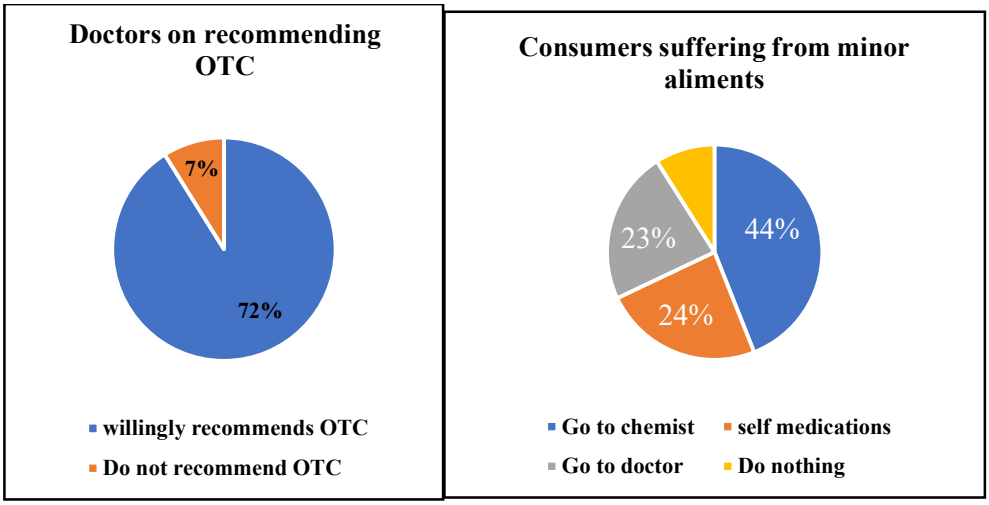

Figure 4
Source: OPPI and IMS consulting group (OTC Final Frontier by Nicholas Hall)

Population of usage in India

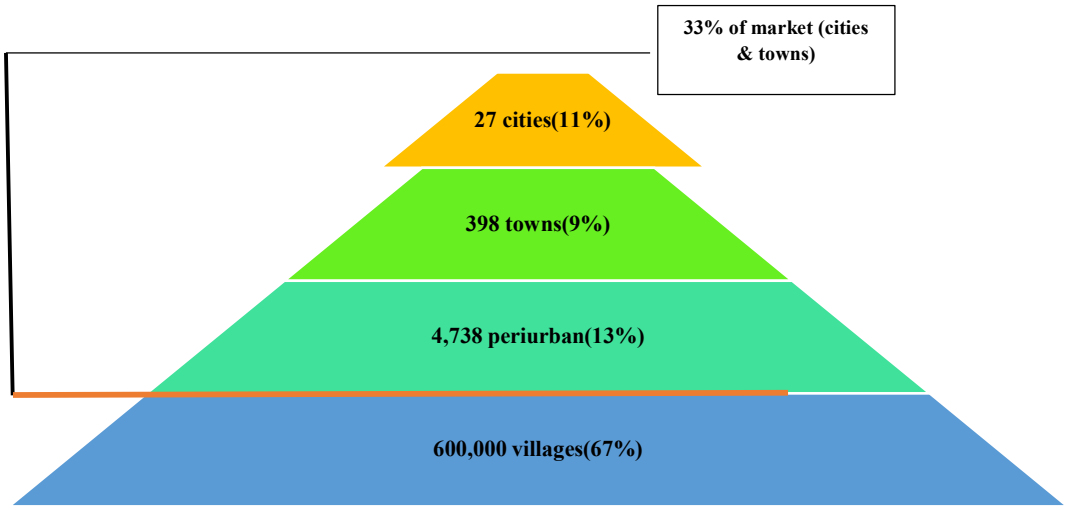

Figure 5
OTC-drug-market-future-growth-driver-for-ipm-65013456

Lack of specific Regulations for OTC Drugs

- Currently industry lacks a strong regulatory framework due to which numerous OTC medications have been recalled in various markets. According to Indian law, OTC medicines are not covered by the D&C act of 1940.The CDSCO intends to establish a strong regulatory structure for over-the-counter medications that will support policies.
- The Drug Technical Advisory Board authorized a list of OTC Drugs in January 2022, including analgesics, antifungals, cough syrups, and decongestants, antiseptic that will be sold without a prescription **[6]**.

