

ONLINE PHARMACIES IN INDIA: LEGAL AND ETHICAL CONSIDERATIONS

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Abstract

The aim of this paper is to ascertain the legal status of online pharmacies with an underlying objective of the understanding of ethical considerations arising in the context of e-pharmacies. The author seeks to evaluate the need and benefits of online pharmacies, assess their drawbacks, study the legal regime governing them in the U.S. and suggest measures to make them legitimate within the legal framework in India. The primary limitation faced by the author was that empirical and scholarly research on this topic is still scarce and evidence provided is often anecdotal. The research questions that will be answered through the course of the paper are- What are e-pharmacies? Why do people opt for ordering medicines online? Are there any risks associated with e-pharmacies? Does India have a well-established legal regime to regulate online pharmacies? How has the international legal regime dealt with the problems associated with e-pharmacies?

Introduction

The growth of e-commerce has opened the online marketplace to products which everyone can access. The internet, apart from providing access to information, facilitates sale of goods including medications. Online pharmacies or electronic pharmacies (e-pharmacies) will have enhanced demand in the next few years. Online pharmacy refers to an internet based seller of prescription drugs, and this term refers to legitimate and illegitimate pharmacies as well. Selling medicines outside regular brick and mortar

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pharmacies is not a new concept, but this has flourished in the age of the internet. In the United States of America (USA) there was a growth in non-regular pharmacies selling prescription medicines as early as the 1980s by sending them through mail orders to their customers, later this changed into internet based pharmacies. This trend caught up in the United Kingdom (UK), where there was a growth in the market of e-pharmacies.

Since a vast section of the Indian population lacks access to basic services like the internet, the online sale of medicines through internet is limited. However with the advancements in technology and introduction of devices like smart-phones along with both public and private sector initiatives, the access to internet has developed. The government is planning to undertake further education projects to increase computer literacy which will enable the masses to take benefit of the internet pharmacies. The investment in Information Technology products and services is also expected to grow thereby assisting in meeting the objectives set out by the health care policies in India.

Pharmacies are ineffectively regulated online because of anonymity maintained by the website owner, which along with the ability to take a website down immediately makes it difficult to impose sanctions. Issues such as jurisdictional obscurity and diversity of governing bodies make it hard to impinge obligations in case of cross border sales.

The aim of this paper is to ascertain the legal status of online pharmacies with an underlying objective of understanding the ethical considerations arising in the context of e-pharmacies. The author seeks to evaluate the need and benefits of online pharmacies, assess their drawbacks, study the legal regime governing them in the USA and suggest measures to make them legitimate within the legal framework in India. The primary limitation faced by the author was that empirical and scholarly research on this topic is still scarce and evidence provided is often anecdotal. The research questions that will be answered through the course of the paper are- What are e-pharmacies? Why do people opt for ordering medicines online? Are there any risks associated with e-pharmacies? Does India have a well-established legal regime to regulate online pharmacies? How has the international legal regime dealt with the problems associated with e-pharmacies?

The Benefits and Risks Associated with Online Pharmacies

Online pharmacies can be categorised into three kinds: traditional, independent and cooperating. The traditional physical stores not only have a brick and mortar outlet but also sell their medications online by selling them

directly to their patient's home or abroad through websites. In independent pharmacies, there is no physical pharmacy for customers to buy medications. In cooperating pharmacies, a group of pharmacies which have physical point of sale will start a website collectively and sell medicines online in a similar way. Also, internet pharmacies generally sell medicines requiring a valid prescription, or those offering online consultations for prescribing and selling medicines and there are even those which sell medicines without a prescription.¹

Even with the international character of online pharmacies, there are stringent national pharmaceutical regulations in each country that tend to get circumvented. Every country has separate regulations that govern licensing of online pharmacies. Licenses are granted through agencies appointed and controlled by government organisations. Their primary role is to ensure the sale of medicines online is in consonance with the regulations of the given country.²

Financial hardship and rising healthcare costs is a significant contributor to the trend of people buying medicines online apart from the convenience and private access to medicines. It also enables the elderly and those in remote locations to avoid travelling to a store for purchase of medicines. Some reputed e-pharmacies allow patients to consult with pharmacists from their home. Online pharmacies allow order to be placed during off hours and cuts trips to the drug store as well. Moreover, the wide selection of drugs makes consumer choice more effective. It also helps consumers to investigate issues of different drugs, and in assessment of which will be more effective. It gives those who do not want to shop in public pharmacies, the privacy they want. The medicines online also tend to be cheaper due to marketplace competition.³ Internet facilitates enable easy access to a pharmacist and allows purchase to be made without having to step out. This makes it convenient for the elderly and those suffering from any condition which restricts their movements. The medicines sold online are often cheaper

¹ Montoya ID & Jano E, *Online Pharmacies: Safety and Regulatory Considerations*, 37(2) INTERNATIONAL JOURNAL OF HEALTH SERVICES 279 (2007).

