

# E-Pharmacy in India: Issues and Challenges

Shivani Dutta<sup>1</sup>

*Assistant Professor, IFIM Law College, Bangalore.*

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## Abstract

The e-commerce industry has reached the zenith of growth in India. One of the recent developments is the pharmaceutical sector targeting consumers online. While it is very convenient for consumers, the business is challenged by regulatory issues. The Drugs & Cosmetics Act, 1940 and the Drugs and Cosmetics Rule, 1945, which regulates the selling and distribution of drugs in the country, prohibits selling of drugs without a prescription by a registered medical practitioner. E-pharmacy carries with it certain disadvantages such as failure to maintain the quality of medicines, storage facility of drugs, self-medication, re-ordering of drugs in the same prescription, confusing the name of the drug with that of the drug manufacturer company. The government has formed a seven-member panel to look into the issue of online drug sales. The DCGI had appointed industry body Federation of Indian Chambers of Commerce and Industry (FICCI) to frame guidelines for the online sale of medicines through e-commerce channels. While the country awaits the decision of the Centre on regulating the sale of drugs online, the association of e-pharmacy Indian Internet Pharmacy Association has formed a body to regulate accredited members. This paper describes the issues and challenges related to e-pharmacy in India.

**Keywords:** E-pharmacy; The Drugs & Cosmetics Act, 1940; The Drugs and Cosmetics Rule, 1945, Issues & Challenges.

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## I. Introduction

The e-commerce industry has reached the zenith of growth in India. The increasing use of smartphones and tablets and the easy accessibility of internet through broadband, 3G, 4G etc. has added advantage to the e-commerce business in India. As the industry is open to a wide arena of market, it serves the interests of the consumers conveniently and efficiently. One of the recent innovations of the industry in the health sector, which is still in the nascent stage is e-pharmacy. E-pharmacy or online selling of medicines, help the patients and the consumers get their medicines delivered at their doorsteps without having to leave their home. As the patients suffering from chronic diseases depend on the medicines for the rest of his life, the retailers sometimes due to shortage of medicines fail to satisfy the interests of the patient, which makes the patient to run from one pharmacy to another. In that scenario, e-pharmacy acts as a better available option to the patients and the consumers which makes the medicines readily available. Though the business of e-pharmacy is a favorable one, yet it is challenged by regulatory issues in India. The question of legality of online pharmacies has arisen with respect to the sale of prescribed drugs. In the absence of any prescribed rules, the owners of the online pharmacy adopt the rules framed for retail pharmacies in India. The selling of drugs in India is regulated by the *Drugs and Cosmetics Act, 1940* and the *Drugs and Cosmetics Rules, 1945*. The *Drugs and Cosmetics Act* makes no difference between the selling of goods online and through brick-and-mortar retail stores. The *Pharmacy Practice Regulations, 2015*, also does not define "e-pharmacy". A number of complaints has been filed by the Food and Drug Administrations (FDA's) of various states against the online pharmacies for selling prescribed drug, which is dealt in detail in this paper. Realizing the need for constituting guidelines for online pharmacies, the Drug Controller General (I) has appointed *Federation of Indian Chambers of Commerce and Industry (FICCI)* as the nodal agency to consolidate the laws relating to e-pharmacy in India. The *Federation of Indian*

*Chambers of Commerce and Industry (FICCI)* on 25<sup>th</sup> July 2016, has come up with a comprehensive guidelines to self-regulate the conduct of e-pharmacy business in India. It is an attempt by the industry to adhere to the highest professional standards and to have proper safeguards so as to ensure that consumer's health and safety is not compromised. However, the All India Organization of Chemists and Druggist, an apex body in sale and distribution of medicines, called for a nationwide strike on November 23, demanding action from the Central government against the illegal sale of drugs online. This paper discussed about the various issues and challenges with respect to online pharmacies in India.

