

ONLINE PHARMA RETAIL IS A PROMISING/UNPROMISING AVENUE: AN INDIAN CONTEXTALAMELU R^{1*}, AMUDHA R¹, L CRESENTA SHAKILA MOTHA², NALINI R¹¹Department of Training and Placement, School of Management, SASTRA University, Thanjavur, Tamil Nadu, India. ²Department of Training and Placement, SASTRA University, Thanjavur, Tamil Nadu, India. Email: alamelu@mba.sastra.edu

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ABSTRACT

To consider the prescription of drugs through online retail is an opportunity or not for the end consumers in an Indian context. This paper described the basic issues and challenges related to online pharma retail in the Indian context through case method. India is among the top six global pharmaceutical producers in the world. The Indian vaccines are exported to 150 countries. India produces 40-70% of the World Health Organization (WHO) demand for Diphtheria-Pertussis-Tetanus and Bacille Calmette-Guérin vaccine and 90% of measles vaccine. Sustained by the amazing success achieved by consumer durables industry in the online space, pharma is the next big sector in India to target consumer online. The growth in the industry has created a great opportunity for the online model for this business. India has now seen pharma players taking the e-commerce route with an intention to offer a solution to a number of problems plaguing the retail pharmacy industry. Though online medicines look like a promising trend today, the business is challenged by regulatory issues.

Keywords: Online pharmacy, Online pharma retail, Online medicines, E-pharma retailing.**INTRODUCTION**

The annual Indian pharmaceutical market is measured at around Rs 79,000 crore, growing at around 20%. India is among the top six global pharmaceutical producers in the world. Indian vaccines are exported to 150 countries. India produces 40-70 percent of the World Health Organization (WHO) demand for Diphtheria-Pertussis-Tetanus and Bacille Calmette-Guérin vaccine (DPT and BCG) and 90% of measles vaccine [1]. It is appreciated that the Indian retail.

Pharmacy industry is widely fragmented throughout the country. If organized at all, shops tend to operate under a unified retail banner with a large number of shops. The market continues to grow with such sustainability, based on the ever increasing incidence of chronic disease that the industry continues to thrive, despite its apparent lack of organization and corporate discipline. The small shops managed to literally stumble their way into an estimated gross turnover of some 83,000 crore and predictions are that the figure will continue to soar. On the surface and on the international level, the industry is highly regulated. However, on a regional and local level, the market is yet to become more organized. As in most government regulated industries in India, cases of abuse far outnumber the regulators' ability to enforce the law, and with literally hundreds of thousands of small shops to watch over and regulate, enforcement becomes a massive challenge, withering the forces of both manpower and money. Buoyed by the amazing success achieved by consumer durables industry in the online space, pharma is the next big sector in India to target consumer online. The growth in the industry has created a great opportunity for the online model for this business. India has now seen pharma players taking the e-commerce route with an intention to offer a solution to a number of problems plaguing the retail pharmacy industry. Though online medicines look like a promising trend today, the business is challenged by regulatory issues [2] (Fig. 1).

Inconsistently, despite the fact that many established stakeholders are warning about the dangers of online prescription drug sales, it just may be that pharmaceutical e-commerce may be more a "blessing than a curse" when it comes to satisfying the public need for quality medication. There are no dedicated online pharmacy laws in India as on date. It is believed that, properly regulated, the online pharmacy business could be of benefit to India [3].



Fig. 1: Guidelines for sale via the web

This case approach has provided various views about selling prescription drugs through online in India.

ONLINE ROAD AHEAD

Advancement of e-commerce in India significantly opened an arena to market most of the products which can reach almost everybody. Online pharmacy is one among the products which is about to create a huge demand in upcoming days. An online pharmacy is an Internet-based vendor of prescription drugs, and the term encompasses both legitimate and illegitimate pharmacies. The sale of medicines outside the regular retail pharmacy is not new. It has just flourished in this Internet age. In the late 1980s, pharmacies began selling prescription medications via mail order in the US. Later, the mail order business transformed into first Internet-based pharmacy called "soma.com" in January 1999. Shortly after that, the Internet pharmacy was launched in the UK. Estimates showed that there were more than 1000 websites selling medicines as of early 2004. Retail pharmacy has so far remained the biggest source of medicines for the Indian population [4] (Fig. 2).