Drug name and Therapeutic category of OTC

Table 2

Drug Name	Therapeutic category
Diclofenac ointment/cream/gel 10 mg of diclofenac sodium	Analgesic
Clotrimazole dusting powder 1%w/w	Antifungal
Dextromethorphan hydrobromide lozenges 5mg	Cough
Povidone Iodine solution 5% w/v	Antiseptic

https://thehealthmaster.com/2022/05/28/govt-draft-notification-to-add-16-drugs-as-otc-under-schedule-k-of-drugs-rules/

Prevalence Percentages of headache segments in India

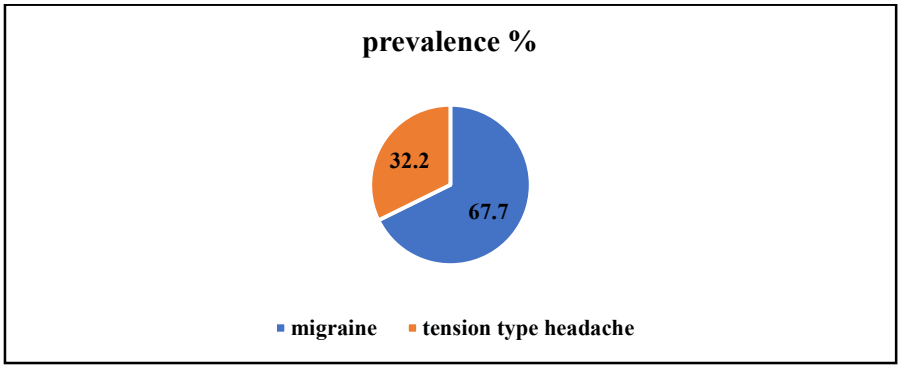

Figure 6
India Over the counter (OTC) Drugs Market Size, Share 2023-2028 (imarcgroup.com)