## II. E-Pharmacy: Meaning

The blooming of the e-commerce business<sup>2</sup> in India has given birth to one of the innovative practice of selling medicines online. The online sale of medicines in India is still in the budding stage. E-pharmacy means selling of medicines online which differs from the traditional brick and mortar retail stores<sup>3</sup> which demands the physical presence of the customers. E-pharmacy no doubt is more convenient to the consumers yet one should also look into the regulatory norms for the selling of drugs online, as it is directly related to the health of the consumers. Many e-tailers such as PharmaEasy, Merapharmacy, Medicare, 3G Chemist, Netmeds and many more are carrying on the business of delivering the medicines to the doorsteps of the consumers. Let us now discuss whether the online pharmacy business conforms to the regulatory norm as laid down in the statute books of India.

## III. Regulatory Framework to Govern E-Pharmacy in India: Issues and Challenges

Where the consumers have shifted from 'offline' to 'online' mode of markets, the pre-colonial laws in India falls short to deal with the recent development of e-pharmacy concept in India. While the e-commerce business comes under the domain of the *Information Technology Act, 2000*, the legislations governing the sale of drugs in India comes within the ambit of the *Drugs and Cosmetics Act, 1940*, *The Drugs and Cosmetic Rules, 1945*, *The Pharmacist Act 1948*, *The Indian Medical Act, 1956*. However, the legislations mentioned neither permits nor prohibits online sale of medicines in India.

## IV. Status of Online Pharmacy

Part VI of the *Drugs and Cosmetics Rule, 1945*, contains the requirements for 'Sale of Drugs Other Than Homeopathic Medicines'. The issuing of license is done under two broad headings, namely, *prescription drugs* and *non-prescription drugs*. The license has to be taken separately for the both the categories. The prescription drugs are those drugs, which are listed in **Schedule H**, which is titled as Prescription Drugs. In accordance with Rule 65(9)(a)<sup>4</sup>, such drugs can be sold only on the basis of a prescription issued by a Registered Medical Practitioner as defined in Rule 2(ee) of the *Drugs and Cosmetic Rules, 1945*.<sup>5</sup> The same rule applies to **Schedule X** drugs. Schedule X drugs also includes narcotic and psychotropic substances-based drugs. In terms of Rule 123, drugs listed in **Schedule K** do not need a license for sale if sold by shop other than a chemist's shop which is a non-prescription drug. Thus, medicines can be sold only by a registered pharmacy that has retail license either online or offline as the rules does not specifically permits nor prohibit online pharmacies. Also, the circular issued by the Drugs Controller General of India (DCGI) mentions that the Rules make no difference between the conventional and over the internet sale/distribution of drugs.<sup>6</sup> Only a strict compliance of the rules is the need of the hour in both cases. Thus, selling of online medicines is not illegal in India

under the present *Drugs and Cosmetics Act* and *Drugs and Cosmetics Rules*. It will be considered illegal only when it acts in contravention of the Rules.

## V. Online Pharmacies: Issues and Challenges

No doubt the concept of e-pharmacy looks very convenient and easy, it surely has certain risks involved with it. The selling on drugs online faces some serious issues and challenges. Some of them are discussed below:

**Inter-State Sale of Drugs:** Rules related to shipping medicines from one state of India to another aren't clear. Every state has a Drug Department that grants license for certain medicines to be sold within a state. There is a possibility that, certain medicines valid in one state might not have license in another.<sup>7</sup> Hence, there is ambiguity regarding shipping of medicines from one state to another. Suppose, 'A' who is a resident of Bengaluru places an order for 'X' medicine through an e-pharmacy website. The medicine is shipped from the State of Andhra Pradesh and is delivered to the consumer. However, it comes to the notice that the medicine 'X' is not a licensed drug in the State of Karnataka thereby violating the rules as provided under 'The D&C Act'. As the e-commerce business in India is operated freely from one State to another, it will be very difficult for one to keep a close monitor on the source from where drugs are delivered to the consumers. . Such an instance has already been registered by Mumbai Food and Drug Administration (FDA) which is discussed in the subsequent paragraphs.