Remote areas in the country too are benefited with retail pharmacies only. Perhaps, since they are not aware of the concept called the online pharmacy or lack of basic requirements such as the Internet, a huge section of the Indian population is not buying medicines online. However, now things are changing. With the introduction of devices such as smartphones, coupled with government and private sector

initiatives, the Internet is reaching almost every nook and corners of the country. Technology can help in meeting the healthcare objective of India [5] (Fig. 3).

The Indian government is planning to spend Rs. 500 crore on computer literacy project for 50 lakh people over a period of 3-year. This would help the Indian citizens to access government services in the fields of e-education, e-health, and e-governance. Healthcare providers in India are also expected to spend \$1.1 billion on IT products and services. With the government focusing all its energy for affordable healthcare to all using IT and telemedicine which also do not have a mandate in the laws, it is only a matter of time when all these pharmacies are brought under the ambit of a revised law. The Indian government is also planning to establish an e-health authority to maintain electronic health record in India [6]. "With the growing use of Internet-based shopping, we are seeing a huge increase in sales via the Internet. However, sales of medicines are not permitted since the law requires the sale to happen in a licensed store, sale to be effected by a pharmacist, and sale to be effected based on a prescription. Some companies have already started to find loopholes in the law and have started to sell medicines over the Internet, recognizing the need for Internet-based sales of medicines and suggest Government of India needs to proactively legislate this to manage unscrupulous elements while ensuring that the new medium of sales is available to all customers [7]."

MARKET POTENTIAL

According to FICCI's spokesperson, "Presently, online pharmacy is at its nascent stage in India, but like other categories, it has the potential to be a very large industry segment. It is expected that the online pharmacy model could account for 5-15% of the total pharma sales in India, largely by enhancing adherence and access to the medicines for a lot of the under-served population." Hemant Bhardwaj, Chief Executive Officer, Co-Founder and MD, PM Health and Life Care draws attention to the benefits of the model and says, "The icing on the cake is the concept of "Marketplace," which is fuelling big dreams among thousands of small retailers. Now, their business is no more constrained by the carpet area of their shops. Moreover, for a minute, if ignore the massive discounts offered by E-retailers, this channel still has a lot to offer to the customers in terms of convenience. Currently, 35 million Indians prefer buying products and services online. This tribe is going to cross 100 million marks by 2016 and is expected to continue to grow with a rapid rate. A smart businessman will not let go of an opportunity to cater to this next generation of buyers, whether he is in the business of selling needles or medicines. The best part is that he can leverage this new promising channel without junking his existing business or clientele." The model has already found favor with many leading pharma players. Bruce Schwack, Director, Marketing, Netmeds.com informs, "Online availability of prescription medication has been discussed in a big way lately. Online pharma space currently has well-heeled players such as Apollo Pharmacy, 1. MG, formerly Healthkart Plus, PM Healthcare, touted by former Igate CEO Phaneesh Murthy, and few others. Netmeds.com, the first-to-market pan-India fully licensed and compliant E-pharmacies is a recent entrant in space [7]."

REGULATORY ISSUES

Though online medicines look like a promising trend today, the business is challenged by regulatory issues. Earlier this year, Maharashtra Food and Drug Administration investigated few e-commerce giants for selling prescription drugs without a proper license. It is becoming clearer that the growth of online pharmacy business depends on how much they will manage to fit themselves in the legal framework. It seems a certainty that it would be far more feasible for regulators and watchdogs to keep a sharp eye on a few licensed, major retailers than hundreds of thousands of small shops [3].

Highlighting the need for such guidelines, Dr. KK Aggarwal, Secretary General, IMA points out "There are no well-defined dedicated laws for online pharmacies. The laws applicable are Drug and Cosmetics Act

