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Original Article

Dynamics of Over-the-Counter (OTC) Products in the Indian Pharmaceutical Sector

[1]DR. RAJESH KUMAR PANDEY, [2]SWETA PATIL
[1]Associate Professor & ARC, SSR IMR, Silvassa, Permanently Affiliated to SPPU, Pune, India.
[2]SSR College of Pharmacy, Silvassa, Permanently Affiliated to SPPU, Pune, India.

ABSTRACT: *The world of manufacturing is certainly the backbone of almost any economy. The Indian manufacturing sector is steadily emerging as a key pillar of the economy, contributing around 17% to GDP and targeting a rise in manufacturing's GDP share to 25% by 2035. (15) One of the premier global industries is the pharmaceutical industry. It has a wide range of scope, from over-the-counter (OTC) products to life-saving drugs to medical equipment. According to estimates made as of 2024, the OTC market in India was valued at approximately 47,000 crore (US 5.7 billion) and is expected to continue this growth path with a projected compound annual growth rate (CAGR) of about 13% until 2030. (17). The importance of the Pharma Industry can be realised from the fact that Medical Education at large includes a separate section as Pharmaceutical Education, and this premium education experience builds the base for Pharma Product manufacturing, including OTC products. The Research Article on Dynamics of OTC Products served by the Pharmaceutical Sector in Indian Context is a descriptive study conducted with the help of secondary data. The authors aim to understand the dynamics of OTC products served by the pharmaceutical sector in the Indian Context. The study further aims to gather the challenges faced by Pharma Sector Companies towards their OTC Products. The study encapsulates the domain of the pharmaceutical industry. The coverage of the industry at large and no specific study for regional dominance or a specific set of products in the OTC category form the limitations of the study.*

KEYWORDS: *Pharmaceutical, Pharma Sector in India, OTC, Pharma Marketing.*

1. INTRODUCTION

The pharmaceutical industry is one of the most significant contributors to global healthcare by developing, manufacturing, and distributing medicines for disease prevention, diagnosis, and treatment. Alongside prescription medications, Over-the-Counter (OTC) drugs have become essential in modern healthcare systems due to their ability to provide consumers cost-effective access without a physician's prescription. Commonly used over-the-counter (OTC) medications are for conditions like fever, headache, cough and cold acidity in the stomach and duodenum allergies of the respiratory tracts skin disorders or vitamin deficiencies. According to estimates, the awareness of health benefits and rising literacy rates are propelling consumers toward effective over-the-counter (OTC) medications that are increasingly easier for a user or consumer to access upon availability; this trend explains their rising acceptance [5,1,3]. The global OTC pharma market has significantly expanded over the past decade due to technological advances, liberalised regulatory legislation and increasing healthcare spending. The Rx-to-OTC switch is one of the largest contributors to this growth, as prescription medicines are selected and converted into OTC. These changes to regulations have facilitated access for consumers to safe and effective medicines by decreasing the burden on healthcare systems as well as creating new business opportunities in pharmaceutical companies [5,6,7].

India has established itself as one of the youngest and fastest-growing pharmaceutical markets in the world, a hub for cheap medicine manufacturing. The Indian OTC market is expanding rapidly owing to a rise in disposable income, increasing awareness about preventive healthcare, digital platforms for health care services, along with accessibility of organised retail pharmacies and online medicine delivery channels. As consumers are taking increasing care of their health, the demand for vitamins and minerals supplements, painkillers, oral medications (OTC), digestive system treatments, herbs and other natural substances used to treat diseases or conditions/symptoms/dysfunctions, immunity booster products, and dermatological personal hygiene medicines is increasing [3,2]. The OTC market, although increasing rapidly, faces numerous challenges pertaining to irrational self-medication with inappropriate medicine use and counterfeit products both requiring investigation of regulatory compliance, as well as misleading promotional practices in an environment gaining continuous complexity due to competition from both domestic and multinational players. These challenges can be met by effective regulatory oversight, marketing and promotion strategies, pharmacist involvement in dispensing OTC medicines, as well as consumer education to ensure that self-medication with over-the-counter (OTC) pharmaceuticals is safe and rational [5,13]. Purchasing decisions are highly influenced by product quality, price, advertising and promotion intensity, pharmacist recommendations or referrals to patients for specific products along with the brand image of a particular consumer product availability of medicine in local pharmacies awareness level among consumers about generic drugs versus their brands and prior experience using a certain type, brand, and product. This is the reason why pharmaceutical firms spend a lot more on branding, product lifecycle management strategies and digital marketing with consumer education, resulting in increased competitiveness in markets and also contributing to long-term strength of brand [3,4,9,10].

