

E-PHARMACY LAWS IN INDIA— A NEED FOR CHANGE

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Abstract

The twenty first century has witnessed a rapid growth in technology. With globalization playing the role of a catalyst, technology has given birth to the idea of e-commerce. India being a third world country is still adapting to the new changes. E-commerce has spread its wings to include e-pharmacy as one of its components, which allows a customer to place an online order of required medicines. Internationally e-pharmacies are encouraged and are regulated, as it is beneficial to the consumers present in that market. The same can be introduced in the context of the Indian market.

Though there are legislations like the Drugs and Cosmetics Act, 1940, which regulates the standard requirements for production and sale of medicines, the Drug (Control) Act, 1950, which regulates the pricing and selling of the medicines and the Information Technology Act, 2000, which regulates the online transaction of any product, there is no specific legislation that regulates or lays down guidelines which have to be followed in the case of an e-pharmacy. Due to this, the legality of the available online pharmacies is questioned.

This problem arises because the available legislations related to medicines do not consider an e-pharmacy as a registered pharmacist, which in turn does not authorise them to sell medicines on the Internet. This article aims to provide for the lacunae in our legal system, which fails to provide for e-pharmacy by referring to the existing legislations and suggesting amendments to the Drugs and Cosmetics Act, 1940.

The concept of e-pharmacy must have proper regularisation, licensing and monitoring of the online sale of drugs. This article also provides for the requirements, which an e-pharmacy has to fulfill to get registered, as it is a duty of the pharmacist opting for e-pharmacy to get registered for an efficient and consumer beneficiary business model.

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I. INTRODUCTION

Post Globalization, Indian society and the Indian market have been in a continuous process of development with advancement in science and technology. Technology has now made it easier to offer and provide services to customers. Developments in cyber technology have also made their mark in the Indian market. A massive growth rate can be seen in the online business and services sector, which is termed as e-commerce.

E-commerce is a business model where trading of goods and services is done through transmission of data and funds from the customer to the producer or service provider over an electronic network or through the Internet. It allows a customer to directly place an order or buy any of the products listed on the website of the producer or the service provider, evoking the physical analogy of business over the Internet.

E-pharmacy is the new marketing method adopted for sale of medicines in this technologically driven age. An e-pharmacy is an online medical pharmacy where a customer can check the available medicines on the database of the service provider and place an order for the medicines. Though there are laws in India that regulate e-commerce, there is no specific legislation that regulates the online sale of medicine. Existing legislations have not yet been amended to regulate the online sale of medicine leading to conflict of interest between the pharmacist, the Government and the consumers.

II. CONSTITUTIONAL PROVISIONS

The Indian Constitution is the *grundnorm* from which all the other legislations derive their authority. Part III forms the conscience of the Constitution guaranteeing various fundamental rights. Under this part of the Constitution, Article 19 guarantees Indian citizens with the fundamental right of freedom.¹ Article 19(1)(g) of the Indian Constitution guarantees citizens the freedom to practice any profession or to carry on any trade, business or occupation. However, it is not absolute in its sense and is subject to reasonable restrictions and regulations by the State. Article 19(6) authorises the State

¹Article 19, the Constitution of India, Protection of certain rights regarding freedom of speech, etc.

to make relevant laws and regulations to impose reasonable restrictions on this freedom in the interest of general public and justice, equity and good conscience.

The Constitution does not define or throw light upon the expression “reasonable restriction”. The test may vary from right to right restricted by the impugned law.² The standard for reasonable restriction is an elastic one; “it varies with time, space and condition” and also from case to case.³

Under the ambit of Article 19(6) of the Indian Constitution, the Government enacted The Drug and Cosmetics Act, 1940, to regulate and lay down guidelines for manufacturing, distribution and sale of medicines in India. It is necessary that the medicines manufactured and sold be in conformity with this legislation as it aims to ensure consumer safety. Article 21 of the Indian Constitution guarantees the right to life which has been judicially interpreted to include right to live with dignity. The scope of this right has been further elaborated upon by our esteemed judiciary to state that one should get all the basic requirements like nutrition, proper health care, clothing and adequate resources so as to enjoy this right. Medical care also forms a part of our basic requirements and needs and therefore its easy availability is our right guaranteed under Article 21 of the Indian Constitution.⁴

III. The Drug and Cosmetics Act, 1940

In other legal jurisdictions, the rules and regulations related to the preparation, manufacture and sale of medicines have been very stringent. However, no such strict guidelines were prevalent in India. This was reflective of the neglected situation of medicines in the Indian market. The quality of the majority of the medicines available was not of the required and prescribed standards, and the production and sale of medicines was not efficiently regulated.