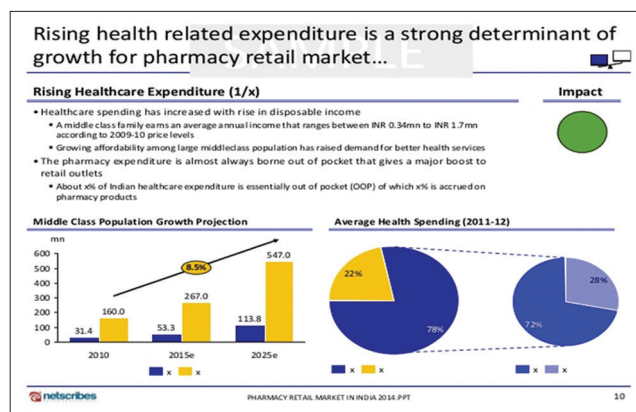


Fig. 2: Pharmacy retail market

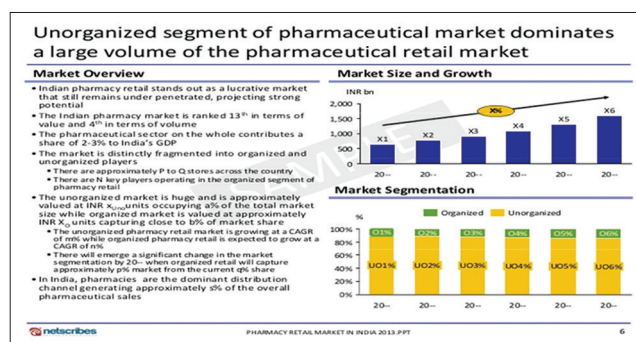


Fig. 3: Un-organized segment of pharmaceutical market

Laws for Pharmacies in India
Drug and Cosmetics Act 1940
Drugs and Cosmetic Rules 1945
Pharmacy Act 1948
Indian Medical Act 1956
Information Technology Act, 2000.
Apart from this, there are few high court judgments that have provided further insights and interpretation of the laws.

Fig 4. Laws for pharmacies in India

1940, Drugs and Cosmetic Rules 1945, Pharmacy Act 1948 and Indian Medical Act 1956. Laws related to e-commerce are defined under the Information Technology Act, 2000." Aggarwal further informed, "The Drugs and Cosmetics Act do not allow home delivery of drugs. The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, have clear guidelines on the sale of Schedule H and Schedule X drugs, which are "restrictive drugs" and can be sold only on the prescription of a registered medication practitioner [7] (Fig. 4).

Schedule X drugs include narcotics and psychotropic substances. Chances of drug abuse and addiction are higher with the Schedule X category. Schedule X drugs require meticulous storage and dispensing records. The prescription has to be in duplicate and one copy of which is to be retained by the licensed pharmacist for 2 years [7].

Realizing the need for constituting guidelines for online pharmacies, Federation of Indian Chambers of Commerce and Industry (FICCI) organized a meet on 'Pharma Guidelines for Reinforcing Due Diligence for Intermediaries (e-commerce Marketplace)' to ensure the safety of consumers. Dr. GN Singh, Drugs Controller General (India) DCG (I) announced that the authority is in the process to formulate guidelines. He also informed that FICCI has been appointed as the nodal agency by the DCG (I) for consolidating the guidelines. A sub-committee has been formed by the DCG (I) under the chairmanship of Harshadeep Kamble, Commissioner Food and Drug's Administration and Food Safety Commissioner, Maharashtra, to assess the feasibility of online pharmacies. The committee also includes other members such as the Karnataka Drugs Controller along with drugs controllers of Delhi and Odisha. It is seeking the views of Organisation of Pharmaceutical Producers of India (OPPI), All India Organisation of Chemists and Druggists, states chemists and druggists associations, Indian Medical Association, CIPI, BDMA, PHD Chamber of Commerce and Industry and consumer forums [7].

CHALLENGES IN ONLINE RETAIL

There are many players who have already stepped into the business or are intending to offer medicines online. However, several challenges are associated with the e-commerce platform.

At present, the D&C Act does not allow sale of Schedule H medicines without a doctor's prescription. In fact, even OTC pharma products can be sold only by licensed retailers. The D&C Act 1940, and the D&C Rules 1945 has guidelines on the sale of Schedule H and Schedule X drugs. These can be sold only on prescription, and there are specific rules, including for labeling and bar coding. There are multiple laws in India that govern dealing with food, health, cosmetics, drugs, medicines, and nutraceuticals in India. Online sale and purchase of prescribed drugs and medicines in India are collectively governed by these and other laws. Many online pharmacies in India are inviting legal risks by not following the applicable laws in this regard. These laws are also too old to deal with the advancements in technology and are currently a gray area. There are some other issues too associated with the online availability of medicines. This encourages more self-medication. The medicines do require appropriate storage (temperature) for retaining potency. There is no assurance of temperature control either at their storage points or during transport. The patients lose the opportunity to have a face to face discussion with the professional pharmacists. The Internet has removed the boundary between the countries. The brand names may often cause confusion. There may be the same brand but with different drugs (even the look-alike drugs). Ultimately, the patient is at receiving end getting wrong medicines. In the absence of clear-cut regulation, the Indian public are likely to fall prey into the trap of Internet pharmacies losing both money and their health. As such, selling medicines online is prevalent in developed markets, and its mushrooming in India is a consequence of the booming e-commerce segment in India. However, clearly selling OTC medicines online, which is permissible, is quite different from selling prescription drugs online where the attendant dangers of abuse are high.