² Letkiewicz S & Gorski A, *The Potential Dual Use of Online Pharmacies*, 16 (1) SOCIAL AND ENGINEERING ETHICS 59, 64 (2010).

³ C. Desai, *Online Pharmacies: A Boon or Bane?* 48 (6) INDIAN JOURNAL OF PHARMACOLOGY 615 (2016). See also, Rashmi Mabiyan, *Will Regulations on E-Pharmacies Affect the Brick-and-Mortar Stores?* ECONOMIC TIMES HEALTH WORLD (2019), <https://health.economictimes.indiatimes.com/news/policy/will-regulations-on-e-pharmacies-affect-the-brick-and-mortar-stores/70036824>.

than in traditional stores. The permanent availability and simple access to online pharmacies is what attracts consumers to online pharmacies.⁴

E- pharmacies also ensures more anonymity to customers with regard to purchase. Customers are also able to get advice from a doctor or pharmacist along with a prescription and medicines across the borders of their country.

The consequence of selling drugs online has both positive and negative aspects. Though the financial turnover of the pharmacies is more, they also generate more tax revenue. However, online pharmacies selling medicines over the internet and through mail without concessions tend to circumvent the tax and regulatory systems and often sell medicines that have crossed their expired date or those which are counterfeit. In addition to this, patients may obtain medications over the counter for medicines requiring prescriptions. The government across the world forbid this practice since it causes threat to the patient.⁵

The burden to consumers is often experienced after the medicine is sold when the patients have to bear the consequences of purchasing the medicine online. Taking unsupervised medication may lead to addiction and cause dangerous complications. Unassisted treatment and self-diagnosis on the basis of advertisements online may pose a number of complications to customers. Problems of overdose especially in case of anti-depressants and purchase of counterfeit medicines can result in death as well. Cyber doctors who offer telephonic consultations to patients without physically examining them and prescribe medicines sent by mail also pose risk to the health of the patient. Though there are online questionnaires filled by patients in some cases on the basis of which doctors make the diagnosis and prescribe medicines. In these circumstances, there is no guarantee that the patients write the truth or that the doctor is of competent nature or that he examines the past health records of the patient.⁶ It is important to note that the Supreme Court of India has ruled

⁴*Internet Pharmacies, Advantages and Risks*, 15 (3 & 4) WHO DRUG INFORMATION (2001) <http://apps.who.int/medicinedocs/en/d/Jh2989e/2.html#Jh2989e.2.1>. See also, FICCI, E-PHARMACY IN INDIA: LAST MILE ACCESS TO MEDICINES (2015).

⁵Lanier WL, *Near-death Experiences Delivered to Your Home by Your Friends on the Internet*, 79(8) MAYO CLINIC PROCEEDINGS (2004), https://www.researchgate.net/publication/298924094_Near-death_experiences_delivered_to_your_home_by_your_friends_on_the_Internet.

⁶THE POSSIBLE DANGERS OF BUYING MEDICINES OVER THE INTERNET, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm>. See also, AhalyaChalasanil, *Diagnosing the Issues of E-Pharmacies* (2019), <https://www.lakshmisri.com/insights/articles/diagnosing-the-issues-of-e-pharmacies>.

that no prescription should ordinarily be given without actual examination.⁷

The internet tends to blur the distinction between inappropriate promotion and drug information. Medicines are sold without patient leaflets sometimes and hence the consumer does not make an informed choice. The World Health Organization (WHO) has come up with a guide to make consumers aware about misleading advertising and to make them capable of identifying legitimate pharmacies. Under the Internet Healthcare Coalition, conferences are held to address problems relating to prescription medicines online.⁸