It was only in the year 1940 that the Drug and Cosmetics Act was passed which sought to regulate the production of medicine. One decade later in the year of 1950, the Drug

²State of Madras v. V.G. Row, AIR 1952 SC 196.

³Golak Nath v. State of Punjab, AIR 1967 SC 1643.

⁴Paschim Banga Khet Mazdoor Samity v. State of West Bengal &ors, (1996) AIR SC 2426.

(Control) Act was passed to regulate the production, sale and distribution of medicines in India.

The Drug and Cosmetics Act, 1940 regulates the standard that a manufacturer of medicines has to comply with and prescribes the requirements which must be followed so that the medicine is of good quality and of benefit to the consumer⁵. Each type of medicine and its chemical group has its own standards. Schedule 2 of the Drugs and Cosmetics Act, for instance lays down the standard for Homoeopathic Medicines⁶.

The standards that are specified in the Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom or Germany for Homoeopathic medicines, and for those which are not included in the Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom, or Germany, the standards given by the Central Government, have to be followed.

The Drug and Cosmetics Act, 1940, prohibits the production and sale of certain drugs and cosmetics that do not match the standard quality mentioned, are misbranded, adulterated or spurious.⁷ Unless the true formula or list of active ingredients contained in the medicine is mentioned together with their quantities, such drugs and cosmetics are prohibited from being produced or distributed.

The Act also regulates the pricing and selling of drugs in the market. The producer and the dealer are defined as persons carrying on the business of selling any drugs, either personally or through any other person, whether wholesale or retail under Section 2(a) of the Act.⁸ Under this Act the producer and the dealer have to follow the guidelines related to the pricing and selling of medicines, which are fixed by the Chief Commissioner, by notification in the Official Gazette.⁹

The Drugs and Cosmetics Rules, 1945 further classify drugs into two broad classifications of Prescription Drugs¹⁰ and Over-the-counter Drugs.

⁵Schedule 2, Drugs and Cosmetics Act, 1940.

⁶ Section 4-A, Schedule 2, Drugs and Cosmetics Act, 1940.

⁷Section 18, Drugs and Cosmetics Act, 1940.

⁸Section 2(a), Drug (Control) Act, 1950.

⁹Section 4, Drug (Control) Act, 1950.

¹⁰ Schedule H and Schedule X, Drugs and Cosmetics Rules, 1945.

Prescription Drugs are drugs which have to be prescribed by a doctor and cannot be bought without such prescription. According to the Pharmacy Practice Regulation of 2015 declared by the Pharmacy Council of India, a prescription is defined as “written or electronic direction” by a registered medical practitioner.¹¹ Hence a person, who wants to buy a prescription drug needs to possess a prescription prescribed to him by a certified medical practitioner, who is a doctor or possesses a license and educational degree of the same value. The Drugs and Cosmetics Rules, 1945, states that a prescription shall be in the written form and signed by the person giving it with his usual signature and should be dated.¹²

Over-the-counter drugs are those drugs which can be bought by an individual without any prescription, and these drugs have no regulation related to their sale.

IV. ONLINE SALE OF MEDICINES

The Pharmacy Act, 1948, describes a registered pharmacist as “a person whose name is entered in the register of the State in which he is residing or carrying on his profession or business of pharmacy”.¹³ An online vendor is not covered under this definition as a website is not registered under the jurisdiction of a state and there is no specific residing address of websites.

A specific statute that is the Information Technology (IT) Act, 2000 (as duly amended from time to time) specifically regulates online marketplaces. Under the IT Act, online marketplaces are specifically categorised as ‘Intermediaries’. E-pharmacies can also be considered as intermediaries. An intermediary with respect to any particular electronic records, means any person who on behalf of another person receives, stores or transmits that record or provides any service with respect to that record and includes telecom service providers, network service providers, internet service providers, web-hosting service providers, search engines, online payment sites, online-auction sites, online-market places and cyber cafes.¹⁴

¹¹ Regulation 2(j)(3), Pharmacy Practice Regulation, 2015.

¹² Rule 65, Drugs and Cosmetics Rules, 1945.

¹³Section 2(i), The Pharmacy Act, 1948.

¹⁴Section 2(w), The Information Technology Act, 2000.

