



Over-the-counter Drug Market in India: A Study to understand the Current Regulatory Perspective and Industry Dynamics

¹Suniel G Deshpande, ²Rajesh K Srivastava

ABSTRACT

Self-medication is on the rise in India. This is due to various reasons that are connected to the environment, demographic factors, changing consumer lifestyles, government policies, and strategies of the pharmaceutical industry. There has been a significant increase in the number of over-the-counter (OTC) products introduced in the health care market in India. On the regulatory front, the government is trying to consider legal recognition to the OTC category of drugs which currently do not have any legal recognition. Over-the-counter drugs in India can be advertised in media unlike some categories of the prescription-only drugs which are totally prohibited. The OTC drugs require a sales license except some drugs in Schedule K, which are categorized as household remedies. However, *Ayurvedic* drugs in India do not require a sales license and therefore, can be sold freely. It is expected that the regulatory policies would undergo changes initiated by the government in the near future.

Keywords: Drug utilization, Over-the-counter, Pharmaceutical industry, Prescriptions, Regulatory policy.

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INTRODUCTION

Self-medication is not a new phenomenon for India, as historically it has been practiced through the use of home remedies for common illnesses in many Indian households. Compared with the United States, the incidence of self-medication in India is slightly less. Around 76% of the consumers in India self-medicate for minor ailments as

compared with 81% in the United States.¹ Self-medication is effected primarily through the consumption of OTC and Otc (combination of prescription and OTC) drugs, which are an important constituent of the Indian Pharmaceutical Industry. Consumption of OTC drugs addresses the needs of the population for easy accessibility, availability, and affordability of drugs in the face of difficulties like inadequate health care infrastructure, inadequate physician coverage, high medical costs, and the burden of health care delivery. Proliferation of the digital media has also added to increasing trends of self-medication in India. There are reports that 1 in 20 searches on Google is related to health.¹ There is a need to have in place an appropriate regulatory framework to support and control such efforts of the consumers. Vitamins, minerals, analgesics, health tonics, cold and cough preparations, topical preparations, and gastrointestinal drugs are some of the drug categories consumed as OTC in India.² There are various prescription drugs that can be moved into the OTC category if there is a proper regulatory mechanism of the government in place to facilitate this movement. Currently, there is no formal recognition of the OTC drugs category in India. Countries like the United States, the United Kingdom, Canada, and the Netherlands have regulatory policies for OTC drugs.

Current Regulatory Practices

Definition of OTC: In India, the manufacture, import, distribution, and sale of drugs are regulated by the Drugs and Cosmetics Act, 1940 (DCA) and Drugs and Cosmetic Rules, 1945 (DCR). The term "OTC" or nonprescription has no legal recognition in India and all drugs which are not included in the list of "Schedule H, H1, X" are considered to be nonprescription drugs (or OTC drugs), which can be sold without the prescription of a registered medical practitioner. Prescription category drugs are those drugs that are included in Schedules H and X of the DCR. Schedule G drugs require the following mandatory text on the label: "Caution: It is dangerous to take this preparation except under medical supervision" (Some examples of Schedule G drugs include antidiabetic, anticancer, immunosuppressant, and some antihistamine drugs). The OTC products have no legal recognition in

¹PhD Student, ²Professor and Head

¹Department of Hospital Administration, MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India

²Department of Marketing and Research, Sydenham Institute of Management Studies, Research & Entrepreneurship Education Mumbai, Maharashtra, India

Corresponding Author: Suniel G Deshpande, PhD Student Department of Hospital Administration, MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India, Phone: +919870330859, e-mail: suniel.deshpande@siescoms.edu/suniel_deshpande@outlook.com

India, as there is no category of OTC drugs in the DCR. Due to this, all drugs which are not included in the list of “prescription only drugs” (Schedules H, H1, and X) category and the ones classified as “household remedies” that are listed in Schedule K are considered by default to be “OTC” drugs. Even nonpharmacists, i.e., stores without drug licenses, are allowed to sell a few drugs in villages with population less than 1,000 that are listed in Schedule K of the DCR.