Another problem associated with online pharmacies is that it encourages individuals to do self-medication. The mushrooming of e-commerce entities is responsible for the higher prevalence of online medicines, especially the non-over-the-counter prescription medicines. Prescriptions given by doctors should not be used again but in online pharmacies there is a danger of the scheduled drugs being re-ordered by the consumer and hence chances of abuse are high. Online pharmacies, often do not meet the strict quality requirements and often engage in selling unapproved drugs. Moreover there is no assurance of their quality since they are often not kept as per the temperature requirements set out for them to remain potent. Hence improper monitoring at the time of storage and transport is risky to the health of the patient.⁹

Some pharmacies do not even sell medicines but are proxies for conducting credit card hacks by stealing personal information or through scams. In addition to that, the false online pharmacies also end up supplying counterfeit products which are dangerous to use. Brand names also cause confusion and similar looking drugs though different in nature but belonging to the same brand are often confused and are being sold through online pharmacies. Today companies like Microsoft, Google and Yahoo permit only the VIPPS-accredited pharmacies to advertise in USA. In fact, credit card companies like

⁷Martin F. D'Souza v. Mohd.Ishfaq, (2009) 2 S.C.C. 40.

⁸Bessel TL, Silagy CA, Anderson JN, Hiller JE, Sansom LN, *Quality Of Global E-Pharmacies: Can We Safeguard Consumers?*, 58 (9) EUROPEAN JOURNAL OF CLINICAL PHARMACOLOGY 568 (2002). See also, Durba Ghosh, *India's Budding e-pharma industry has just received a sickening blow*, QUARTZ INDIA (2018), <https://qz.com/india/1494451/delhi-high-court-bans-e-pharmacies-like-netmeds-medlife-1mg/>.

⁹ S. Davis, *Advantages, Disadvantages, and Legal Issues Associated with Online Pharmacies*, 7 (6) INTERFACE: THE JOURNAL OF EDUCATION, COMMUNITY AND VALUES (2007).

VISA have also begun declining payments to online pharmacies that are not certified.¹⁰

One of the major concerns with respect to e-pharmacies is that they operate and supply medicines to consumers in different countries. The regulatory framework of the country where they operate will only apply since jurisdiction is dependent on physical location within a nation or state. Hence the national regulations do not protect the global consumers from poor practices that involve the sale of medicines online because the internet acts independent of geographic boundaries, and legal jurisdiction is difficult to establish in a global online environment. Difficulty in identifying the country of origin selling medicines creates jurisdiction issues in claims under consumer protection for privacy, disclaimers, return policies, etc.¹¹

However in the absence of a prior physical check up by a doctor, the prescription may not be the most effective remedy. Since no follow up monitoring is done, there is noway to ascertain the effectiveness of the drug given. Questionnaires may not be filled correctly and lack of direct interaction can easily cause misdiagnosis since the effect of the drug may be different for different individuals and may cause adverse reactions if individuals are taking other medications. There is no way to check if the cyber doctor is licensed to practice as well. The confidentiality of patient information is also lacking in the absence of strict protocols, and liability issues arise if no doctor-patient relationship exists since there is no duty of care involved. Medicines sold without a prescription also have a chance of falling in the wrong hands, for example, of drug addicts or children. Some pharmacies try to keep themselves clear of liability by asking the purchasers to sign a waiver form. This clearly violates the principles of medical ethics and is an unfair contract. Medicines sold online tend to be expired, or of wrong dosage, improper potency and not shipped properly. Though some claim they are manufactured in safe countries such as USA and Canada, inquiries have revealed that they are sourced

¹⁰ Amy Nordrum, *US Patients Turn To Online Pharmacies For Cheap Meds, But Drug Companies Say The Sites Endanger Consumers*, INTERNATIONAL BUSINESS TIMES (May 21, 2015), <http://www.ibtimes.com/us-patients-turn-online-pharmacies-cheap-meds-drug-companies-say-sites-endanger-1932079>.