Being an intermediary platform, an e-pharmacy is susceptible to risk, wherein a third party user may misuse the platform of the intermediary, to sell his products over the internet. This might lead to breach of privacy of a patient. This is because online pharmacies utilise the personal and financial information of patients which can be misused and can lead to identity theft and fraud, which are criminal offences.¹⁵

Information Technology Act, 2000, under Section 79 exempts the liability of intermediaries from third-party information, data or communication link shared or made available or hosted by the intermediary. This exception is limited only for the following conditions.

- Transmission of information should not be initiated
- Receiver of the information should not be selected
- Transmitted information should not be modified
- Access provided to the system should be limited
- Due diligence must be observed.

There are several issues related to e-pharmacies which have to be addressed and regulated. In 2015, a police complaint was filed against the e-commerce giant Snapdeal by the Drug Regulator of Maharashtra for listing of prescription medicines on its website and the next day the office of this company was raided.¹⁶ The Food & Drug Administration (FDA) authority in the state of Maharashtra filed a First Information Report (FIR) at a police station after a sting operation by it which allegedly revealed that it was possible to buy emergency contraceptives without a doctor's prescription.

¹⁵Section 416, The Indian Penal Code, 1908.

¹⁶ *Online Medicine Sale: FIR against Snapdeal CEO Kunal Bahl*, ET Retail (2/5/2015), available at <http://indiatoday.intoday.in/story/snapdeal-online-medicine-sale-fda-norms/1/433240.html>, last seen on 12/5/2017.

V. ISSUES RELATED TO E-PHARMACY

5.1. Registrations and Licensing

According to Pharmacy Act, 1948, only “a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner”.¹⁷ It further states that anyone who contravenes this provision shall be punished with imprisonment for a term extending to a period of six months, or with fine which shall not exceed one thousand rupees or both.¹⁸

The aforementioned provisions of the Pharmacy Act make it clear that only a registered pharmacist is authorised to deal with medicines and no other individual is allowed to compound, prepare, mix or dispense the medicine. The major issue with e-pharmacy is that it has not been recognised as a pharmacist under this Act, which means that the operation of e-pharmacies is in gross violation of the provisions of the Pharmacy Act, 1948, as they are not allowed or authorised to perform the activity under Section 42(1) of the Act.

Under the Drugs and Cosmetics Act, 1940, a license is required for importing any drug that is not of standard quality, any misbranded, adulterated or spurious drug or any other drug. Importing of any drug, which by any means claims to cure any disease is prohibited by this Act.¹⁹ Import of medicines requires licensing in order to prevent persons from importing unsafe, fake or mislabeled drugs and subsequently introducing them in the Indian market potentially causing suffering for the common man. E-pharmacies do not have such importing license as they are not recognised as pharmacies under the Drugs and Cosmetics Act, 1940, and hence, they cannot import medicines, which limit their options to the medicines that are produced in India.

For sale and manufacturing of medicines, a person requires a license under the Drugs and Cosmetics Act²⁰. If a person performs these two activities without a valid license, he

¹⁷Section 42(1), Pharmacy Act, 1948.

¹⁸Section 42(2), Pharmacy Act, 1948.

¹⁹Section 10, Drugs and Cosmetics Act, 1940.

²⁰Section 18(c), Drugs and Cosmetics Act, 1940.

will be liable to be punished with a penalty in the form of imprisonment or fine or both²¹.

5.2. Quality of Medicines

Under The Drugs and Cosmetics Act, 1940, medicines have to be stored and monitored properly by a manufacturer and the seller has to store these medicines as directed. If these guidelines are not followed, the medicines are considered to be adulterated.²² If they get exposed to high temperature or problematic storage conditions in transit then it could become a potential health risk. In an online pharmacy, this cannot be checked, as there is no regulation that directs an online pharmacy to follow the guidelines set forth in this respect.

Hence, one cannot be certain if the medicines available on the website of the online pharmacy have been stored efficiently and properly, and if it is safe for these medicines to be sold and consumed by the consumers.

5.3. Authenticity

On an online pharmacy, anyone can place an order for any medicine that is available on the site. Even minors can access these websites and place an order for medicines. It is suggested that online pharmacies in this way may be tacitly promoting drug abuse, drug misuse, self-medication and other such acts. Without the supervision of doctors this can not only be dangerous but also potentially life-threatening.