Medicated dressings and bandages for first aid, oral rehydration salt, nicotine gum, and lozenges containing up to 2 mg of nicotine and substances intended to be used for destruction of vermin or insects that cause disease in humans or animals, i.e., insecticides and disinfectants, are legally permitted for sale without the requirement of a license to sell.³

The Government of India through the Central Drugs Standard Control Organization is planning to include an independent schedule for OTC drugs in India. A separate category for OTC drugs to treat minor illnesses like colds, fevers, contraceptive pills, and treatment for allergies is likely to be created.⁴

Ayurvedic Medicines

The OTC drugs that are registered as “Ayurvedic medicines,” i.e., the medicines of the Indian traditional system containing herbal/natural ingredients, also come under the purview of the DCA, 1940 and the DCR, 1945. The manufacturing of Ayurvedic drugs comes under the manufacturing license issued by the state licensing authorities for Ayurvedic products. Ayurvedic drugs in India do not require a drug selling license and can be sold legally at all nonchemist outlets. Some of the highest selling OTC brands in India are registered as “Ayurvedic Medicines,” as they contain active ingredients that are plant based. Examples: Pudina Hara, Itch Guard Cream, Vicks Cough Drops, Iodex Pain Balm, Moov Pain Cream, and Zandu Balm.²

Regulatory Authority for OTC Drugs in India

All OTC drugs in India come under the purview of the DCA, 1940 and the DCR, 1945. The other regulations that have a bearing on the OTC drugs in India are the Pharmacy Act, 1948, Drugs Prices Control Order, 2013, and Drugs Magic Remedies Objectionable Advertisement Act, 1964. All the categories of drugs, viz., Allopathic, Ayurvedic, Siddha, Unani, and Homeopathy, either manufactured and/or imported are covered by the above legislation. The Ministry of Health and Family Welfare and the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers, Government of India, are responsible for the overall control of the

domain. Approval of new drugs, molecules, dosage forms, clinical trials, introduction of new formulations, grant of export and import licenses, manufacturing, and import of medical devices are being controlled by the Drugs Controller General of India. Statutory authority to grant manufacturing and selling licenses of a drug is the responsibility of the state governments through the Food and Drug Administration.

Labeling for OTC Drugs

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

- Generic name and brand name
- Contents of ingredients and total contents
- Details of the manufacturer including name, address, and manufacturing license number
- The batch details, dates of manufacturing, and expiry dates
- The maximum retail price

Rule 127 of DCR mentions the list of approved colors.

Rule 161 states the labeling provisions of all Ayurvedic, Siddha, and Unani drugs while Rule 169 stipulates preservatives and coloring agents.

Distribution and Supply of OTC Drugs Online

For online sale of OTC drugs, there is no specific law till date to regulate online pharmacies in India. But all drug sales are governed indirectly by DCA, 1940 and Food Safety and Standards Act. To regulate online sale of drugs (including OTC drugs), Maharashtra government has directed that all manufacturers, wholesalers, distributors, and retailers who are interested in selling drugs and medicines online will have to register themselves on an e-portal which would be set up soon by the Central government. An e-enabled autonomous body under the supervision of Ministry of Health and Family Welfare will control this portal. Unless registered on the portal, the government would not allow any retailer, chemist, and e-pharmacist outlet to sell any medicine or drug to any consumer. It would be mandatory for all the retail pharmacy outlets also to enter details of all receipts, sales of medicines or drugs, medicines returned to the manufacturer, or disposed of in any other manner.⁵ Drugs included in Schedules H, H1, and X of the DCA shall be sold online only on a prescription of a registered medical practitioner.

Advertisements of OTC Drugs

The promotion of all drugs is regulated through the Drug and Magic Remedies (Objectionable Advertisement) Act

and Rules, which mentions a list of ailments for which there is no advertising permissible in India. Recently, the government made an amendment to DCR 1945, vide a G.S.R. number 289 (E) dated April 15, 2015,⁶ wherein the advertisements of all drugs in Schedule H, Schedule H1, and Schedule X are prohibited by law. Over-the-counter drugs are allowed to be advertised on various media.

Pricing of OTC Drugs

The Drugs Price Control Order is the one mechanism through which the government exercises control on the pricing of all the allopathic drugs in India. There are around 370 drugs under price control and those that are not under price control are under the nonscheduled category. Over-the-counter drugs do not come under price control except a few OTC actives, viz., acetylsalicylic acid, ephedrine, and its salts, etc., which are under price control.⁷ All Ayurvedic drugs fall outside the ambit of price controls.

