

Review Article

E-Pharmacy in India and Legal Scenario: A Critical Approach

Anu Singhai^a, Vishnu Dubey^{*b}, Laxmi Tripathi^c

^aDepartment of Law, Rabindranath Tagore University, Bhopal, Madhya Pradesh, India.

^bDepartment of Law, Oriental University Indore, Madhya Pradesh, India

^cDepartment of Pharmaceutical Chemistry, Agra Public Pharmacy College, Delhi–Agra National Highway-2, Agra, Uttar Pradesh, India.

* **Corresponding Author:** Tel.: +91-8094047437, Email: vanshjivishnu@gmail.com

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ABSTRACT

E-Pharmacies in India mainly work through an integrated network that connects both the distributors and the retailers directly to the customers. Investors are willing to fund the e-Pharmacies because they know that this model is potential enough to revolutionize the Pharmaceutical Industry. This model shows promised and prominent growth in the Indian market when there is condition of recession across the globe. However, many organizations have been protesting against proliferation of e-Pharmacies, the traditional Pharmacies see them as competitors eating their pie whereas human rights groups have raised concerns over the unregulated sale of medicines leading to potential health epidemic. The lack of regulatory provision and recent judgments by two different high courts could not help to ease out the problem. The current article focuses on the issue of e-Pharmacy in India and global stand, while highlighting the key benefits of the same. The article further lays down the challenges faced and current legal scenario while suggesting the amicable solutions.

1. INTRODUCTION

The dictionary meaning of Pharmacy is not restricted to the study of medicine preparation only but the term is also used to indicate part of a hospital where medicines are prepared or the activity or study of medicine preparation. Thus, in nut shell Pharmacy is the science and technique of preparing, dispensing, and reviewing drugs and providing additional clinical services. It is a health profession that links health sciences with Pharmaceutical sciences and aims to ensure the safe, effective, and affordable use of drugs. In the recent decade the trend of border free market and online market has gained tremendous popularity. To add to it Make in India and Digital India, Healthcare Start-ups have revolutionized the e-healthcare.

Even the field of Pharmacy has witnessed a shift from the “brick and mortar sale” to “online sale” of medicines. Thus, the current article focuses on the scenario of the “e- Pharmacies” i.e. online sale and purchase of the medicines.

2. PHARMACY AND INDIAN MARKET

According to Frost & Sullivan in a recent white paper on e-Pharmacies in India - the market in India is estimated to be around \$512 million (~Rs 3,500 crore) in 2018 and is estimated to grow at a CAGR of 63% to reach US \$3,657 million (~Rs.25,000 crore) by 2022. [1-5] Industry experts estimate the market to be generating 3,000-4,000 orders on a daily basis. Remarkable growth has been observed during the last five years. There is no specific law to deal with online Pharmacies in India but multiple

laws govern online Pharmacies in an indirect manner. The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, are amongst some of them that provides guidelines on the sale of Schedule H and Schedule X drugs that can be sold only on prescription along with specific rules, including for labelling and bar coding.

3. HOW E-PHARMACIES WORK?

E-Pharmacies mainly work through an integrated network that connects both the distributors and the retailers directly to the customers. This can broadly be classified in to three types of models [2] that exist in India organized, non-organized and illegal.

4. ORGANIZED E-PHARMACY

There are two models which operate in this category.

- The *market place model*, where a technology company connects neighbourhood licensed Pharmacies to the end user;
- The *inventory based model*, where e-Pharmacy is the online service of an offline licensed Pharmacy.

Thus these are the companies that adhere to all the regulations put forth by the Government with regards to the management of the accounts, valid prescriptions etc. They have a particular involving registered Pharmacist that screen, check and validate the authenticity of the prescriptions uploaded. Taking e-Pharmacy scenario to another level some organized e-Pharmacies using the intelligence combination and data analysis have started profiling their customers in a particular area thus, reducing the contingency of misuse of the medicine, reducing the logistic cost and providing an end to end solution to e-Pharmacy.

5. NON-ORGANIZED E-PHARMACY

In this model prescription medicines are ordered without any validated prescription. There is no check on the genuineness of the order due to absence of qualified Pharmacists. Also, improper record keeping and no audit is a major area of concern [6].