Another major issue related to e-pharmacies is phishing. Phishing is an attempt to acquire personal information such as username, password and bank details by an act of misrepresentation in an electronic communication.

It is possible for scammers to setup a fake pharmacy websites and look legitimate. They can use such websites to send misleading emails and offers that will attract the consumers to take up the offer and pay the retailer and end up never receiving the

²¹Section 27(a)(ii), Drugs and Cosmetics Act, 1940.

²²Section 9A, Drugs and Cosmetics Act, 1940.

product. The act of phishing is punishable under the Information Technology Act, 2000.²³

VI. ANALYSIS

The International Narcotics Control Board, (INCB) is an independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions and was established in 1968 in accordance with the Single Convention on Narcotic Drugs, 1961. It has drafted guidelines called the “Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet”²⁴. While describing the problem, the Board states that the illegal sale of pharmaceuticals is facilitated by websites that present themselves as Internet pharmacies and supply controlled narcotic drugs and psychotropic substances without meeting the legal and administrative requirements established for traditional pharmacies.

The International Narcotics Control Board has laid down 25 guidelines that they recommend Governments should include provisions in national legislations so as to empower the appropriate authorities to investigate and take legal action against Internet pharmacies and other websites, hosted by Internet service providers.

In the United States, e-pharmacies have to comply with the rules and regulations under the Ryan Haight Online Pharmacy Consumer Protection Act, 2008. This Act regulates e-pharmacies as well as the distribution of medicines over the internet. Under this Act, “Online Pharmacy” is defined as “a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses a controlled substance by means of the Internet”²⁵.

Under this legislation, an online pharmacy has to comply with the following guidelines:

²³Section 66, The Information Technology Act, 2000.

²⁴*Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet*, International Narcotics Control Board, available at https://www.incb.org/documents/Narcotic-Drugs/Guidelines/internet/NAR_guide_Internet_guidelines_English.pdf, last seen on 12/5/2017.

²⁵Section 3, Ryan Haight Online Pharmacy Consumer Protection Act, 2008, amending Section 102 (52) of the Controlled Substances Act (21 U.S.C. 802).

- Display specified information on its Internet home page, including a statement that it complies with the requirements of the Ryan Haight Act, its name, address, and telephone number, the qualifications of its pharmacist-in-charge, and a certification of its registration under the Ryan Haight Act;
- Comply with state laws for the licensure of pharmacies in each state in which it operates or sells controlled substances; and
- Notify the Attorney General and applicable state boards of pharmacy 30 days prior to offering to sell, deliver, distribute, or dispense controlled substances over the Internet.²⁶

The Ryan Haight Act, 2008, states that no controlled substance, that is prescription drug as determined, may be delivered, distributed or dispensed by means of the Internet without a valid prescription. The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of a patient”.²⁷

In 1997, the World Health Organization called on its Member States to tighten controls on the sale of medical products through the Internet. WHO was especially concerned that Internet sales may bypass national drug regulatory authorities, thereby liberating such medical products onto the market, which are unapproved, fraudulent, unsafe or ineffective. WHO had declared that ordering medical products without the safeguards offered by competent regulation could endanger public health and pose a risk to individual patients.²⁸

Production and sale of medicines as already known has developed. Producers of these medicines have now adopted and upgraded to e-commerce sites to reach out to a larger consumer base. The use of e-commerce in the field of medicine raises certain legal issues, which have not been addressed till date in the laws, related to production and sale of medicine. The main issue and problem related to e-pharmacy is the sale and supply of prescription drugs.

²⁶Section 3 of Ryan Haight Online Pharmacy Consumer Protection Act, 2008, amending section 311 of Controlled Substances Act (21 U.S.C. 829).

²⁷Section 2 of Ryan Haight Online Pharmacy Consumer Protection Act, 2008, amending Section 309(e)(2) of the Controlled Substances Act (21 U.S.C. 829).

²⁸Judy Siegel-Itzkovich, *WHO calls for tighter controls on Internet*. 314 British Medical Journal 1501 (1997).

In India there are specific medicines that need prescription from a licensed medical practitioner. Without a prescription, one is not legally allowed to buy these medicines. However on an online pharmacy, one can place an order for these drugs with or without a prescription, which breaches the provisions of Drugs and Cosmetics Act. Such online pharmacies can in no way determine the age and the mental health of the customers who are ordering from their website. This might result in children exploiting this facility and purchasing drugs they do not require, leading to severe addiction to drugs which will cause immense harm to them.

