

# JOURNAL FOR LAW STUDENTS AND RESEARCHERS

## E-PHARMACIES

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### INTRODUCTION

*“Unless the legislation keeps pace with the technology, the commerce based on technology has to lag behind”*

*Justice Pushpa Satyanarayana*

Growing technologies and the advancing internet have driven and affected different models as well as sectors. Technologies have changed the definition of customer and service providers. Every aim of the producer has changed but one thing has been constant which is serving potential customer in a fast pace and in an efficient way. One of the progressive technological models which has been evolved is telemedicine where there is accessibility of the finest doctor by one click. Where the evolution was making its mark in the medicine and health care space it effected to the quick access of medicine which is through E-pharmacies.

Factors like growing population and changing lifestyles, affecting the health problem and which is remaining a key issue and a hazard in the growth of the country. In such a state, providing easy availability of quality medicine to even the remotest part has emerged as benchmark for driving the health sector in the appropriate direction. This is the right time for the internet to play a crucial role in the scene of the medicine and making health care accessible to every varied place of the country with affordable rates. E-pharmacy is one of the technological advancements which will bridge this gap by providing easy and affordable access medicine to the consumer at the doorstep by one click.

Law develops with the society and humans living in it. Every law had an amendment when the subject had been effected by technology. So, in support of the above statement, rules and regulation

which control drugs in the country shall also be updated time to time. E pharmacy is a market giving a lot of employment as well a lot other benefits to the patient.

### **RULES AND ACTS**

Laws which govern the subject are The Drugs and Cosmetic Act, 1940 and the other one is the Pharmacy act. The Union Health ministry has come out with a suggestion to draft and amend some rules of the Drugs and Cosmetics Rules 1945 under the heading “Sale of Drugs by e-pharmacy” by inserting Part VI-B to it after Rule 67H and before Part VII which will officially legalize the e-pharmacies. Now according to the draft which defines aAn e-pharmacy as “*a business of distribution or sell, stock, exhibit or offer for sale of drugs through web portal or any other electronic media*”. Hence, this definition has made it clear that e-pharmacy need not be in 'bricks' only, type of physical pharmacies that deal with patients/ customers face-to-face. Virtual or on-line pharmacies can now function as e-pharmacies in India. According to the new Rule, “**prescription**” means an instruction from a Registered Medical Practitioner to a patient, written by hand or in any electronic mode duly signed, to dispense a drug and quantity of drug to a patient. Now the doctors can legally write electronic prescriptions in any electronic modes by specifying the name and quantity of the drug and the details of the patient on the screen. A doctor from any part of the country can write a prescription for any patient across India. E-pharmacy organizations may have to collect the phone number and the prescriber for the effective functioning of the organization.

**Section 18** (c) of the Drugs and Cosmetics Act prohibits manufacture and sale of any drug without a license, only a licensed retailer is entitled for the sale of drugs and that too on the basis of prescription of a doctor only.

**Section 27** - provisions for penalty for manufacture, sale, etc., of drugs in the form of imprisonment and monetary fine. It is very clearly stated in subsection ‘b’ further in **Section 10** of the Drugs and Cosmetics Act prohibit the import of any drug that is not of standard quality, any misbranded, adulterated or spurious drug or any drug for requires a license for import. It also does not permit import of “any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or alleviate any disease.” Imported medicines may be fake, mislabeled and unsafe, which is further explained in Section 10(a).

Both the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, have somewhat same clear guidelines on the sale of **Schedule H** and **Schedule X**<sup>1</sup> drugs to the general public, which are '*restrictive drugs*' (i.e. which can be sold only on the prescription of a registered medication practitioner) if we talk specifically, Schedule X drugs include all those which contain narcotics and psychotropic substances. They require proper meticulous storage with the dispensing records. The prescription can be in a duplicate form, one copy of which is to be retained by the licensed pharmacist for 2 years. The symbol 'Rx' conspicuously displayed on the left top corner of the label. Schedule X includes narcotic and psychotropic substances-based drugs. Section 65 of Drugs and Cosmetics Rules, 1945 prescribes the procedure to be adopted by the medical stores while selling the prescription drugs and under which the prescription from the registered medical practitioner is necessary for sale of Schedule H drugs under the Act.

**Schedule H1** of the Drugs and Cosmetics Rules, 1945 mandates a licensed pharmacist to maintain a separate register for sale of drugs, details of the patient, doctor and the name of the drug/s including quantity; it is to be kept for three years and is open to inspection by regulatory authorities only.