¹¹ Carlisle George, *Online Healthcare : Internet Pharmacies May Not Always Be Good For Your Health*, International Federation for Information Processing Digital Library: The Information Society: Emerging Landscapes (2006). See also, Chetan Dasharathbhai Parikh, ChetnaKalpan Desai, MeghaKiritkumar Shah, Vishal Rameshchandra Mishra, *An Evaluation of Online Pharmacies for Compliance to Regulatory Criteria and Price Variation of Listed Medicines*, 11(2) JOURNAL OF YOUNG PHARMACISTS 207 (2019).

from other countries in South Asia and lack the required approval. Illicit manufacturers in developing countries continue to supply to online stores and reap profits from illicit sales taking place on the online pharmacy. Service providers also get financial benefits from the illegal transactions taking place online when they take payments for advertisements, optimisation, processing fees, etc. Websites giving ratings of online pharmacies though not directly participating in online drug sales, help in facilitating illegal activity by profiting from sponsored ads and membership fees. Some pharmacies do not provide any contact information or address or locations which creates difficulties in tracing the seller.¹²

There is also a risk of terrorist attacks taking place through online pharmacies. This happens because terrorists can either establish companies online or acquire the existing ones. Parcels may be used by them for contamination or sending dangerous material. Sale of medications online is thus dangerous and needs international regulations. Low production costs of biological tools and easy access to them makes bioterrorist attacks dangerous.¹³

Moreover, data generated from online businesses is capable of being misused in the absence of proper laws governing the data of users, websites may be willing to share the patient information submitted online with hospitals and doctors who may target these patients for their services.¹⁴ Search engines receive profits by advertising and often allow non-verified sellers to advertise as well.¹⁵ pharmacychecker.com in the U.S. runs a verification program to approve websites selling prescription drugs if they have a valid license, display needed information and secure confidentiality of patient data.¹⁶

As per a study done in India, it was revealed that though some pharmacies

¹² Tim Mackey & Bryan Liang, *Promoting Online Drug Safety: Using Public - Private Partnerships To Deter Illicit Online Drug Sales*, 17 (3) JOURNAL OF COMMERCIAL BIOTECHNOLOGY 270 (2011).

¹³ *Supra* note 2, at 59.

¹⁴ Alamelu R, Amudha R, L Cresenta Shakila Motha, Nalini R., *Online Pharma Retail Is A Promising/Unpromising Avenue: An Indian Context*, 9(2) ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH 26 (2016). See also, Prabal Chakraborty & Alok Satsangi, *Online Pharmacy in India: A study on Digital Marketing perspective 2* INTERNATIONAL JOURNAL OF RESEARCH IN ENGINEERING, IT AND SOCIAL SCIENCES 232 (2019).

¹⁵ Robert F. Forman & Lauren G. Block, *The Marketing of Opioid Medications without Prescription over the Internet*, 25(2) JOURNAL OF PUBLIC POLICY & MARKETING 135 (2006).

¹⁶ See www.pharmacychecker.com.

request for prescriptions, if drugs are not to be consumed domestically then the pharmacies evade liability under domestic safety laws. For instance, when Canadian websites are used to source illicit drugs from India or China and transfer them to patients in UK, then the online pharmacy registered in Canada will not be made liable since the consumers are in USA.¹⁷ Few websites even provide online consultation services. And only few of the sites give proper details of dosage, efficacy and side effects while most of them had been diligent in mentioning their contact details and in encouraging consumers to consult a physician.¹⁸

In the recent past, the online pharmacies have been unable to wholly participate in online advertising significantly and it is because of this that some pharmacies have started going towards social media. Online drug sellers also use deceptive marketing to prey on consumer preferences and conceal the risks of the products they offer. They also engage in targeted marketing so they attract the vulnerable sections such as senior citizens, adolescents, handicapped persons and those having a low socio-economic status. Use of social media and the increase in online advertising will only increase the intensity of threat in the future.¹⁹

Legal Regime Governing Online Pharmacies in India

Online buying and selling of prescribed medicines is governed collectively by the laws relating to drugs and technology. Pharmacies are exposed to legal risks if they do not follow the applicable laws. Moreover the laws have not kept pace with the changing times and have become obsolete to deal with the technical advancements, a grey area.

As far as India is concerned, there is no single law dedicated to electronic-health or telemedicine. Entities selling medicines online are also required to comply with a number of laws such as those related to medicines, pharmacist and cyber laws. In India the Central Drugs Standards Control Organisation is

¹⁷ Tim Mackey & Bryan Liang, *Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales*, 35 AMERICAN JOURNAL OF LAW & MEDICINE 130 (2009).

¹⁸ A. Nagaraj *et. al.*, *Counterfeit Medicines Sale On Online Pharmacies In India*, 3 (4) JOURNAL OF RESEARCH IN PHARMACY PRACTICE 145 (2014). See also, United States v. Yates No.00-00109-CR-N2 (2006), United States v. KwikMedInc No.02-CR-993 (2002) and United States v. Chhabra No.03-530-A (E.D. Va.2003).

