



Review Article

A Study on OTC products in India and Europe: Market Prospective

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ABSTRACT

India has a growing market for pharmaceutical over-the-counter medications, which indicates that the pharmaceutical industry in this nation is expanding rapidly. In the past ten years, the Indian pharmaceutical business has experienced a significant change in marketing tactics. Companies actively publicize their over-the-counter products to promote them. In contrast to Europeans who rely on their local chemist to treat small ailments, North Americans place a greater emphasis on seeking medical guidance for treating minor ailments. Only ongoing public education with a broad perspective on the good health and wellbeing of society may raise awareness of rational drug use. Compared to other consumer commodities, OTC medications have significant brand loyalty. But going forward, it is also expected that merchants with strong sales capacities will be able to boost the market presence of their own private-label goods. The government and several pharmaceutical firms are undertaking a number of programmes to raise awareness about various medications and shift Rx to OTC.

INTRODUCTION

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.

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

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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. ^[10]

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. ^[11]
- Size of the Indian Over-the-Counter Drugs Market, 2022–2027 Indian OTC drug market was valued at USD 7.62 billion in 2022, and by 2027, it is anticipated to increase to USD 18.49 billion. ^[6]
- 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%. ^[4]
- **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. ^[3] Size of the Indian Over-the-Counter Drugs Market,



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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. [4]

Drivers and Restraints India

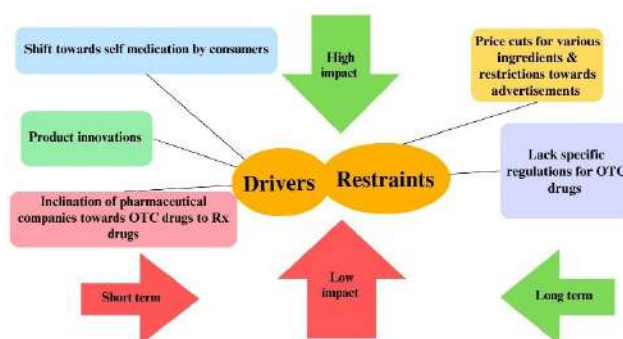


Fig no.1 India OTC Market Analysis - Industry Report - Trends, Size & Share (mordorintelligence.com)

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. [11]

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. [4]
- **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. [3]
- 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**. 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. In April 2020, **Cipla Health** will transport over-the-counter wellness products to customers' homes in India in collaboration with Zomato, Swiggy, and Dunzo. [3]

| | |
|-------------------------------------|---|
| India OTC Market Top Players | <ol style="list-style-type: none"> 1. Emani limited 2. Dabur India limited 3. Procter & gamble 4. Abbott laboratories 5. GlaxoSmithKline 6. Cipla 7. Sun Pharmaceuticals Limited 8. Johnson & Johnson |
|-------------------------------------|---|

Table no.1:

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

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. [18]

Opportunities & challenges of OTC medications

| Opportunities | Challenges |
|--|---|
| 1. Consumers have more flexibility with less restrictive price controls. | 1. Benefit-based product differentiation must become ingrained in customers' minds. |
| 2. OTC items are | |



| | |
|---|--|
| <p>becoming more widely perceived as FMCG goods.</p> <p>3. An excellent option for successfully promoting OTC brands in fragmented media.</p> | <p>2. To make their product line more accessible to the public, OTC merchants in India need to review their pricing strategies.</p> <p>3. An excessive number of firms are entering the market, with fierce rivalry.</p> |
|---|--|

Table no.2: Source: OPPI 46th Annual report 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.