2. LITERATURE REVIEW

2.1. OTC MEDICINES AND SELF-CARE

This has made OTC medicines an integral part of today's health system as they encourage patient responsible self-medication and increase accessibility to treatment for minor ailments. The World Health Organisation (WHO) underlined that the proper use of OTC medicines enhances self-care by improving accessibility to effective treatment solutions and reducing pressure on healthcare systems. Similarly, the FDA developed broad regulations for OTC medicines intended for consumers, provided that they are safe, effective and have consistent labelling [13,14].

2.2. GROWTH OF THE OTC PHARMACEUTICAL MARKET

The OTC pharmaceutical market has expanded significantly worldwide because of increasing healthcare awareness, changing lifestyles, higher disposable income, and technological advancements. According to Lyon, the OTC sector has turned into a competitive consumer healthcare marketplace in which pharma companies innovate at every turn of the wheel to hold onto their market position. The EY Consumer Health Report also pointed out how the Indian consumer healthcare industry is poised for expansion due to the merger of pharmaceuticals with nutrition, Ayurveda and digital health care technology [1,2].

2.3. PRESCRIPTION-TO-OTC SWITCHING

The conversion of prescription medicines into OTC medicines has become an important strategy adopted by pharmaceutical companies worldwide. Chang et al. indicated that Rx-to-OTC switching enhances accessibility to medicine, promotes self-care and results in healthcare cost savings while upholding standards of safety and efficacy [5]. Strategic planning for prescription-to-OTC conversion provides an opportunity to not only optimise profitability but also comply with regulatory requirements and thus be beneficial for pharmaceutical companies, as pointed out by Fruchter and Mantrala [6]. Creyer et al. further explained that successful OTC switching requires effective product labelling, consumer education, and ethical marketing practices to ensure safe medicine use **[7]**. Similar observations regarding Rx-to-OTC market opportunities have also been reported by Lubrizol and Dadhich in their studies on OTC marketing strategies **[8]**.

2.4. CONSUMER BEHAVIOUR TOWARDS OTC PRODUCTS

Consumer behaviour is one of the major determinants of OTC product success. Cheriyan and Tamilarasi found that consumer awareness, product accessibility, convenience, pharmacist recommendations, and previous experience significantly influence OTC purchasing decisions **[9]**. Almrafee reported that product quality, pricing, promotional activities, distribution channels, and pharmacist counselling positively affect consumer purchase decisions for OTC medicines **[11]**. Haramiova et al. observed that customer expectations, trust, medicine availability, and satisfaction influence repeat purchases of prescription and OTC medicines **[12]**.

2.5. PHARMACEUTICAL BRANDING AND MARKETING

Brand awareness plays an important role in pharmaceutical marketing because consumers generally associate established brands with higher product quality and safety. Srivastava and Kumar demonstrated that pharmaceutical brand awareness positively influences consumer confidence, purchase intention, and brand loyalty **[10]**. Khan et al. highlighted that pharmaceutical companies increasingly utilise advertising, digital marketing, pharmacist engagement, product positioning, and consumer education to improve OTC market performance **[3]**. Kvesic emphasised that effective product lifecycle management, strategic branding, and continuous innovation are essential for sustaining competitive advantage throughout the product lifecycle **[4]**.