By product segmentation

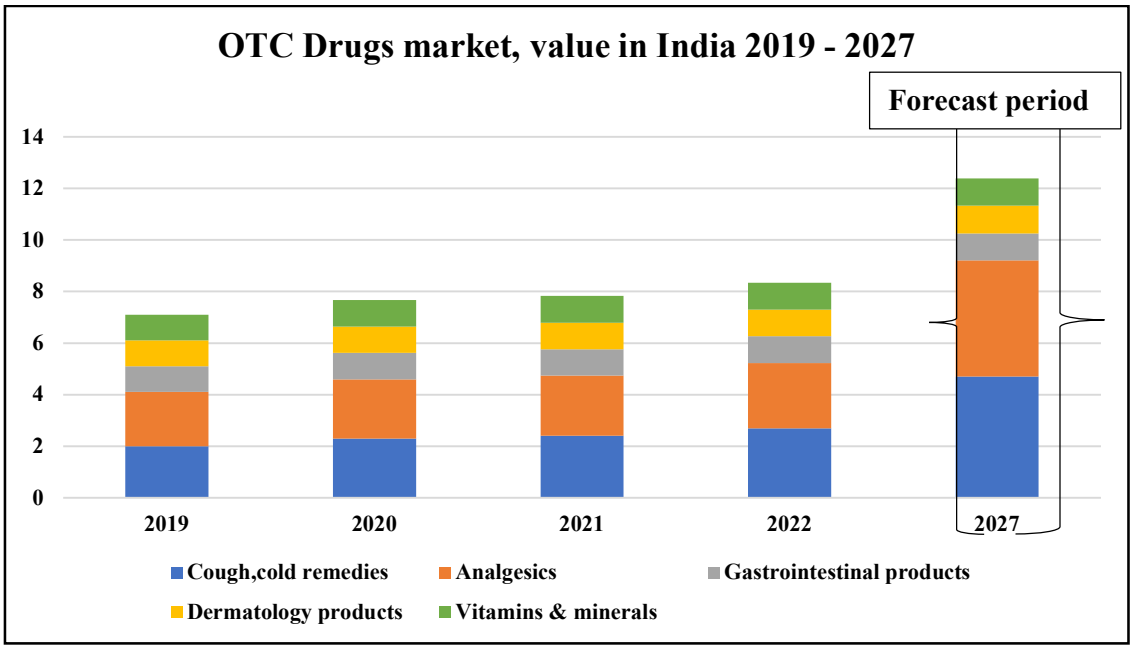

Figure 7
Source: Mordor Intelligence (India)

India OTC Market Recent Developments

- The top OTC products available in India include Dabur Honitus lozenges, cough syrups, Vicks VapoRub, Zandu balm, Iodex, Moov, cough drops, and lozenges. One of India's most significant economic sectors is the Pharmaceutical industry, which exports $15 billion worth of goods each year and boasts some of the world's best manufacturers.
- OTC and prescription medicines are India's second-largest export to the US.
- Bayer announced its intention to join India's OTC Drug market in June 2022. Bayer's consumer health business in India, which recently introduced the new product

Saridon Advance for severe headaches, is scheduled to introduce another product in the nutrition category in July, according to the company.

- The Union Government suggested in May 2022 to alter the law to introduce OTC drugs into India to the Drugs and Cosmetics Rules, enabling their retail sale without a medical prescription.
- As a result of the development of technology and marketing, higher levels of workplace stress, and rising health awareness, urban India has picked up with the idea of OTC drugs.
- A few FMCG companies, including Hindustan Unliver and P&G, are expanding their markets by joining the OTC space and reaching previously inaccessible regions. Pharmacies' inability to reach the country's outlying areas is one of the primary challenges they face.
- India's Pharmaceutical sector makes up around 2.5**%** of the global Pharmaceutical market in terms of value and 10**%** in terms of volume.
- Continuous improvement innovation and rising investments in substantial (R&D) efforts drive the industry even further. Other factors affecting the marketplace involve rising disposable income levels among the public, growing stress levels among working professionals, and rising health consciousness among many citizens.
- In April 2020, **Cipla Health** will transport over-the-counter wellness products to customers' homes in India in collaboration with Zomato, Swiggy, and Dunzo.
- The launch of a novel nasal decongestant portfolio in India under the Otrivin brand was announced by **GSK** Consumer Healthcare in December 2020. Additionally launched was **Otrivin** Breathe Clean Daily Nasal Wash **[6]**.

Table 3

India OTC Market Top Players	**1. Emani limited** **2. Dabur India limited** **3. Procter & gamble** **4. Abbott laboratories** **5. GlaxoSmithKline** **6. Cipla** **7. Sun Pharmaceuticals Limited** **8. Johnson & Johnson**