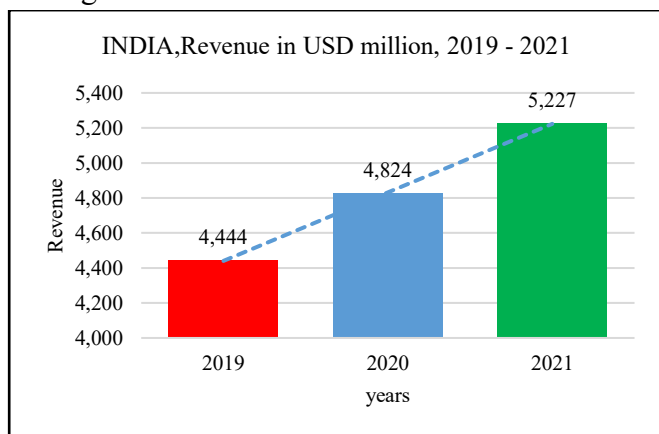


Fig no.2: Source: company website, annual and quarterly Reports

Company Highlights - Consumer Healthcare creates, manufactures, and sells a range of over-the-counter goods for things like skin care and baby care. These goods are promoted to the public and sold online (E-commerce), as well as through retail outlets and distributors worldwide. [8]

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

| Drug name | Drug class | Therapeutic uses |
|-----------|------------|---|
| Tylenol | Analgesics | pain reliever, fever reducer, arthritis |

| | | |
|-----------|-------------------|--|
| Sudafed | Upper respiratory | signals in the brain that trigger cough reflex |
| 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 |

Table no.3:

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

Prevalence of headache in India

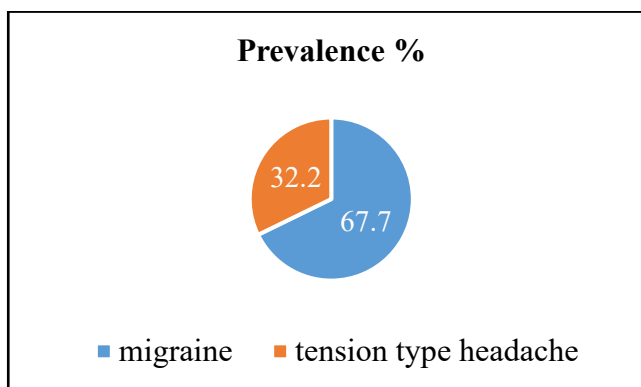


Fig no.3: India Over the counter (OTC) Drugs Market Size, Share 2023-2028 (imarcgroup.com)

Europe

- According to Article 70 (1), the European Medicines Agency (EMA) divides medicinal products into two categories: prescription medications and nonprescription medications. Nonprescription medications are classified as drugstore medicines or general sales medicines, and they are available without a prescription. Prescription medications cannot be self-selected and must be sold under the supervision of a registered pharmacist. [11]
- People purchased dietary supplements and vitamins to boost their defenses and stop COVID-19 from spreading. In accordance with a journal publication, Pharma nutrition in December 2021 titled "Dietary Supplements and Nutraceuticals Market Growth During the Coronavirus Pandemic - Implications for Consumers and Regulatory

Oversight," vitamin sales climbed by 63% in March 2020 in comparison to the same month the year before in the United Kingdom. Based on an Article from Eurostat on population structure and ageing (updated in February 2022), approximately 20.8% of individuals in the European Union in 2021 were older than 65. In 2020, this percentage grew from 20.6% of the EU's population, by 0.96%. [12]

- Finland seemed to have largest aging people of any European country, with approximately 22.7% of the individuals above the age of 65. The growing geriatric population causes an increase in health problems associated with old age. The expansion of online pharmacies, as well as the e-commerce goliaths are about to start their anticipated online pharmacy services. such as Amazon, are anticipated to fuel market expansion. Other variables influencing the market's expansion involve the rise in self-administration usage & recent innovations in products. For example, Vaneeghen introduced a mineral complex for plant-based joint wellness on the European market in May 2022. [9]

| | |
|-------------------------------------|---|
| Europe OTC Drugs Market Top Players | <ol style="list-style-type: none"> 1. AstraZeneca 2. GlaxoSmithKline 3. Bayer 4. Cardinal Health 5. Johnson & Johnson 6. Novartis |
|-------------------------------------|---|