6. ILLEGAL INTERNATIONAL TRADE THROUGH E-PHARMACY

In this model, drugs are shipped across the International borders without any prescription and approval from the concerned authorities. This is generally used to order cheaper version of drugs like Viagra. The powers regarding framing of the rules have been distributed amongst the state and centre. But when it comes to e-Pharmacies there is still avoid regarding unambiguous, clear-cut regulatory framework to regulate and monitor e-Pharmacies.

The whole process of e-Pharmacy involves 4-5 steps. Beginning with the customer uploading the prescription, selecting the medicines that he requires or any alternative if desired, followed by selecting and locking the choice after which the payment is to be done. Thus, the desired medicine is delivered at the door step.

7. OVERVIEW OF E-PHARMACIES REGULATION IN INDIA

Currently regulatory powers have been distributed between the centre and the state Governments. Central Government is responsible for licensing of drug imports and the state Governments are responsible for the manufacture, sale and distribution of drugs. Central Government exercises regulatory control over drugs by New Delhi based Central Drugs Control Organisation headed by the Drugs Controller General of India. State authorities exercises regulatory control over drugs by state based Drugs Control Administration headed by the State Drugs Controllers. Every state has its own Drugs Control Administration.

The laws governing Pharmacies in India are derived from Drugs and Cosmetics Act, 1940; Drugs and Cosmetics Rules, 1945; Pharmacy Act, 1948; Indian Medical Act, 1956 and Code of Ethics Regulations, 2002, etc. [7] These laws were written in the era when computers did not even start. So, basically there are no laws related to internet and e-commerce. The Information Technology Act, 2000 governs all activities related to computers and cyber space. When e-pharmacies regulation is concerned, there is lack of accurately and unambiguously stated laws and clear-cut guidelines to regulate, control and monitor e-Pharmacies. For ensuring efficient and legitimate running of e-Pharmacies, it is a need of the hour to make hassle free rules for e-Pharmacies.

E-Pharmacies comes under the purview of the Drugs and Cosmetics Act, 1940 and the Information Technology Act, 2000 but it doesn't distinguish between online and offline Pharmacies. Thus e-Pharmacy players make interpretation of laws and rules as per their convenience for taking advantage for their business when there is uncertainty on the applicability of these laws to this model. It seems that online players do not abide to these regulations and try to bypass them. There is a big misconception of believing that rules applied for off line Pharmacies could be easily applied to the online Pharmacies too. This may lead to dangerous consequences and may be proved as dangerous trend in future. Hence, amendments are required to the prevailing acts to bring e-Pharmacies within the scope of Drugs and Cosmetics Act, 1940.

8. GLOBAL STAND ON E-PHARMACY

Various Governments are making e-prescriptions and e-health records mandatory which automatically feed in to e-Pharmacies for fulfilment. For instance, New York has completely banned paper prescriptions. China is seeing street side kiosks which are one-minute clinics which can be used by customers for immediate health consultation and medicines dispensing or delivery to home by end of the consultation. [8] Many e-pharmacies globally offer the Pill Pack style of dispensing where medicines are pre packed as per the day's & time's dosage. Automation at retail level is allowing Pharmacies to bring down costs and extend the benefit to customers with a lower Pharmacy fee. [9]

For instance in Canada any licensed Pharmacy that offers internet services must meet the standards of practice within its own province. The licensing is done at the provincial level rather than at the national level. Thus e-Pharmacy must be a brick and mortar Pharmacy with a physical street address to dispense drugs over internet. Similarly, USA has a programme called Verified Internet Pharmacy Practice Sites (VIPPS) certification which is given to Pharmacy websites that practice the defined rules and standards set by the VIPPS programme. The online registration of the Pharmacies with the DEA (Drug Enforcement Administration) is a must in order to dispense the “controlled substances”. They must also comply with the guidelines laid down by the food, Drug and Cosmetic Act. Along with these provisions it is a mandate that the Pharmacy must be domiciled within the U.

Further the FDA Guidelines [10] suggests that a legal, regulated “online Pharmacy” requires a valid prescription, a physical address in the United States, in addition to that, is licensed by the state board of Pharmacy in the state where the Pharmacy is operating. Moreover e- prescription or original paper prescription is the only allowable form of prescription for a VIPPS Pharmacy. VIPPS does not allow the Pharmacy to dispense based on scanned prescription or an image of prescription.

But not all the countries stand on the same footing. On the contrary some countries have stringent rules and regulations while some countries are still in process to make the framework. However the developed countries like Japan, Italy, Ireland, Spain, Korea, Thailand, Turkey and Russia do not permit sale of medicines through online pharmacies.