https://business.mapsofIndia.com/fmcg/over-the-counter.html

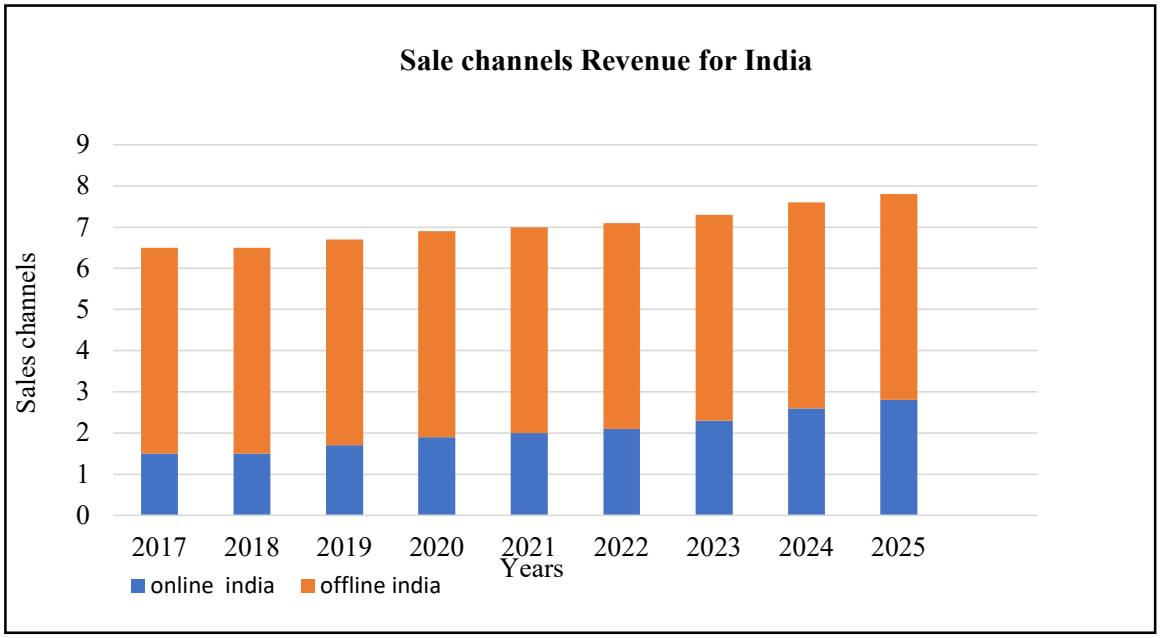

Figure 8
https://www.statista.com/outlook/cmo/otc-Pharmaceuticals/India#sales-channels

Competitive landscape – JOHNSON & JOHNSON SERVICES INC

- Sales of USD 5,277 million were generated by the company's OTC counter segment in 2021, a rise of 8.4% from FY2020.
- Analgesics like Tylenol and Motrin, as well as products that promote hydration, (ORSL)were primarily responsible for the growth.