¹⁹The Internet Pharmacy Market in 2016, PREPARED BY LEGITSCRIPT.COM FOR THE CENTER FOR SAFE INTERNET PHARMACIES (January 2016).

the entity that is responsible to approve drugs, regulate them and issue license to pharmacies. The retail sale of drugs is governed by laws like the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945, the Pharmacy Act, 1948, the Indian Medical Act, 1956, the Code of Medical Ethics Regulations, 2002, and the Pharmacy Practice Regulations, 2015. These laws do not recognise the online pharmacy model and hence there is ambiguity with respect to how these laws will apply to the electronic pharmacy model. The stringent licensing and registration requirements under the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948, are not being followed by the online pharmacies.²⁰

However the Information Technology Act, 2000, (IT Act) does provide a basic legal framework for the cyber laws by focussing on aspects like protection of privacy, data, confidentiality, etc. Unfortunately most of the online pharmacists are not aware of the intermediary obligations and due diligence requirements and are hence said to exist in violation of the provisions of the IT Act. Aggregators engaged in selling drugs online fall under the definition of 'intermediaries' and hence the Rules under the IT Act should apply to them.²¹

The IT Act provides a safe harbour to these intermediaries in case their platform is misused by third parties even after due diligence requirements have been fulfilled by intermediaries while they discharge their duties and observe the guidelines issued by government.²² Hence these rules can be important while understanding liability issues of the online portal selling medicines. Another concern of consumers is with respect to the confidentiality of the information given to the websites as there are chances of misuse. To deal with this, Section 43A and Section 72 of the IT Act may be relevant since it provides for liability of body corporates handling personal data if they do not adopt secure practices and if they disclose the information to third parties in violation of the contract with the user, or without their consent, or if they

²⁰See also, Teena Thacker, *GOM Meets To Discuss Regulating E-Pharmacies*, THE ECONOMIC TIMES, November 9th, (2019), <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/gom-meets-to-discuss-regulating-e-pharmacies/articleshow/71931522.cms>.

²¹Alamelu *et. al.*, *Online Pharma Retail Is A Promising / Unpromising Avenue: An Indian Context*, 9(2) ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH 26 (2016).

²²Section 79 of the Information Technology (Amendment) Act, 2008.

know that the disclosure may cause wrongful gain or loss to the consumer.²³

The question of selling medicine with a digital copy of the signature can be sought to be addressed within the IT Act that recognises electronic records. Though in conjunction, this would probably make e-prescriptions legal, this continues to be a grey area. Online pharmacies need to accept prescriptions in a scanned or electronic form for purchasing the purchase orders of prescription drugs. But the issue is whether scanned copies or electronic forms of prescription will meet the criteria of being 'signed' by registered medical practitioners. The IT Act stipulates that a document will be signed under the law only if it is authenticated by an electronic signature. An electronic signature is a way of authenticating an electronic record. The Drugs and Cosmetics Act, 1940 requires the registered medical practitioner to sign the prescriptions, the scanned copy in electronic form will be valid when the practitioner assigns his or her electronic signature. This is problematic since less than 1% of practitioners have an electronic signature since it is very costly.²⁴

Though the validity of e-prescription is a grey area, e-pharmacies accept scanned copies of prescriptions. Section 4 of the IT Act legally recognises electronic records while Section 5 accords this approval to electronic signatures. Hence as per these provisions, an electronic prescription is legal and hence scanned copies should be valid as well. The Pharmacy Practice Regulations, 2015, in fact recognises under Regulation 2(j)(3) that a prescription is an electronic or written direction issued by a registered medical practitioner. But it is unclear whether this means that the patient can use the

²³Section 43A: "Compensation for failure to protect data. - Where a body corporate, possessing, dealing or handling any sensitive personal data or information in a computer resource which it owns, controls or operates, is negligent in implementing and maintaining reasonable security practices and procedures and thereby causes wrongful loss or wrongful gain to any person, such body corporate shall be liable to pay damages by way of compensation, not exceeding five crore rupees, to the person so affected."

Section 72A: "72A Punishment for disclosure of information in breach of lawful contract. - Save as otherwise provided in this Act or any other law for the time being in force, any person including an intermediary who, while providing services under the terms of lawful contract, has secured access to any material containing personal information about another person, with the intent to cause or knowing that he is likely to cause wrongful loss or wrongful gain discloses, without the consent of the person concerned, or in breach of a lawful contract, such material to any other person, shall be punished with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both."