Indian Pharmaceutical Industry and OTC Drugs

The Indian Pharmaceutical Industry ranks third with respect to volumes and thirteenth with respect to value, on the global level. It contributes around 10% of the global production of pharmaceuticals by volume. It is growing at an annual growth rate of around 5.5%.⁸ One of the major components of the Indian Pharmaceutical Industry is the business of OTC products.

Over-the-counter Drugs Market in India

The market for OTC products in India can be categorized which includes: (1) frank OTC products which are advertised on public media and construed as true OTC products, (2) prescription brands that are not advertised, but which are promoted to the physicians and also purchased by consumers without prescription called Otx brands.⁹

The value of the Indian OTC drugs market is estimated to be US\$ 2.7 billion (Rs 188.6 billion) at a compounded annual growth rate of 9% to reach around \$6.5 billion (Rs 441.1 billion).¹⁰ The major players for OTC products in India are: Cipla, Abbott India Limited, Amrutanjan Health Care Limited, Boehringer Ingelheim Limited, Mankind, Dabur India Limited, Pfizer, Emami, GlaxoSmithKline, Sanofi, Himalaya Herbal Health care, Novartis, Marico, Merck, Piramal Enterprises, Procter & Gamble, and Lupin.¹¹

Composition of the Indian OTC Drug Market

The OTC market in India comprises of the main product categories¹² listed in Table 1.

Table 1: Composition of the Indian OTC drug market—main drug categories

| <i>Drug category</i> | <i>% contribution</i> |
|-------------------------------------|-----------------------|
| Vitamins, minerals, and supplements | 30 |
| Gastrointestinal products | 19 |
| Cough, cold, and allergy products | 18 |
| Dermatology products | 15 |
| Analgesics products | 15 |
| Lifestyle-related products | 3 |

Factors driving the Indian OTC Drug Market

India is the 11th largest market for OTC drugs in the world.¹³ The growth in the OTC drugs market is a result of various socioeconomic factors impacting the various stakeholders in the health care industry. The factors driving OTC drug consumption in urban India are changing lifestyles which involve a fast and stress-oriented lifestyle where timely solutions become paramount in health care; changing food habits, increasing literacy rates, increasing awareness of health and illnesses through individual efforts and government promotion, prevalence of untreated common illnesses, high medical costs, proliferation of social media, increased promotion of newly shifted OTC drugs by manufacturers, and changing concept of good health from illness to wellness are some of the driving factors for increasing OTC drug consumption in India. With both the husband and wife employed in urban areas, there is an increase in the disposable incomes in the family which is reflected in the trend of the per capita income in India. The real per capita net national income at constant (2011–2012) prices is an important pointer for the well-being of the people of a nation. As per the Government of India's economic survey report for 2017 to 2018, it is expected to improve from Rs 77,803 in the year 2015 to 2016 to Rs 86,660 in the year 2017 to 2018 with an annual average growth rate of 5.5%. In nominal terms, it demonstrates an average growth rate of 9% per annum from Rs 94,130 in the year 2015 to 2016 to Rs 1,11,782 in the year 2017 to 2018.¹⁴ There is a clear thinking among the consumers toward good health, fitness, and prevention of diseases that are responsible for driving the growth for OTC products in categories, such as nutraceuticals, antacids, vitamins and minerals, health drinks, dietary supplements, and dermatological preparations.

Since the cost of medical treatment is increasing due to increase in the consulting fees of physicians and other factors, more and more people today are driven toward the use of OTC drugs for self-medication. The power of internet can be effectively used by OTC drug manufacturers to promote their drugs. Moreover, decisions of consumers are also influenced by reviews posted by peers about certain OTC drugs on internet blogs. The OTC manufacturers should thus use internet as an effective platform for promotion and brand building of OTC drugs.

CONCLUSION

Unlike a product which is present in the prescription only category, the OTC products are used in health conditions that do not require the direct supervision of a registered medical practitioner. The parameters that are important determinants of a successful OTC treatment are safety of the drug, clarity in the indications and administration of the drug, and easy availability. With changing macro-environmental factors, further increase in the consumption of OTC drugs can only be expected. The Government of India has taken cognizance of this fact and is working toward giving recognition to OTC drugs. In the future, we would see more and more health care organizations introducing newer OTC products in India and also newer organizations making an entry into the OTC segment in India. With these changes, it becomes imperative for the government to introduce strict regulatory policies that would help the government to meet national health care objectives in a satisfactory manner.

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