9. BENEFITS OF E- PHARMACY

The easy access and availability of the medicines over online platform has made it quite convenient for the patients to access the medicines in just a click. Thus the patients don't have to wander around in search of the medicine as the e-Pharmacies cover both kinds of medicines, general and specific. Additionally they offer huge discounts as the medicines are collected directly from the manufacturer and then sold, reducing the expenses of the agents, transportation, MRs etc.

The benefits of having your prescribed drug delivered to your home include cost-savings, safety benefits and convenience. It is thus very useful for old age, ill and physically challenged people who have wander around in search of medicine.

Availability of generic medicines and Right to compare at e-Pharmacy gives an opportunity to the customers and consumers to compare the manufacturing company and price of the medicines as it may create a huge differences in terms of medical expenses of them. Moreover they can also check the available Generic medicine with same formula as the Government of India is also now promoting the use of generic medicines in India.

E-Pharmacy is a step towards the aim to change India's future through digitalization. Demographic dividend needs digital strength. Digital connectivity and access to

technology is extremely important for a poor, if India want to bridge the wide gap between its rich and poor. And this e-Pharmacy plan also fulfils all these aims of Digital India.

10. CHALLENGES BEFORE E-PHARMACIES IN INDIA

However, many organizations have been protesting against proliferation of e-Pharmacies, the traditional Pharmacies see them as competitors eating their pie whereas human rights groups have raised concerns over the unregulated sale of medicines leading to potential health epidemic. [11] Most recently the Delhi HC has observed in a petition that unlike common items, drugs are highly potent and its misuse or abuse can have serious consequences on human health, not just for the one person consuming it but for humanity at large as some drugs can be addictive, habit-forming and harmful to the body. A large number of children/minor or people from uneducated rural background use the internet and can be victims of wrong medication while ordering medicines online.

11. CONFLICTING OPINION OF HIGH COURTS

In a recent judgment by the division bench of Delhi High Court in a PIL filed by Dr. Zaheer Ahmed, Delhi based dermatologist, the honourable court has imposed a ban on the sale of medicines from the online portals. It was contended that the e-Pharmacies are running without any registration, thus exposing the public to substandard products. Further it was contended that the committee setup by the central government has failed to take any concrete step in this regard. The concern was laid down over the sale of medicines which are prescriptive, habit forming or addictive, and online portals have eased the access of same to even underage kids. It is also apprehended that the uneducated and poor people from the rural may fall victim of wrongful medication. And hence state would fail in its duty to protect the public health under Article 21 of the constitution of India. Taking in to account these considerations the court has thus prohibited the sales of all the medicines through such online portals and has imposed a ban on the sale of medicines through these portals. The outcome of this case will have a significant impact on online Pharmaceutical sale sector and lay down the future course of action for these online sellers, their consumers and the Government's role in regulating them. [12]

On the other hand in another case [13] where similar plea was raised the Madras High Court has refrained itself from imposing a ban on e-Pharmacies. Though the major part of the decision of the Madras High Court deals with the current case being barred by the provisions of *res judicata* [14], yet the honourable court has indicated its concern over the need of the comprehensive provision dealing with e-Pharmacies. In the current scenario of technology based business, legislations are required that are in tune with the technology, in absence of which technology based commerce would lag behind. The high court has also stated that in absence of the draft rules published in the gazette it is certain that there will be conflicts among the law makers, drug companies, on-line traders, off-line Pharmacies and finally the consumers.

In the absence of any such centre or state legislation the online Pharmacies can hardly be constrained.

12. CONFLICT BETWEEN TWO FR 19(1) (G) AND 21

Article 19 (1) (g) of Constitution of India provides Right to practice any profession or to carry on any occupation, trade or business to all citizens subject to Art.19 (6) which enumerates the nature of restriction that can be imposed by the state upon the above right of the citizens. The provision further provides that the state can make any law that provides professional or technical qualification necessary for practising any profession carrying on any occupation or trade or business and the same shall not be deemed to be in violation of article 19. Provided there must be nexus between the restrictions made or qualifications laid for the trade, business or profession.