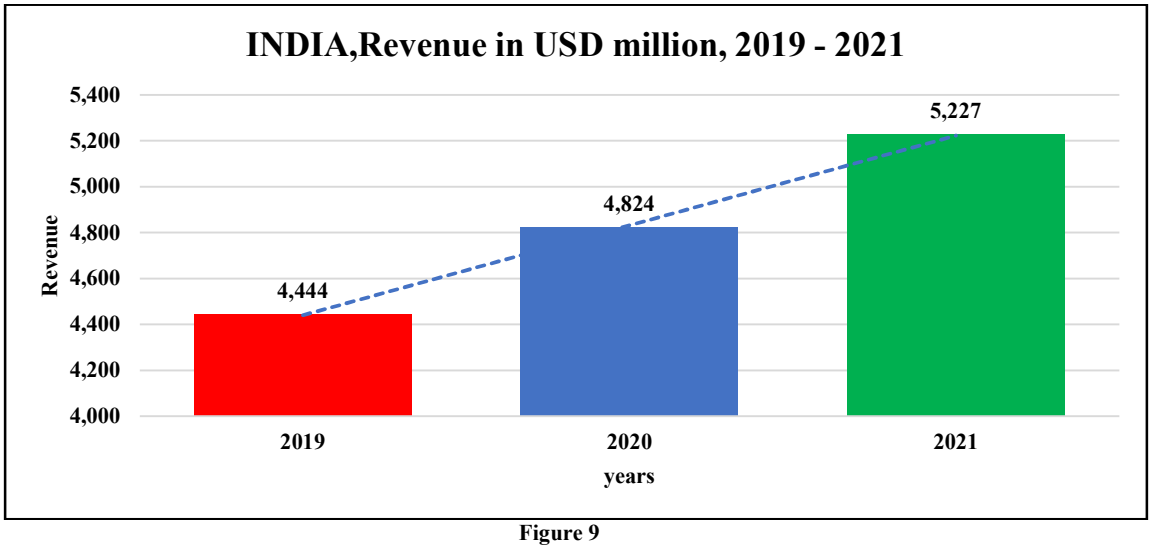

Figure 9
Source: company website, annual and quarterly Reports

Top supplier of over-the-counter medications – J&J

Table 4

Drug name	Drug class	Therapeutic uses
Tylenol	analgesics	pain reliever, fever reducer, arthritis
Sudafed	Upper respiratory	signals in the brain that trigger cough reflex
Benadryl	Upper respiratory	nose stuffiness
Zyrtec	Antihistamines	itching and swelling caused by chronic urticaria (hives)
Motrin IB	NSAIDS	inflammation caused by many conditions such as toothache, arthritis, menstrual cramps, or minor injury

https://www.drugs.com/mtm/pepcid-complete.html#uses

Growth Drivers for OTC Drug Market in India

- Rising popularity of self-treatment for minor illnesses.
- Products are offered at pharmacies and large supermarkets.
- Urban India is beginning to catch up with idea of over-the-counter medications since the development of technology and ads, high levels of workplace stress, and rising health awareness.
- The government and several Pharmaceutical firms are leading numerous programs to increase understanding of various medications and switch prescription to OTC **[7]**.

Opportunities & challenges of OTC medications

Table 5

Opportunities	Challenges
1. Consumers have more flexibility with less restrictive price controls. 2. OTC items are becoming more widely perceived as FMCG goods. 3. An excellent option for successfully promoting OTC brands in fragmented media.	1. Benefit-based product differentiation must become ingrained in customers' minds. 2. To make their product line more accessible to the public, OTC merchants in India need to review their pricing strategies. 3. An excessive number of firms are entering the market, with fierce rivalry

Source: OPPI 46th Annual report

SWITCHING IN INDIA FROM Rx TO OTC

- Numerous Rx goods could be revitalised in India using OTC switches. The emphasis is on NSAIDs, antacids, antipyretics, cough and cold remedies, and vitamins as potential areas for switch in India, according to an analytical interpretation of different data.
- India lacks a clearly defined procedure or law that addresses switches from Rx drugs to OTC Products,despite the fact that these things are urgently needed.
- The "Rx-to-OTC switch" is a formal procedure that many nations use to convert Rx to OTC classification.
- By enhancing the most affordable

form of healthcare with OTC medications, the Rx to OTC switching is also viewed as an effective method to lower healthcare costs in these markets.

- In India, regulators should explicitly define Over the counter as a category in order to promote market access. In reality, switching will likely become one of new players' most popular methods of entering OTC in future **[4]**.

SWITCHING PROCESS IN INDIA

The shift in consumer attitudes towards self-medication, product changes, and Pharmaceutical companies' propensity towards OTC drugs from prescription (RX) drugs are the main reasons propelling the growth of the Indian OTC drugs market.

Apart from these regulations, OTC products can be categorized into:

1. True OTC products are released to the market and promoted in the media.
2. Rx drugs changed into over-the-counter drugs that are bought as OTC-OTx drugs **[2]**.

Current regulation for OTC products in India

Table 6

Legal Recognition	**There is no clear formal recognition. Products listed in schedules H, G, X, which do not require a prescription but must be labelled as such, and schedule K are regarded as non-prescriptions.**
Drug registration	**Prior to applying for the transition to OTC, the product must have a valid prescription.**
Criteria for acceptance	**Stability information for the plant's three validation batches that were approved for good manufacturing practises.**

https://innovareacademics.in/journals/index.php/ajpcr/article/view/42393/25291

- Schedule K of the Drug and Cosmetics Act and its Rules contains potential OTC drugs such as paracetamol, liquid paraffin, eucalyptus oil, tincture iodine, and various formulations for the treatment of cough and cold.
- For instance, even though topical diclofenac is present in schedule H, it is not a medication in that schedule. Aspirin, which had previously been listed on the Schedule K list of home medicines, was made illegal to purchase without a prescription in Delhi, according to a 2015 state government announcement. This was due to a rise in deaths among dengue patients who purchased aspirin Over the counter.
- The Drugs Consultative Committee **(DCC)** has made some suggestions that have led to development. The Central Drugs Standard Control Organization **(CDSCO)** had previously proposed to include a separate schedule for OTC drugs to the D&C Act and D&C Rules to define the scope of the word "OTC."
- In India, where the doctor-to-patient

ratio is pitifully low, designating OTC drugs as a distinct class can increase access to safe medications bring about clarity to regulation framework regulating those medications.