"A prescription issued by a doctor cannot be re-used randomly. There is a danger that scheduled drugs can be re-ordered and misused by the consumer," Jayesh Lele, president, IMA, said. "Besides, there are several 'do's and don'ts' with regard to storage and dispensing of prescription medications that need to be adhered to," he added. According to Lele, "self-medication is a rampant practice in India, and online sale of drugs would only encourage it. Indiscriminate use leads to patient resistance which is very dangerous as has been the case with tuberculosis drugs." KK Aggarwal, the secretary general of IMA, highlighted another challenge. He said that data generated from the online business could be misused. Websites may use data to sell luxury items to people who visit online stores for costly medicines. They may even sell the data to hospitals and doctors. While the Supreme Court has ruled that doctors cannot give consultancy on the phone, except during emergencies, the

attempts to use technology to render medical services has also not taken off. As far as India is concerned, we have no dedicated e-health and telemedicine laws in India. However, a basic level legal e-commerce framework has been provided by the Information Technology Act, 2000 (IT Act 2000) that is the cyber law of India. Even essential attributes of these laws such as privacy protection, data protection, data security, cyber security, confidentiality maintenance, etc., are not governed by much needed dedicated laws. When technology is used for medical purposes, it gives rise to medico legal and techno legal issues. Individuals and companies selling pharmaceutical products through the website are also required to comply with various laws. These include laws related to medicines and pharmacy profession and cyber law of India. Surprisingly, most of the online pharmacies stores and websites in India are not aware of the cyber law due diligence requirements and Internet intermediary liabilities. As a result, they are violating the provisions of IT Act, 2000 [6]. Aggarwal expressed his concern and said, "Online pharmacies will promote drug abuse, drug misuse, self-medication, etc. Any medication taken without the supervision of doctors may be dangerous and even potentially life-threatening. There is every chance that the prescriptions submitted via fax/email may be fake, and it could be difficult to verify their authenticity." Aggarwal also indicated, "Online pharmacies may provide rebates and commissions to doctors to provide prescriptions on the basis of online information that has been filled by the patient. This way doctors will be vulnerable to malpractice suits and MCI code of ethics (Regulation 6.4) prohibited giving or receiving any rebates or commissions by doctors [8]."

These are serious issues that require immediate attention, and the government should have provisions in the guidelines being drafted to tackle them effectively. Furthermore, generating awareness among the consumers could also help in overcoming these challenges.

WHETHER ONLINE PHARMACIES SMACK RETAIL OUTLETS?

Currently, online pharmacies are liable to violate various Acts such as Pharmacy Act, Drugs and Cosmetic Act and Violation of Human Rights. However, many e-commerce players have already ventured into the segment. Bhardwaj explains the phenomenon, "e-commerce or online retailing or m-commerce is still a very small fraction of the total retailing market in India. However, it is making headlines because customers and opinion leaders are seeing it as an efficient and effective channel of distribution of the future. It offers quick, massive reach if backed by strong logistics network. This is accompanied with the fact that it gives assured access to medicines in the quickest possible time to the needy."

The growth of online pharmacies has also given rise to a fear among the retail sellers that their business would be adversely affected. However, Dr Gopakumar G Nair, Chief Executive Officer, Gopakumar Nair Associates, refutes this theory and opines, "The fear of all these physical distributors and suppliers that E-tailing/E-retailing such as Snap deal, Flipkart, Amazon, Local banya, etc., will adversely affect the footfalls, has proved to be unfounded. As such, medical shops and pharmacies need not have fear for E-retailing which will only be additional and supplementary for enabling affordable access. Around 75-90 per cent of the current customers of medicine shops and pharmacies will continue to access physically. Only the web-enabled or web-assisted community who don't have proximity medicine shops will opt for E-retailing on the web."