²⁴Milind Antani & Anay Shukla, *Indian Online Pharmacies and Drug Stores in Legal Tug of War*, eHEALTH LAW & POLICY 6 (2015).

electronic prescription to buy drugs at the physical pharmacy or at the online stores as well. The regulations also require that the drug must be delivered either to the patient or to the carer but the definition of carer is not clear.²⁵

The Drugs and Cosmetics Act, 1940, further states that the license of reselling drugs is given to the license holder for a specific place and hence the drugs can be sold at the approved premises only but when drugs are sold online, it will be hard to identify the place of sale especially if the online pharmacy has no tie up with a physical pharmacy. However we may consider the location of the patient where the drugs are handed over or where payment is made to be the place of sale.²⁶ The Pharmacy Practice Regulations, 2015 require the drugs to be handed over by the pharmacist to the patient or his carer. This is problematic not only because the definition of carer is open to interpretation and cannot be determined to whom the drugs are going finally in case of online pharmacy but also because no physical handing over can be done directly by the pharmacist to the patient in case of online pharmacies²⁷

The Maharashtra FDA initiated investigation into a number of online pharmacies and seized their drugs. The All India Organisation of Chemists and Druggists also called for a nationwide protest to oppose the government's attempt to regularise the sale of medicines through the internet. The reason behind this is that by doing so, the number of unreported adverse reactions of drugs will also increase and will lead to sale of misbranded drugs, those of low quality and the irrational use and overuse may lead to drug addictions because of their easy access. The protest by brick and mortar stores is because that they recognise that they will lose a significant portion of their customer base due to the expected migration to purchase of medicines through smart-phone apps and websites.²⁸

Presently, under the Drugs and Cosmetics Act, 1940, sale of 'Schedule H' medicines are not permitted without the prescription of a doctor. Even over-the-counter products can be sold by licensed retailers only. The online pharmacies such as Practo and IMG only require users to upload a prescription through their apps and hence feel that they are complying with the legal requirements

²⁵ Guest Post, Legality Of Selling Medicines Online In India (September 30, 2015) <https://blog.iplayers.in/legalityofsellingmedicinesonlineinindia/>.

²⁶ *Supra* note 24.

²⁷ Pharmacy Practice Regulations of 2015.

²⁸ Priyanka Sahay, *Will Online Pharmacies Work in India, and are they even Legal?*, Live Mint, (Jan 14, 2016), <http://www.livemint.com/Companies/EGTOILRRNF0T3J4OfUg9SN/Will-online-pharmacies-work-in-India-and-are-they-even-lega.html>.

The Drug Controller General of India (DCGI) has in fact called for the formulation of a mechanism to facilitate online sale of medicines through e-commerce portals. Before this is done, the role, responsibilities and liability of sellers has to be identified clearly especially when the safety and the health of the recipient is of prime importance.

The Drugs and Cosmetics Act, 1940, is being amended so that it account for the latest trends like e-pharmacies.³³ The Ministry of Health and Family Welfare in fact clarified that the current law does not distinguish between online and offline pharmacies. Hence we can infer that the online pharmacies are expected to conform to the standards set out for offline pharmacies.³⁴ Though the Supreme Court of India has ruled that doctors should not give consultations on the phone except in emergency cases, the use of technology to give medical assistance has not been successful. The pharmacists associated with online pharmacies may be charged for practising without any license specifically allowing them to dispense medicines online and they may be in trouble for taking any kind of legal measures for getting reimbursement.³⁵

We can design a website like it is there in USA to check the legality of e-pharmacies. Having guidelines in place for consumers to safely access the e-pharmacies is also needed so they know how to buy medicines safely from the online pharmacies. There should be specific rules for selling, prescribing

³³Bureau, *Drugs/Cosmetics Act being Recast to Reflect New Trends, Changes*, The Hindu, (July 25, 2016), <http://www.thehindubusinessline.com/economy/policy/drugscosmetics-act-being-recast-to-reflect-new-trends-changes/article8897968.ece>. On 23rd February 2019, the Department for Promotion of Industry and Internal Trade published the Draft National e-Commerce Policy. Suggested recommendation regarding E-Pharmacies in India deals with License, Geographical Restriction, Prescription, Dispensing medicines by registered pharmacists, Storage and Transportation, patient confidentiality and Supervision by drug inspector. See also, *Current status of E-Pharmacy in India. 2019 Review*. <https://www.pharmatutor.org/articles/current-status-of-e-pharmacy-in-india-2019-review>.