Deliberations by the DCC - *57th meeting of the DCC*

On August 20, 2019, at its 57th meeting, the DCC stated that the Ahooja Committee had given the following recommendations:

1. Assist self-care while maintaining patient safety to cut down on treatment expenses.
2. Establish the D&C Rules' description of OTC drugs.
3. Include fundamental aspects of OTC medications.
4. Regulate the switch from Rx to OTC medications.
5. Regulate the approval of *new OTC medications.*
6. *Regulate the advertisement, distribution, and sale of OTC medications.*

Initially drafting any amendments to the D&C Rules, the Ahooja Committee must first name the OTC medications. In contrast to the long overdue amendment of the Drugs & cosmetic Act, the government has been aggressively amending the D&C Rules.

Labelling criteria

- Labeling is crucial for over-the-counter medicines. It provides consumers with important drug information, and the content should be easy to understand. According to Rule 95 of the D&C act, labels must adhere to the requirements.
- The most important characteristics of over-the-counter medications will also be modified, and they will be classified as OTC-1 and OTC-2 based on safety, therapeutic index, patient accessibility requirements, availability, non-addictive nature, supply chain mechanism, and sociodemographic conditions of the nation. Along with the definition and rules for advertising, these changes will be made **[8]**.

List of drugs switched from Rx to OTC switch in the recent past year in India

Table 7

Name of drug /API	Therapeutic indication	Approval date
Oxytrol 3.9 mg/Oxybutynin	Overactive bladder	25 Jan 2013
Nasacort Allergy HR (nasal spray)/Triamcinolone acetonide	Allergic rhinitis	11 Oct 2013
Allegra 30, 60, or 180 mg/ Fexofenadine hydrochloride	Antihistamines	25 Jan 2011
Prevacid 24 HR 15 and 30 mg/ Lansoprazole	Proton pump inhibitor / acid reducer	18 May 2009
Zegerid OTC 20 mg/ Sodium Bicarbonate	Proton pump inhibitor / acid reducer	12 Jan 2009
Zyrtec allergy and Zyrtec syrup & chewable tablets for children's 10 mg/ Cetirizine HCI	Antihistamines	16 Nov 2007
Lamisil derma gel 1 %/ Terbinafine	Topical antifungal	24 July 2006
MiraLAX 17g/ Polyethylene glycol 3350	Laxative	10 June 2006

https://www.researchgate.net/figure/List-of-drugs-switched-from-Rx-to-OTC-switch-in-the-_recent-past-years_tbl1_309730845

Case history: Allegra Rx to OTC switch

- Fexofenadine HCl, an active ingredient in Allegra, has been demonstrated to interfere with the injection of histamine's H1-mediated function in causing skin wheal and flare in a dosage-dependent way, with the 40 mg bid dose being the lowest effective dose. Four randomized, double-blind, placebo-controlled trials involving participants with seasonal allergic rhinitis were conducted.
- 60 mg twice daily of fexofenadine hydrochloride minimizes overall symptoms in three trials when compared to placebo. After the initial 60 mg dose, a statistically significant decrease in symptoms was seen, and the impact persisted for the full 12-hour period. For subjects with ragweed pollen allergies, the onset of action for fexofenadine HCl was noticed 60 min after a single 60 mg or 120 mg dose was given, as opposed to 100 min for this allergen is exposed in an environmental exposure unit through placebo.
- When compared to a placebo, fexofenadine 60 mg substantially reduced all symptoms in patients with perennial allergic rhinitis aged 12-78 (n=668). The study showed no sign of carcinogenicity. On January 25, 2011, Allegra was finally converted to an OTC drug **[2]**.