However, Schwack tries to balance it out and says, "Although the 'brick-and-mortar' pharmacy operators in India are voicing some concern about this shifting paradigm, at least, a part of that concern seems to be unfounded. While some of the opposition is based on a genuine concern for the public's safety, since by and large the community of pharmacists is recognized as a group of dedicated healthcare professionals, another concern is probably the threat of a loss of business as their loyal customers migrate to the net or their smartphone to purchase their medications."

He further elaborated, "In reality, industry analysts are predicting about a 5-10% market share for the E-pharmacies as they emerge, jockey for position and settle in over the next few years. That means, that of the roughly 3,000,000 transactions that are going through local neighborhood pharmacies and chemists each and every day, perhaps, as scant a number as 150,000 of those may be lost to "the web," and in most cases, these pharmacies can actually enjoy an increase in business rather than a loss, by launching their own e-presence, extending their reach and appeal to their own customers and by enrolling in various "marketplace" engagements and providing fulfillment for some of the regional and national players." FICCI spokesperson highlights the importance of certification and says, "We recommend a certification for the online marketplace, so they register with the regulator and are certified as organized players within the purview of the regulator. Online companies should clearly display the certificate on their home page, and consumers should be made aware to only buy from certified online pharmacies."

Though the mindset is changing and moving toward technology, the real challenge is how to strike a balance? Will providing certifications to chemist shops and online pharmacy be a solution?

Garg suggested, "Over a period of time, the government should create a secure app which will be used by doctors to prescribe medicines. Registered pharmacies can then deliver medicines on the basis of this app. This will ensure complete transparency. Though there will be an initial resistance, customer push will drive doctors and pharmacies to have this implemented." Schwack opined, "The public not only wants it but in many cases, needs it. The population is aging and with age comes greater dependence on health maintenance drugs. The incidence of chronic disease is on the rise as the emerging 'technocrat' class is setting new records not only in income levels but also in areas of obesity, diabetes and heart disease. A regular supply of health maintenance drugs and supplies, affordably offered and conveniently delivered will prove to be an important weapon in the fight against the rise of chronic disease. "Nair ponders," Is it too much for me to look forward to seeing the E-dream of riding on 'Digital India' turn into a reality during my lifetime? We would eagerly wait to order at least my vitamin supplements through the E-way, even if it is the local speed-postman delivering it, with the government enabling the statutes to make the provisions legal and transparent, not prone to abuse"[9].

CONCLUSION

"The role, responsibilities, and liabilities of e-commerce marketplace and the product sellers need to be clearly defined. It becomes, even more, critical to have a framework in place when the intermediary is selling drugs where the safety and health of the consumer are of paramount importance," industry body FICCI's statement quoting Drugs Controller General (India) G N Singh said [10]. The Government has already planned to formulate a framework for online sales of medicines through e-commerce channels to define the role, responsibilities, and liabilities of e-commerce marketplace and the product sellers. A nodal agency has been appointed by the DCGI for consolidating the guidelines and

was to get views from industry bodies such as OPPI, All India Chemists and Druggists Association, States Chemists and Druggists Associations, Indian Medical Association. The Indian pharmaceuticals industry needs a new regulatory framework to effectively bring e-pharmacy under its ambit. The Drugs and Cosmetics Act does not have any guidelines for e-commerce players in the pharmaceuticals sector. The government authority has also aimed to integrate e-pharmacy in the existing system [3]. The government's stance so far has been to ensure that only licensed pharmacies sell prescriptions drugs, which is in line with the position taken by most regulators in the US, the UK, and many Euro nations. The public has made clear that they want access to every commodity and consumable, from asparagus to zucchini, online and delivered to their home. This new paradigm in pharma retailing will require both a commitment to "getting it right" by the stakeholders and an eye on regulation. It is becoming clearer that the growth of online pharmacy business depends on how much they will manage to fit themselves into the legal framework. That's the gap many of the new entrants are looking to fill in. If operated within the legal framework, online medicines or Internet pharmacy provides an easy and convenient tool for the consumers. With so much traction visible in this space, the future seems to be bright for these new entrants in the e-commerce business [3].

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