³⁴P. Sahay, *Will Online Pharmacies Work in India, and are they even legal?*, <https://www.livemint.com/companies/egtoilrrnf0t3j4ofug9sn/willonlinepharmaciesworkinindiaandaretheyevenlega.html>.

³⁵*Supra* note 29.

and delivering medicines via e-pharmacies.³⁶ A list of illegal websites will help consumers stay away from scams. A common logo should be one achesite or even a domain name for legitimate pharmacies for easy identification. Guidelines on drug importation need to be established as well. The data gathered by the e-pharmacies should be used for targeted advertising or for business purposes. Banned drugs should not be imported into India *via* e-pharmacies. All stages of transaction through the online portal must be monitored and regulated to prevent smuggling. In order to ensure adequate checks and balances, e-pharmacies must be required to establish their servers in India. Regular follow up to check compliance with laws is also needed. Steps such as the registration or accreditation of e-pharmacies before they participate in these activities, use of a common logo for the legal e-pharmacies, encouragement for self-regulation of online sellers are aspects that require the attention of the regulator.

The International Scenario

In USA, every state mandates a pharmacy to have a license which is given from the state. The multiple state laws in USA makes it difficult for them to organise a safe market for online medicines. Moreover, the Food and Drug Administration lists websites that are not permitted to send medicines needing prescription to USA. Hence, pharmacies as well as online pharmacies operate under the control of government and professional organisations at multiple levels. In USA, state boards have the primary duty to regulate e-pharmacies. They are subject to the same regulations as traditional pharmacies. The National Association of Boards of Pharmacy (NABR) mandates that a VIPPS certification of privacy, confidentiality, quality and consultation requirements are met. In 2008, the Ryan Haight Online Pharmacy Consumer Protection Act (2008 Act) was passed to regulate online pharmacies. The legislation

³⁶ The Indian Internet Pharmacies Association (IIPA) or Digital Health Platforms (DHP) also is working actively with the Indian Government to bring in changes to the regulations including the use of AADHAAR UID number to be linked to prescriptions for ensuring no misuse of medicine online. As per Digital Health Platforms following are the set of rules which association members like 1 mg, M-Chemist, Netmeds, Pharm Easy to name a few and other online pharmacies key players follows for sale of the Rx medicines online: No sale without a valid prescription issued by RMP (registered medical practitioner), No sale of Schedule X drugs (narcotic and psychotropic substances-based drugs), Final packing in a tamper-proof cover under the personal supervision of registered Pharmacist of the pharmacy, Valid invoice bill for every order or sale of a medicine, Facilitate medicine recall in case directed by the Indian Government. See also, Current status of E-Pharmacy in India: 2019 Review, <https://www.pharmatutor.org/articles/current-status-of-e-pharmacy-in-india-2019-review>

stipulates that no controlled substances that are prescription drugs can be dispensed through the internet without a prescription which is valid. Moreover, it requires that the person who is writing the prescription should have had one personal visit with the patient requiring this prescription. Also, it requires the pharmacies to be registered in the states they are operating and selling controlled substances and this is to be disclosed on the website as well. This also has its drawbacks since it cannot prosecute pharmacies operating outside USA and hence is of no use given that most online pharmacies operate overseas. The 2008 Act regulates controlled substances only and hence the uncontrolled substances such as pain relievers, muscle relaxants, etc. do not fall within its ambit. No effective procedural rules to secure privacy of patients have been laid down as well.³⁷

Raising consumer awareness will help in distinguishing between the legal and illegal e- pharmacies. Sites like the Verified Internet Pharmacy Practice Sites have a seal that is displayed on their site if it complies with certain standards established by the National Association of Boards of Pharmacies in USA. The National Association of Boards of Pharmacy in USA monitors the industry for the individual state boards and their study found that as many as 96% of the online pharmacies operate outside the ambit of accepted practices. The Interpol conducted Operation Pangea with the aid of a private actor to track online pharmacies.³⁸

In USA since the NABP publishes a list of pharmacies it has accredited through its verification program called Verified Internet Pharmacy Practice Sites, the users can check if a pharmacy is legitimate or not. The certificate is given after a review of policies and procedures, on-site inspection to receive and dispense medicine, etc. For a VIPPS certification, the pharmacies must comply with licensing requirements of states where they are registered and to which their drugs are dispensed. Respecting rights of customers with respect to privacy, authorisation as well as security of prescriptions, adherence to quality assurance standards, and provide meaningful consultations between customers and pharmacists are all important considerations. The Federal Trade Commission in USA has stringent rules which require the contact details and address of the pharmacy dispensing drugs, states where it is licensed to do business, details of the physician reviewing information submitted by

³⁷B. Schultz, *Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem*, 16 SAN DIEGO INTERNATIONAL LAW JOURNAL 381 (2015).