A fruitful solution for the same would be requiring customers to upload a scanned copy of the prescription on the website of the pharmacy before placing an order for the medicines. An online licensed pharmacist can verify the same and then give his consent for the shipment of the ordered medicines.

The Indian Parliament should draft legislation for the same or amend the existing laws to increase their ambit to include e-pharmacy. To regulate e-pharmacy in India, the term “E-pharmacy” has to be defined and should be brought within the scope of the Drugs and Cosmetics Act, 1940. This will allow the e-pharmacists to register their companies as registered pharmacists for online sale of medicines. Registered pharmacies should follow the guidelines that are laid under different legislations related to production and sale of medicines. They cannot have their own policies and once these e-pharmacies are registered as pharmacies under the Act, then it will be mandatory duty to follow all the rules and regulations and guidelines for manufacturing, distribution, storing and selling of the medicines.

These Internet pharmacies should maintain patient registers. The online pharmacy should also try to avoid potential drug interactions by asking new patients to complete a form indicating what other medications they are consuming at the time of the order, a brief medical history, and describing related health conditions. Each patient must be provided with a unique personal identifying and confidential ID to protect the interest and private information of the patient.

E-pharmacy is one such development of e-commerce where an online pharmacy is created and it provides the customers with options to buy medicines online which makes it easier for the customer with respect to the availability of the medicines. It benefits the customer by making their life more comfortable by allowing them to order their medicines online. It is no more necessary to go to the medical stores to purchase medicines and one can invest his time in doing something else. The availability of medicines is higher, the service provided is enhanced. Internationally e-pharmacies are encouraged and are regulated, as it is beneficial to the consumers in that market. The same can be introduced in the context of the Indian medicine market also with the implementation of a few necessary changes.

Though the force of technology drives our daily life, there are certain fields, which are still backward and need immense research and legislation such as e-pharmacy. E-commerce should not be used loosely to defeat the purpose for which the prevalent legislations are drafted and our legislature should act upon the current laws and bring in the requisite change. Though e-pharmacies make the life of a common man easier and convenient, the dangers attached to them should also be urgently recognised and addressed besides awareness for the same being spread.

VII. CONCLUSION

It is evident that the production and sale of various products has developed due to the advancement of science and technology. E-commerce is the new business model that has been accepted by the consumers of the market as it provides for an easy access to various types of products available.

E pharmacy is the new model for pharmacist that enables sales and distribution of medicines over the Internet, a patient or a customer has the opportunity to place an order, for any required medicine that is made available on the website of the owner of the online pharmacy.

It was only during the 20th century that the production and sales of drugs and cosmetics was regulated in India. There was no concept of e-commerce. The concept of e-commerce took the market by force only in the 21st century and accordingly various laws

were amended and new regulations were enforced to regulate this business model. However the lack of laws meant to regulate e-pharmacy leads to different legal as well as ethical issues. These e-pharmacies are not recognised in the Indian market by the legislations available due to which the government has no control over the functioning and formation of such companies. Legal issues relate to the sale of drugs that need prescription from a registered medical practitioner and the other issue is related to the standard of production and storage of these drugs. The ethical issues related to e-pharmacies include but are not limited to phishing, fake pharmacies which can be established with ease and the availability of illegal drugs that can be sold to anyone who wishes to buy them.

In the United States, e-pharmacies have been recognised and are legally regulated. The pharmacists have to comply with the rules and regulations under the Ryan Haight Online Pharmacy Consumer Protection Act, 2008. This Act regulates e-pharmacies as well as the distribution of medicines over the internet. This ensures the safety of the consumers using this medium of e-pharmacy by protecting them from any illegal act of the pharmacist.

The International Narcotics Control Board (INCB) has laid down around twenty five guidelines that it recommends Governments should include in their national legislative provisions in order to empower the appropriate authorities to investigate and take legal action against internet pharmacies and other websites, hosted by internet service providers operating from their country, that are used in the illegal sale of internationally controlled substances and also establish standards and publish guidelines for doctors providing their services to internet pharmacies on patient evaluation, treatment and consultation, on the issuing of prescriptions and on the maintenance of medical records.

The available legislations and documents can be referred to so as to understand the most viable situation in this respect. The authors suggest that the existing Acts in India that regulate the sale and distribution of drugs in India should be amended so as to protect the interest of the Government and the consumers of the Indian market by recognising e-pharmacy and regulating their functions.