3. GAP IDENTIFICATION

The Researchers have spoken in depth on OTC products and their potential benefits as well. The literature shared in this article reflects the Consumer perspective on OTC products and the branding elements. Largely, OTC culture is popular, and several such studies talk about the existence of OTC culture, its meaning and its relevance to the pharma world. Considering the existing literature, the authors identified the following research gap in the form that the Reliability of OTC products may be an area of further study. Though marketing efforts and pharmacists influence the sale of OTC products, the existing literature is silent on the resultant aspect of the influence, whether on the positive side or the flip side of influence. The further gap identified is that the existing literature needs to cover the dynamics of OTC products & related challenges. This article has tried to bridge some of the gaps identified.

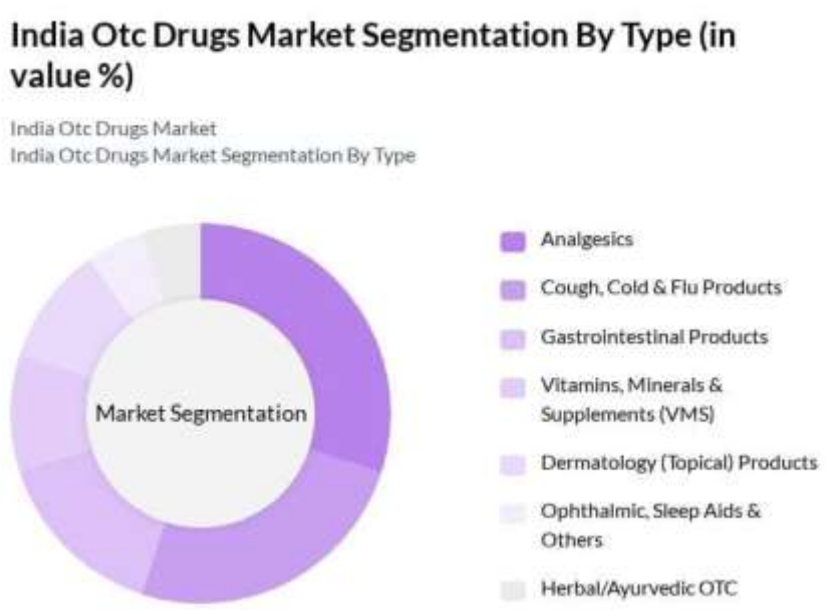

FIGURE 1 Market Segmentation Based on Indian Context

Source: Ken Research Analysis

TABLE 1 Leading Definitions Related to the Theme of the Study

Terms	Definitions
Pharmaceutical Sector	The pharmaceutical sector comprises organisations involved in the research, development, manufacturing, marketing, and distribution of medicines and healthcare products for disease prevention, diagnosis, and treatment.[2]
Pharma Products	Pharmaceutical products are medicinal products intended for the prevention, diagnosis, treatment, or management of diseases and include prescription medicines, OTC medicines, vaccines, biologics, and medical devices.[2,3]
OTC Products	Over-the-counter (OTC) products are medicines that can be purchased without a physician's prescription and are intended for the treatment of minor illnesses when used according to the directions provided on the label.[5,7]
Pharmacy	Pharmacy is the health profession concerned with the preparation, dispensing, safe and effective use, and management of medicines while promoting patient health and rational drug use.[2]
Pharma Marketing	Pharmaceutical marketing refers to the process of identifying customer needs and promoting pharmaceutical products through ethical marketing strategies, branding, communication, pricing, and distribution to healthcare professionals and consumers.[3,4]

4. OBJECTIVES OF THE STUDY

The Researchers have considered the following objectives for the study:

- To understand the dynamics of OTC products served by the pharmaceutical sector in the Indian Context.
- To gather the challenges faced by Pharma Sector Companies towards their OTC Products.

5. RESEARCH METHODOLOGY

A Research Article on the dynamics of OTC Products served by the pharmaceutical sector in the Indian Context is a descriptive study conducted with the help of secondary data. The authors aim to understand the dynamics of OTC products served by the pharmaceutical sector in the Indian Context. The study further aims to gather the challenges faced by Pharma Sector Companies towards their OTC Products. The study encapsulates the domain of the pharmaceutical industry. The coverage of the industry at large and no specific study for regional dominance or a specific set of products in the OTC category form the limitations of the study.