³⁸A. Lavorgna, *The Online Trade In Counterfeit Pharmaceuticals: New Criminal Opportunities, Trends And Challenges*, 12(2) EUROPEAN JOURNAL OF CRIMINOLOGY 237 (2015).

consumers for a prescription, states where orders will be accepted, and also a legal notice stating that selling medicines without a prescription violate the federal laws. Online auction sites are required to clarify that selling drugs is prohibited on their sites.³⁹

For instance in *Durck v. Ebay*,⁴⁰ it was held that since the auction site's agreement with the customers clearly stated that selling prescription drugs online is prohibited, and since the defendant had registered as a dentist with eBay and engaged in selling the prescription drugs despite being notified that he was violating his membership agreement and the contract of the parties which made him liable to be sued and he continued selling these medicines, hence termination of his membership was valid.

The NABP also publishes a list of pharmacies it will not recommend, thus making users more cautious so they don't buy drugs without a prescription or those which are not FDA approved. However this may also mean that it is including pharmacies outside USA to the unsafe category. In order to save money, a number of consumers in USA purchase drugs online from pharmacies in India, UK, Canada, etc. since almost all countries except USA controls the drugs prices. Illegal pharmacies may sell expired, counterfeit medicines or inappropriate medications without a proper prescription. In fact, in USA, the Federal Trade Commission frequently investigates websites to assess the quality of the medicines sold.

Conclusion

From the considerations outlined above, it is concluded that selling medicines online constitutes a hazard on a global scale. The problem remains that the procedures at the national and international level are not keeping pace with the expansion of the internet. Only if there is a well-coordinated program that controls international trade through online pharmacies can the consumers feel safe when they choose a cheap way of buying medicines online. However, since the pharmaceutical industry is a strong financial lobby, it might not be easy to impose sanctions on it at an international level.

Although the e-pharmacies are not complying with the law, they cannot be annihilated since the idea of purchasing medicines online has become popular due to the convenience it offers, reliability of online chemists, etc. Hence the need of the hour is to legalise and regulate them. Hence, the Drugs and

³⁹ *Supra* note 36.

⁴⁰ *Durck v. Ebay* (Case No. 05MA198, And 2006), The Ohio Court Of Appeals.

Cosmetics Act, 1940, needs to be amended to bring online pharmacies within its ambit. Laws need to be brought into place to regulate e-pharmacies. Since e-commerce is the way forward, undoubtedly, traditional chemists would eventually like to partner with online forums to move towards a better efficiency and old models will be recast to create a better way of functioning. If e-pharmacies are a success they will create easy access to consultations and medicines to those in rural areas. However this will have to be accompanied by significant efforts for promoting penetration of technology in those areas.

The government should in fact create a safe app which the doctors can use to prescribe medicines and the registered pharmacies can deliver the medicines on this basis. Sites which do not adhere to the standards required should be banished. This will not only ensure transparency but it will also help in fighting against rise of diseases by easy and quick access to medicines.

The role and duty of the e-commerce marketplace and sellers has to be defined clearly especially since it is the health of the consumer which is at risk. The DCGI has already constituted a nodal agency to collect the views of different industry bodies. The Indian pharmaceutical sector needs a new framework to bring e-pharmacies within its scope. Having a central portal with a list of e-pharmacies will be helpful.

There should be an independent regulation of online providers by third parties. Effective evaluation as well as enforcement of sanctions in the event of dissemination of harmful information is required, self-regulation along with enhanced consumer education is a necessity. Information must be shared to consumers through news in order to promote safe use of medicines. Safeguarding the health of consumers should be the prime agenda of the government while framing legislation and they should take initiatives to curb misleading advertisements and illegitimate websites. This can be done by international cooperation and surveillance. We need to have a system which balances the public health requirements along with consumer choice.