**Taking Money Prior to Delivery:** There is ambiguity in the Indian law whether a pharmacy is allowed to take money prior to delivery of medicines. Certain provisions of the law mandate, money to be collected from the customer only after medicines are physically handed over to the customer. The various payment options provided by the e-pharmacy websites such as Credit/ Debit payment, payment via mobile wallets etc on placing an order will surely raise questions of contravening the Rules as provided.

**Selling Scheduled Drugs:**online selling of drugs poses a serious risk of selling **Schedule X and Schedule H** medicines to customers. Drugs which fall within the two schedules shall not be delivered to customers without prescription and is a crime. Proper customer record needs to be maintained including name of the patient, doctor and address for every Schedule H and Schedule X medicines sold by the pharmacy. A single prescription can be used for multiple delivery of drugs through different e-pharmacy websites. A proper regulatory framework is the need of the hour to deal with this complicated issue as this may rise the percentage of drug abuse in India. Another important issues which needs proper regulation is the selling of drugs to minors. It will be very difficult to trace the authenticity of the prescription when it is uploaded in the websites for online purchase of drug.

## VI. Selling Drugs without a Registered Medical Practitioner

The *Drugs and Cosmetics Act* and the *Drugs and Cosmetics Rules* makes it very clear that the drugs are to be sold only after the supervision of a registered medical practitioner (RMP). <sup>8</sup>In case of online orders of drugs it will be very difficult to check whether they have appointed a RMP to monitor the drugs which is delivered to the customers.

## VII. Cases Registered Against E-Pharmacy Websites

A number of websites dealing with the sale of drug online are found contravening the provisions of the present law in India. Some of the instances are discussed in the subsequent paragraphs.

A complaint was made by SwadeshSevaSantha, an NGO against Myra Medicines, an e-pharmacy app for clandestine selling of Schedule H drugs and other banned medicines under the *Drugs and Cosmetics Act, 1940*, *Drugs and Cosmetics Rules 1945*, the *Narcotic Drugs and Psychotropic Substances Act, 1985* and Food and Drug Administration regulations, in the state of Karnataka, without a valid prescription signed by a registered medical practitioner. Following the complaint, the Drug Controller of Karnataka has registered a case against the e-pharmacy. The plot to catch them red-handed was planted by the members of the NGO by placing orders through **Myra Medicines** app. To the utter surprise of the members Myra delivered all orders including banned medicines like Corex, Schedule H medicines like Moxikind CV 625mg, Jalra M 50/500mg, Daonil 5mg and Nurokind 500 mcg without a valid prescription. This instance poses a serious question on the health of the consumer, where taking the drug on a regular basis may lead to serious side effect. Also, the selling of drug without the identity and age of the patient will result in the high rise of drug abuse in the country.<sup>9</sup> However, the ill-effect which will cause by the use of banned drugs is not within the ambit of this paper.

Another similar instance happened in the state of Mumbai. The drug arm of state Food and Drug Administration has filed a FIR against two online medical stores for selling medicines online to patients on basis of the prescription uploaded by the consumers. An FDA inspector posing as a customer bought medicines from **Mera Pharmacy**- an online portal. The inspector bought painkillers which were delivered to his residence from Gujarat. Similarly in the second case, a woman on behalf of FDA, posing as a customer bought medicines from Chemist Global which was delivered to her residence from Delhi.<sup>10</sup> As discussed earlier in the paper, drugs supplied from one state and sold in another is barred by the *Drugs and Cosmetic Rules*. In both the cases, the medicines were being supplied to patients in Mumbai from outside Maharashtra which is a clear violation of the Rules. It is pertinent to mention here the important observation made by BR Masal<sup>11</sup> "What if the patient uploads a fake prescription on the website? They can also use a valid prescription on several websites to buy medicines in bulk, which are then abused, such as sleeping tablets." This is a serious concern where one prescription can lead to multiple orders online. This issue needs to be dealt in an appropriate manner. Two public interest litigations, one in the year 2015 and 2016 in Bombay<sup>12</sup> and Madras High Court respectively, against the illegal delivery of Schedule H drugs without prescription and cash memos. The Bombay High Court directed the state government to take necessary steps to prevent unauthorized sale of drugs online. The Madras High Court also issued notice to the Centre on the PIL seeking to ban websites from selling scheduled medicines online in violation of *Drugs and Cosmetic Rules*.<sup>13</sup>