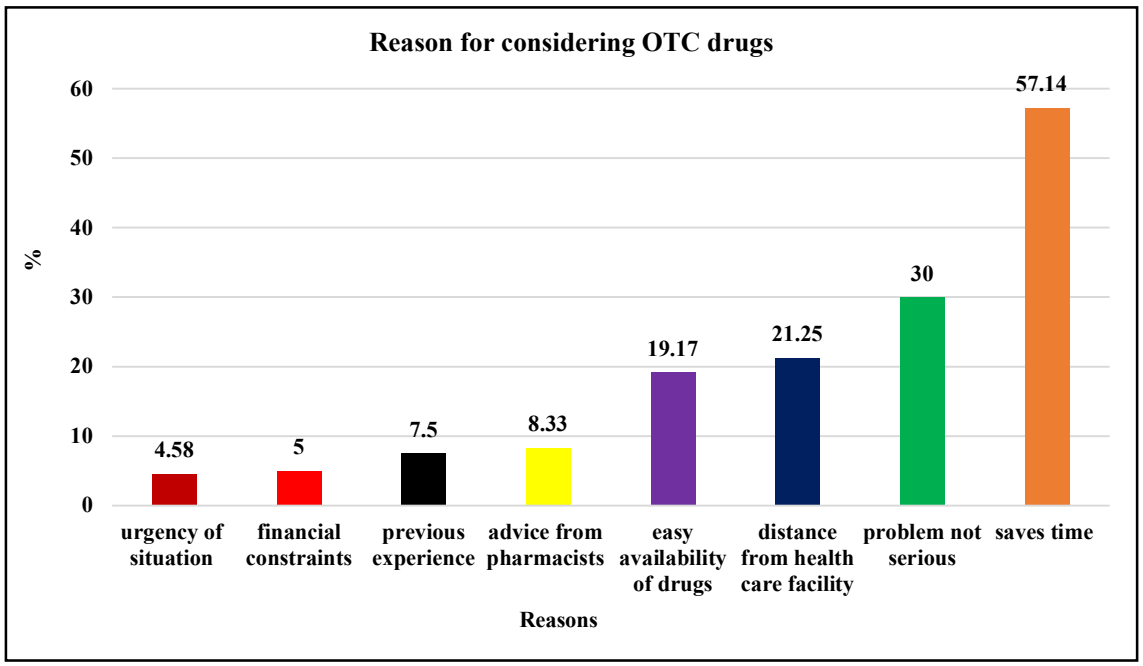

Figure 10

https://www.cureus.com/articles/126621-prevalence-pattern-and-reasons-for-self- medication- a-community-based-cross-sectional-study-from-central-India#!/

- Self-medication is defined by the WHO as either the continuous use of Rx Pharmaceuticals for chronic sickness, or the use of medications to treat self-diagnosed disorders. Additionally, it covers the administration of family members' drugs, particularly while caring for young children or the elderly.

OTC Policy – India

1. The Organization of Pharmaceutical Producers (OPPI) of India conducted a study on India. The crucial role of OTC medicines in maintaining viability in the most remote places has long been disregarded in discussions about "access to medicines in India." **A Vaidheesh**, President-OPPI and MD India & VP - South Asia, Glaxo SmithKline Pharmaceuticals, stated that the already A well-regulated OTC guideline will improve patient access.
2. The 2018 OTC Policy in India is an example of the Pharmaceutical industry's collective endeavor to enable people to make responsible choices and self-manage their health results. This policy emphasized that it was important for fundamental factors like quality, safety, and efficacy criteria to stay the also for "Prescription" medications **[9]**.