With the increasing ambit of Article 21 i.e. protection of life and personal liberty, it tends to incorporate in itself, now, right to health also. Thus article 21 prevails over article 19. Hence by the virtue of article 19 (6) the state can make law for the regulation of e-Pharmacies further by the virtue of article 21 it becomes a mandate for the state to make such laws that ensures right to health. If ever there occurs any conflict between the fundamental rights, article 21 prevails above all for being in greater concern with public morality and public interest.

13. HARMONIOUS WAY

Since the conflicts like these are inevitable where there are plethora of rights which are protected and given the vast horizons of human dignity and fundamental rights, they are bound to clash in the name of competing interests. The solving of such clashes is no easier. Thus, the Supreme Court has finally explicitly stated a near definite formula to solve such conflicts by balancing of the fundamental rights which is truly in sync with the interpretation of fundamental rights clashes in other jurisdictions. Balancing of the fundamental rights aims to ensure that the “paramount collective interest” that is the larger public interest is ensured.

Justice Mishra wrote that “sustenance of public confidence in the justice dispensation system” should guide all constitutional courts to ascertain the “greater community interest” in recognizing the right of one of the two parties, which has to be protected as the “paramount collective interest”. It must be kept in mind, however, that the interest of the collective sub serves a legitimate public purpose, and is not an idea such as “class honor”.

14 GOVERNMENT TO MAKE WAY FOR REGULATIONS

It should be made mandatory for e-Pharmacies dealing with online drugs importation and re-importation to be registered and to get licence for the same from regulating body. As the power of drug regulation is distributed between Central and State Government, role of Central Government and State Government should be well defined. Specific and clear-cut rules should be made for selling, prescribing, dispensing, and

delivering prescription drugs through e-Pharmacies. List of illegal and blacklisted e-Pharmacies should be provided to help out consumers and stop them using such fake websites. Government should make a common logo for legally operating e-Pharmacies to distinguish them from illegal ones. To ensure efficient running of e-Pharmacies substantial compliance and strict adherence to the laws is required. Concerns have also been raised over the issue that include potential lack of confidentiality, improper packaging, inability to check for drug interactions, and several other issues like illegal or unethical Pharmacies sometimes send outdated, substituted, or counterfeit medications, can be dealt with provided that there are regulatory provisions regarding online Pharmacies.

Government should also make guidelines for online drugs importation and re-importation for legislators, dealers and consumers. Further continuous watch should be kept on importation of banned drugs through e-Pharmacies outside India which don't come under Indian jurisdiction. Each and every activity and transactions made through e-Pharmacies must be under regulatory scanner to prevent it from underworld and smuggling. E-pharmacy must establish its server in India as if it is outside the boundaries of India, it is difficult to control and regulate it.

By granting the licence to e-Pharmacy Govt. can regulate and control the functions of these e-Pharmacies along with that compulsory licensing will make them responsible for their all conduct. In other words after proper licensing these e-Pharma companies cannot run away from their liability to pay compensations to the consumer in case of any catastrophe due to fault in their services or otherwise. Sometimes an online Pharmacy may not be located in the country that is claimed. For example, one study of drug shipments claiming to be from Canada revealed many actually originated in several different countries and were often bogus medications. Thus it will ensure that the companies' in business are genuine and domiciled in India. This will in turn provide an easier and hassle free process to get justice. In case of any such situation gov't can also take the step towards the cancelling of the licence by the virtue of law.

It is an undeniable fact that in India there is still a major sector of population that is not very educated, thus, guidelines for consumers for safe access to e-Pharmacies. Government schemes like National Rural Health Mission can aid in promoting proper procedures to acquire drugs, prevent self-medication through campaigns on television, radios and social media.

15. CONCLUSION

E-Pharmacy is the need of the hour but in the current scenario of absence of proper regulatory provisions amendments in the prevailing laws is not a mandate. The conflicting opinion of the two different high courts have made the scenario more complex. Given that the high courts have territorial limitations as compared to the Supreme Court where the guidelines are applicable to the whole of the country unanimously. Currently draft regulations have been made yet they have no application in the present scenario unless they get published the official gazette. Till any

such regulations shapes up as a enacted law or any direction is given by Supreme Court the decision of the high courts will remain in force in their respective field.

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- [13] Tamil Nadu Chemists and Druggist Association through K.K. Selvan v. Union of India and Others 2018
- [14] *Res judicata* means a matter that has been adjudicated by a competent court on the same subject matter, between the same parties on same cause of action and therefore may not be pursued further by the same parties on the same cause of action on same subject matter.