Table no.4:

<https://www.businesswire.com/news/home/20220930005390/en/Europe-Over-the-counter-OTC-Drugs-Market-Report-2022-Increasing-Self-medication-Practices-Driving-5.4-Annual-Growth--->
ResearchAndMarkets.com

Market Dynamics

- In Europe, antihistamines, cold and cough remedies, and decongestants are the most frequently abused goods.
- Painkillers like Dopliprane and Dafalgam cannot be purchased by French citizens

directly from the shelves of pharmacies, according to the National Agency for Medicines and Health Products Safety (ANSM) 2020. Additionally, the fact that all these OTC medications are kept behind the pharmacist counter may enhance their ability to counsel patients on the risks associated with pain.

- Ibuprofen and diclofenac gel abuse is primarily detrimental to public health. Rural regions are host to 26% of Europeans. As per world bank group, in 2018, Australia and Italy have 41% and 29% of their people living in rural areas. One of the goals includes people not having access to healthcare and the beneficial effects of OTC medications. [9]

Drivers and Restraints EU

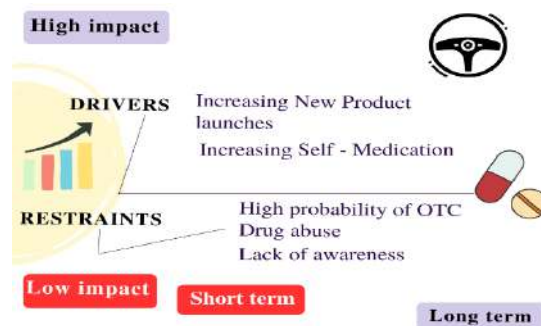


Fig no.4:

<https://www.mordorintelligence.com/industry-reports/europe-over-the-counter-otc-drugs-market-industry>

Europe OTC Drug Market Recent Developments

- To increase customer vitality and longevity, Cymbiotika opened an online shop in the United Kingdom in March 2022.
- P&G introduced its highest strength Omega-3 under the Seven Seas brand in the United Kingdom in January 2022.
- The COVID-19 pandemic also increased demand for over-the-counter medications to address the virus's typical symptoms. Although it was discovered that none of the

over-the-counter medications were able to cure viral infections, they could relieve the signs of virus infections includes cold, cough, & flu. To obtain a competitive edge, market participants frequently introduce new products. [9]

Germany

- Germany will likely see a growth in the industry because of the presence of major international players. To broaden the portfolio, for example, Euro OTC pharma of Germany and Sanat products of India announced a collaboration in March 2020.
- To expand its OTC drug business across Europe, Stada, a German company, in February 2020 acquired 15 prominent consumer health brands from GSK.
- For e.g., Comfrey-based Kytta gains with the growing desire for ecological alternatives; brand motto appears in TV advertising starting in 2020. “The power of nature against pain,” depicting a woman who had her back pain relieved by Kytta playing with her grandchildren in the wild once more.
- In October 2020, diphenhydramine and caffeine were combined with APAP Intense tablets (paracetamol 500 mg, ibuprofen 200 mg) to have a more potent analgesic impact and function for up to 8 hours.

France

- Flurbiprofen Pills' switch-back in May 2019 and the compelled shift of BTC's alpha-amylase brands in January 2020 both have an impact on this category.
- During the Covid-19 pandemic, Pharmaceutical convenience brands tended to stand up better than registered medicines because of their accessibility to the public.
- Major brands like Lysopane and Strepsils are facing increased generic rivalry.
- Ricola, a brand of medicated confectionery based on herbal extracts, leads the market due to prominent consumer promotions,

positioning for year-round freshness, and frequent line extensions as well as new flavors. [5]

Competitive Landscape – Johnson & Johnson

- In comparison to FY2020, the company's sales increased to USD 93,775.0 million in FY 2021 from USD 82,584 million. In FY 2021, consumer healthcare made a \$14,635 million contribution.
- J&J stated in November 2021 that it would split off its consumer health business segment to form a new publicly traded company. By 2023, J&J plans to shut down its Pennsylvania facility that produces OTC medications. The plant currently produces OTC Pepcid and Imodium.