## VIII. Present Scenario

To tackle the menace of online sale of drug in India, the Drugs Consultative Committee, the advisory arm of the Drug Controller General of India (DCGI), in July 2015 constituted a seven member sub-committee under the Chairmanship of Maharashtra Food and Drug Administration (FDA) Commissioner Harshadeep Kamble. In the meanwhile, The Federation of Indian Chambers of Commerce and Industry (FICCI) - an apex business organization has developed a white paper- e-pharmacy in India-Last mile access of medicines'. It is a **Self-regulation Code of Conduct for the E-pharmacy sector which was released** in the presence of Government dignitaries and the concerned stakeholders on 21st November, 2016, FICCI, New Delhi. In the absence of the concrete law on the subject the association binds themselves by the code of conduct.<sup>14</sup>

Thereafter, the sub-committee after inviting comments and suggestions from general public, submitted the following draft recommendations<sup>15</sup> to DCC:

- Creation of a national portal to act as the nodal platform for transacting and monitoring online sale of drugs and necessity of evolving a mechanism to register e-pharmacies.
- Sale of drugs through e-prescription.
- Audit trial to prevent drug abuse and linking prescriptions to Aadhaar Card.
- Geographical restrictions for operation of e-pharmacies.
- The existing licencees involved in retail sale of drugs could also register on the national portal for carrying out online sale of drugs.
- Certain categories of drugs viz. the narcotic and psychotropic drugs, tranquilisers, habit forming drugs and Schedule X drugs that are prone to being abused or misused be excluded from sale through e-pharmacies.
- All matters relating to sale of drugs including through online will continue to be regulated in accordance with the provisions of the Drugs and Cosmetics Rules, 1945 as amended from time to time

## IX. Conclusion

From the above discussion it can be concluded that operation of e-pharmacy websites and selling of online drugs in India is not illegal. It comes well within the purview of the Drugs and Cosmetics Act and Drugs and Cosmetics Rules. The only cause of concern for the online pharmacies is to abide by law on the subject. From the draft recommendation of the sub-committee it is clear that selling of narcotics, tranquillizers, Schedule X drugs which are prone to be misused are to be kept out of the reach from the e-pharmacy sellers. E-pharmacy makes the medicines readily available to customers without much hazard. This also comes with the disadvantage as the customers can experiment self-medication which could adversely affect their health. Also, as the customers do not personally inspect the medicines before buying, there is a chance that wrong medicine from the same manufacturer get delivered. The need of the hour is to see if the recommendations given by the sub-committee are incorporated into the legislation by the method of amendment, bringing an end to the battle between offline pharmacies and online-pharmacies.

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- 3 Brick and mortar is a traditional street-side business that deals with its customers face to face in an office or store that the business owns or rents. The local grocery store and the corner bank are examples of brick-and-mortar companies. Brick-and-mortar businesses can find it difficult to compete with web-based businesses because the latter usually have lower operating costs and greater flexibility.<http://www.investopedia.com/terms/b/brickandmortar.asp>
- 4 Substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years.
- 5 For detailed study read: *Muktiaar Chand & Ors v/s The State of Punjab & Ors* (1998) 7 SCC 579.
- 6 No. 7-5/2015/Misc/(e-governance)/091 Dte. General of Health Services Office of Drugs Controller General (India) <http://www.cdsc.nic.in/writereaddata/Online-Sale-dec-2015.pdf>

- 7 **Rule 62 deals with** sale at more than one place: 'If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate license shall be issued, in respect of each such place...'
- 8 Rule 69(a), D&C Rules, 1945.
- 9 <http://timesofindia.indiatimes.com/city/bengaluru/karnataka-drug-controller-registers-case-against-e-pharmacy-app-for-selling-banned-drugs/articleshow/56704427.cms>. Last visited on 10/02/2017 at 11.05 am.
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