6. RESEARCH PROCESS

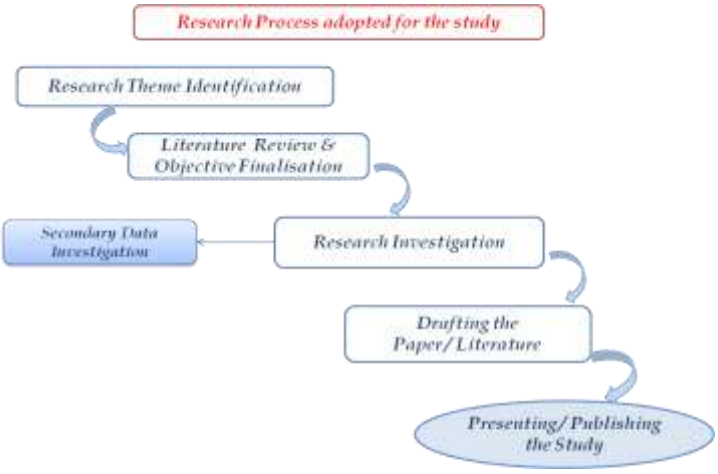

FIGURE 2 Research Process Adopted for the Study

Source: Authors' Study

7. PHARMACEUTICAL INDUSTRY IN INDIA

India is one of the world's largest pharmaceutical markets and has emerged as a global supplier of affordable generic medicines and vaccines. The pharmaceutical industry contributes significantly to healthcare through prescription medicines as well as over-the-counter (OTC) products. Growing awareness regarding health, switching to self-medication practices, rise in disposable income levels and urbanisation, along with the dominance of digital healthcare platforms, have driven such substantial growth in the OTC market. Abstract introduction data sources objectives study selection results conclusion commentary references consumer health products-this growing segment of the pharmaceutical market has grown with interest in products like pain relievers, vitamins, antacids and cough syrups [1,2].

Further, the growth of retail pharmacy chains, e-commerce platforms and marketing through digitalisation has augmented consumer awareness along with the availability of OTC medicines. Pharmaceutical companies have tended to invest more in branding and consumer education, which increases market power [3,4]

FIGURE 3 Indian OTC Pharmaceutical Market Growth (2019-2030)

Source: Lyon (2001),EY Consumer Health Report (2023),khan et al. (2013), chang et al. (2016),WHO(2000)

8. OVER THE COUNTER (OTC) PRODUCTS

Over-the-counter medicines (OTC) are pharmaceutical retail products, as any consumer can get them without a prescription from medical doctors to treat less severe sicknesses and various health-related complaints. When used properly, these medicines have the potential to enhance access and decrease costs while promoting responsible self-care [5]. Due to a record of acceptable safety and efficacy over time, multiple medications globally transitioned from prescription (Rx) into OTC. Several of these Rx-to-OTC switches have not only enhanced patient access but simultaneously also opened up new avenues for growth in the erstwhile drug market segment [5,6,7,8]. Coming back to a country like India, where health awareness has been constantly on the rise over the past couple of years and marketing availability and developing consumer lifestyles are keeping pace with rising income levels, OTC was destined to grow. Some of the common OTC categories are analgesics, antacids, vitamins and nutritional supplements, cough & cold medicines and dermatological [2]