CONCLUSION

As a result, to conclude OTC medication plays a vital role in day-to-day life. According to the Report, Cough and cold remedies occupies half of worldwide Market. Due to Covid – 19 era most of population is dependent on self – medication instead of visiting hospitals and pharmacy. There is an increase in demand for e-commerce sites as compared to offline channels. Analgesics are the most used medication for geriatric as well as adult population. Prevalence rate is more in United States followed by Europe and India. India is under development phase due to lack of proper OTC regulation. Pharmaceutical companies focus on pricing strategy, target of audience with diseases, safety, and efficacy guidelines. In OTC drug marketing point of view, consumer and customer are same. The demand for OTC medications is steady and they have the features of everyday commodities. Additionally, even though OTC medications are distinguished by high brand loyalty in comparison to other consumer items, merchants have a great sales record and are anticipated to increase the availability of their private labels in markets in the future. Labeling of OTC medication should be clearly visible, easily understandable, easily accessible for uneducated populations. Cost-effectiveness of OTC medications and self-medication is another significant factor driving market expansion. 50**%** of physicians believe that Medicare and insurance coverage should be included for

OTC medications. For instance, use of antacids (Maalox) instead of pantoprazole for moderate stomach upsets, which improves health satisfaction. It is preferable to use technology to accelerate the expansion of OTC medicinal products.

Rx-to-OTC switchovers have significant potential for economic rewards in addition to benefits for health. To estimate cost reductions from switching from Rx to OTC drugs, policymakers rely on economic models. The switching process helps manufacturers recover lost revenue from prescription sales. It is important to educate the public on drug product labelling, abuse, and misuse of Rx to OTC medications. These initiatives would prevent people from using substandard and fake products to treat minor ailments, which could endanger their health. The government should enforce regulations stating that only licensed people should offer OTC products.

REFERNCES

[1] Lynch SS. Overview of over-the-counter drugs - drugs [Internet]. MSD Manuals; 2023 [cited 2023 May 11]. Available from: https://www.msdmanuals.com/en-in/home/drugs/over-the-counter-drugs/overview-of-over-the-counter-drugs#:~:text=At%20one%20time%2C%20most%20drugs,products%20without%20notification%20to%20users.

[2] G Meghana, Swetha K Sreegreeshma, Reddy J Ravikumar, Raju K Venkateswara. Review of regulations governing switching drugs from RX to Over the counter in the USA, India, and EU. Asian Journal of Pharmaceutical and Clinical Research. 2021;12–9.

[3] Over-the-counter drug [Internet]. Wikipedia. Wikimedia Foundation; 2023 [cited 2023Apr18]. Available from: https://en.wikipedia.org/wiki/Over-the-counter_drug.

[4] Switching drugs from RX to OTC Status – A Regulatory Perspective [Internet]. [cited 2023Apr16]. Available from: https://www.researchgate.net/publication/312175214_Switching_Drugs_from_Rx_to_OTC_status_-_A_Regulatory_Perspective.

[5] India Over the counter (OTC) drugs market size, share 2023-2028 [Internet]. India Over the counter Drugs Market Size, Share 2023-2028. [cited 2023Apr18]. Available from: https://www.imarcgroup.com/India-over-the-counter-drugs-market.

[6] O. T. C. Market in India [Internet]. Maps Of India. [cited 2023Apr18].

Available from: https://business.mapsofIndia.com/fmcg/over-the-counter.html.

[7] India OTC market size & share analysis - industry research report - growth trends [Internet]. India OTC Market Size & Share Analysis - Industry Research Report - Growth Trends. [cited 2023Apr18]. Available from: https://www.mordorintelligence.com/industry-reports/India-otc-drugs-market.

[8] [Internet]. [cited 2023 May 11]. Available from: https://www.complianceonline.com/articlefiles/Regulatory_Requirements_Prescription_to_OTC_Switches_USA_India.pdf.

[9] Das S. OPPI OTC Task Force releases Shaping India's OTC policy 2018 [Internet]. Express Pharma. 2018 [cited 2023Apr18]. Available from: https://www.expresspharma.in/oppi-otc-task-force-releases-shaping-Indias-otc-policy-2018/.