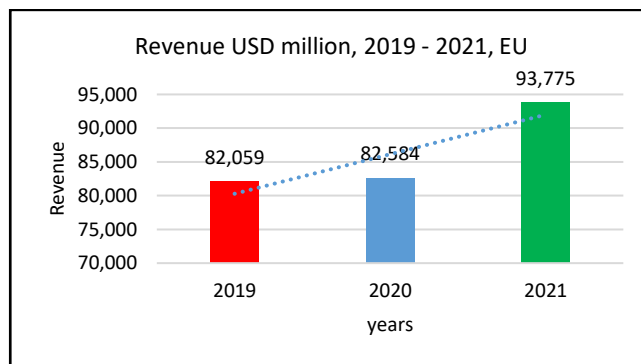


Fig no.5: Source – company website annual & quarterly Reports

Top 10 Corporations Europe Value Share & Latest Year Growth (%)

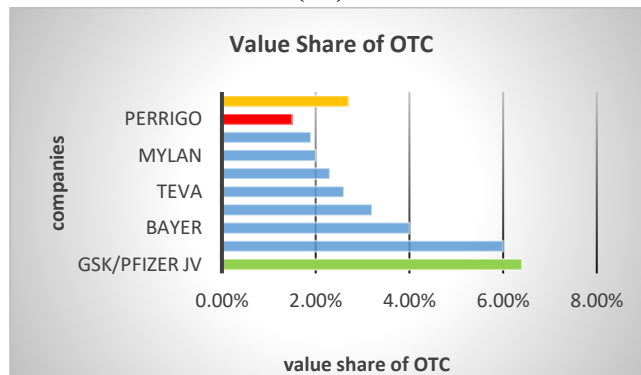


Fig no.6: IQVIA™ OTC Global Insights Key Highlights

- Bayer experienced a decrease in sales in CCR, Digestives, and Pain Relief. Supply problems in the area had an effect as well.
- Sales at RB increased due to the CCR and Pain Relief products. Nurofen, RB's top product, saw high single-digit increase.
- The main cause of JV's poor performance was GSK's company, which lagged behind market growth. ^[14]

Lifecycle Highlights

1. Participants in switching to Rx to OTC are primary emerging for R&D investments to consolidate growth in competitive and fragmented market. Allergy and respiratory have potential growth over coming decades.
2. Lifecycle management begins the moment the manufacturer submits an NDA request. While a moment approaches, Pharmaceutical producers have utilized multiple approaches to extend a product's patent protection, including providing a new delivery mechanism, altering product strengths, and adding new indications.
3. Consumer brands have endured for so long that many brand managers in the Pharmaceutical industry are in awe due to their loyal customer bases. When compared to a rival, loyal customers are willing to spend a little bit more for a reputable brand. ^[13]

Challenges

1. The development of internal OTC expertise is more successful than licensing the product to a "consumer products" company. For e.g. (Merck's acquisition of Schering-Plough and its consumer products division or Abbott's Ross Products Division).
2. The qualified sales force's leadership needs to be included in the prescription to Over-the-counter conversation due to it may affect the sales representatives' interactions with physicians. ^[19]

Advantages

1. OTC medicines are typically not eligible for reimbursement plans.
2. To secure higher sales volumes, Pharmaceutical companies typically price OTC products much lower than their prescription counterparts.
3. The consumer benefits from the lower prices of the switched product. Profits are undoubtedly lower due to the lower prices. ^[20]

SUMMARY

As a result, 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.

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