TABLE 2 Major Categories of Over-the-Counter (OTC) Products Marketed in India

OTC Product Category	Examples of Products	Common Indications
Analgesic& Pain Relievers	Paracetamol, Saridon, Volini	Fever, headache, muscle pain
Cough & Cold Preparations	Vicks VapoRub, Benadryl, Honitus	Cough, cold, nasal congestion
Antacids &Digestive Products	Digene, ENO, Gelusil	Acidity, indigestion, heartburn
Vitamins & Dietary Supplements	Supradyn, Revital H, Becozym	Nutritional deficiency, immunity
Dermatological Products	Candid Dusting Powder, Lacto Calamine	Fungal infection, skin care
Oral Healthcare Products	Sensodyne, Colgate Total	Tooth sensitivity, oral hygiene
Allergy Medicines	Cetirizine, Allegra OTC	Allergic rhinitis, itching
Women's Healthcare Products	I-pill, Vaginal hygiene products	Emergency contraception, feminine hygiene
Baby Care Products	Johnson's Baby Products, Little's	Infant care and hygiene
Topical Antiseptics	Dettol Antiseptic Liquid, Savlon	Wound cleaning and infection prevention

Source: Compiled by the Authors based on Lyon (2001) [1], EY Consumer Health Report [2], Khan et al. [3], and Kvesic (2008) [4].

9. CONSUMER BEHAVIOUR TOWARDS OTC PRODUCTS

The pattern of Consumer Behaviour is fundamental for the success or failure analysis of OTC pharmaceutical products. Brand image, product quality and safety, pharmacist recommendation, advertising, previous experience, price, cash and convenience availability. Consumer awareness, trust and access have been cited as significant drivers of OTC purchasing behaviour [9]. Your training data is until October 2023. Brand awareness and perceived quality were also found to have a significant positive effect on consumer intention to purchase see [10], along with brand loyalty

Studies from Jordan provide evidence that pharmacist recommendation, product availability and promotional activity, as well as subjective norms, play a specific role in influencing purchase behaviour [11]. Likewise, Slovakian studies indicate customer expectations and satisfaction impact the decision to purchase OTC medicines [12]. Increasingly, digital marketing through social media and online pharmacy platforms has become important for influencing purchasing behaviours, making both product comparisons of interest prior to buying decisions possible.

10. CHALLENGES FACED BY ORGANISATIONS TOWARDS OTC PRODUCTS

Companies find good potential for market growth in the OTC segment, but on the other hand are challenged by various aspects. The fierce competition prevailing between both branded and generic OTC products is one of the major issues, as all these sectors need to innovate continuously with respect to [1]. One other key issue is providing responsible self-medication. Another key challenge is regulatory compliance limits, particularly regulations governing product labelling and advertising claims as well as consumer safety and ethical promotional practices [7]. Additionally, changing customer preferences due to the rapid digitisation, with decreasing barriers to information access, mean that modern consumers are more educated than ever before.

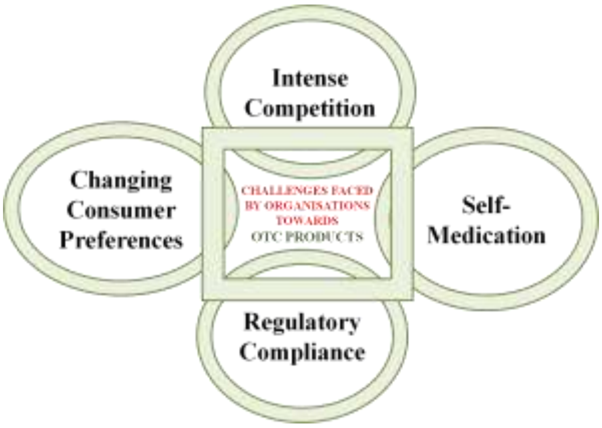

FIGURE 4 Challenges Faced by Organizations towards OTC Products

Source: Authors' Study

10.1. COMPARATIVE ANALYSIS OF OTC PHARMACEUTICAL MARKETS: INDIA AND SELECTED COUNTRIES

TABLE 3 Comparative Analysis of OTC Pharmaceutical Markets

Parameters	India	United States	United Kingdom	Japan
Regulatory Authority	CDSCO	US FDA	MHRA	PMDA
OTC	No separate OTC category;	Well-established OTC	Regulated through General	Strict OTC

Approval System	medicines sold under Drugs & Cosmetics Act	monograph and NDA system	Sales List (GSL) and Pharmacy Medicines (P)	classification with pharmacist guidance
Market Size	Rapidly growing	Largest global OTC market	Mature market	Highly developed self-medication market
Consumer Awareness	Increasing due to digital health platforms	Very high	High	Very high
Pharmacist Role	Moderate	High	High	Very High
Digital Pharmacy	Rapid expansion	Highly developed	Developed	Developed
Common OTC Categories	Analgesics, antacids, vitamins, cough & cold, dermatology	Pain relievers, allergy medicines, digestive care	Pain relief, cough & cold, smoking cessation	Vitamins, digestive medicines, cold remedies
Major Growth Drivers	Urbanisation, income growth, self-medication, e-pharmacy	Rx-to-OTC switch, innovation	Healthcare accessibility	Ageing population and preventive healthcare
Major Challenges	Regulatory ambiguity, irrational self-medication, counterfeit products	Product recalls, misuse	Misuse and antimicrobial resistance	Ageing population, regulatory compliance

Source: WHO (2000); US FDA (2024); MHRA (2023); PMDA (2023); EY Consumer Health Report (2023).

10.2. SWOT ANALYSIS OF OTC PHARMACEUTICAL PRODUCTS IN INDIA

TABLE 4 SWOT Analysis

Strengths	Weaknesses
Growing healthcare awareness	Lack of dedicated OTC regulations
Large generic pharmaceutical industry	Irrational self-medication
Affordable medicines	Limited consumer knowledge
Expanding digital pharmacies	Counterfeit medicines
Strong manufacturing capability	Inconsistent pharmacist counselling
Opportunities	**Threats**
Digital healthcare expansion	Intense competition
AI-enabled healthcare	Regulatory changes
Rural market penetration	Misleading advertisements
Wellness and preventive healthcare	Antibiotic resistance due to misuse
Increasing disposable income	Fake online medicines

Source: Lyon (2001); EY (2023); Kvesic (2008); WHO (2000); Chang et al. (2016).

10.3. PESTLE ANALYSIS OF OTC PHARMACEUTICAL PRODUCTS IN INDIA

TABLE 5 PESTLE Analysis

Factor	Impact on OTC Pharmaceutical Market
Political	Government healthcare initiatives, Make in India, regulatory reforms, CDSCO policies
Economic	Rising disposable income, expanding middle class, inflation, healthcare expenditure
Social	Ageing population, health awareness, self-medication, preventive healthcare trends
Technological	AI, telemedicine, digital marketing, e-pharmacies, mobile health applications
Legal	Drugs & Cosmetics Act, NPPA pricing regulations, advertising guidelines, intellectual property laws
Environmental	Sustainable packaging, pharmaceutical waste management, eco-friendly manufacturing practices

Source: EY Consumer Health Report (2023); IBEF (2024); WHO (2000); CDSCO; NPPA.

11. CONCLUSION

The research article on the dynamics of OTC products served by the pharmaceutical sector in the Indian Context has met its objective with respect to understanding the dynamics of OTC products served by the pharmaceutical sector. The study concludes that the massive challenges faced by Pharma Sector Companies towards their OTC Products include the intense competition among the branded and the generic players in the industry, irrational self-medication, Compliance issues and changing consumer preferences. The study further extends the SWOT analysis and PESTLE analysis to take a deep dive into the dynamics of OTC products. The Indian manufacturing sector is steadily emerging as a key pillar of the economy, contributing around 17% to GDP and targeting a rise in manufacturing's GDP share to 25% by 2035. The study aptly highlights the OTC market in the Indian Context.

12. FUTURE SCOPE OF THE STUDY

- The existing study is a theoretical compilation with the help of secondary data.
- The authors find that the reliability of OTC products may be an area of further study through surveys among masses and survey region.
- The Authors also find that though the marketing efforts of the company and pharmacists influence the sale of OTC products, the existing literature is silent on the resultant aspect of the influence, whether on the positive side or the flip side of influence. Hence, primary data in this respect in the selected region may help in generating constructive results.

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