**Schedule H1** drugs are also required to have special labelling, with symbol Rx in red to be clearly displayed on the left top corner of the label and a box warning with a red border- "It is dangerous to take this preparation except in accordance with the medical advice. Not to be sold by retail without the prescription of a registered medical practitioner."

The objective of Schedule H1 was primarily to check the indiscriminate use of antibiotics in India which are harmful, in view of the rising incidence of multi-drug resistant bacteria, which is a serious public health issue worldwide. Easy access to antibiotics via e-pharmacies will defeat this very purpose, Indian Medical Council Act, 1956 and Code of ethics regulations, 2002

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<sup>1</sup>Schedule H, Schedule X and Schedule H1 Drugs - General Knowledge Today Gktoday.in, <https://www.gktoday.in/gk/schedule-h-schedule-x-and-schedule-h1-drugs/> (last visited Apr 11, 2019)

## **REGISTRATION AND LICENSE**

E-pharmacies are required to grant of registration by the Central Licensing Authority (CDSCO) in Form 18AA through online portal along with the required fee (which is originally fixed as Rs 50,000). On the other hand, the registration issued to the e-pharmacy in Form 21AA shall remain valid for three years and the premises of the e-pharmacy center will be inspected and checked by a team of officers authorized by the Central Licensing Authority. The e-pharmacies can sell medicines only if the support of cash bill or credit memo generated through e-pharmacy portal and these bills or memos shall be maintained by the e-pharmacy registration holder as record and which shall contain-

- Name, address and sale license number of the licensee as uploaded in the e-pharmacy portal.
- Number and date of the bill or memo.
- Name of the drug, quantity, batch number (not mentioned in the draft Rule), expiry and manufacturer of medicines dispensed.
- Name and address of the e-pharmacy registration holder.

## **GREY AREAS IN NEW RULES**

One of the most important issue is that the new Rules failed to specify the outline of Standard Operating Procedure (SOP) for the e-pharmacy organization, which including storage, transport inventory control and the role of personnel employed including pharmacists which plays important role in medicine. Storage plays a vital role in preserving the potency of medicines such as medicine which is to be preserved in 'cool' and 'cold' places in particular. Quality and effectiveness of medicines also have to be preserved while packaging, transporting and delivering. Many international e-pharmacies are operating as well developing illegally in India and the new draft Rules are silent on that issue. As we know India had a bitter experience of less professionalism in the management and in work place of community pharmacies and hospital pharmacies in the past. Such things should not happen in e-pharmacies which make these types of organization very far as business motto. While trading two highly reactive medicine and if they react or by mistaken mixed or then can lead to major loss. Discouraging people with business motive to enter into

pharmacy practice areas like e-pharmacies and community pharmacies<sup>2</sup>. There are example of some countries where Pharmacists alone are permitted to own e-pharmacies. Further research thinks that certain clauses of the Pharmacy Practice Regulations 2015 also need to be modified.

## **CENTRAL DRUGS STANDARD CONTROL ORGANIZATION**

### **As per draft 2018**

"No e-pharmacy shall advertise any drug on radio or television or internet or print or any other media for any purpose,".<sup>3</sup>

"Any person who intends to conduct business of e-pharmacy shall apply for the grant of registration to the Central Licensing Authority in Form 18AA through the online portal of the Central Government,".

"The supply of any drug shall be made against a cash or credit memo generated through the e-pharmacy portal and such memos shall be maintained by the e-pharmacy registration holder as record,".

## **RECENT VERDICTS ON THIS ISSUE**

### **The Bombay High Court:**

In October 2015, in a Public Interest Litigation held that the online sales of medicines included in drugs of Schedule H without prescription and proper cash memo are illegal and court directed the state Government to take appropriate steps to prevent and regulate such practices in market. In July 2016, the Government of India while supporting online pharmacies and Central Drugs Standard Control Organization (CDSCO) issued directions to all State regulators stating that there

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<sup>2</sup> Worldwidejournals.com,  
[https://www.worldwidejournals.com/paripex/recent\\_issues\\_pdf/2018/August/August\\_2018\\_1533650783\\_\\_99.pdf](https://www.worldwidejournals.com/paripex/recent_issues_pdf/2018/August/August_2018_1533650783__99.pdf)  
(last visited Apr 11, 2019)

<sup>3</sup>Health Ministry comes out with draft rules on sale of drugs by e-pharmacy The Economic Times,  
<https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/health-ministry-comes-out-with-draft-rules-on-sale-of-drugs-by-e-pharmacy/articleshow/65637924.cms> (last visited Apr 11, 2019)

are no objections to E-pharmacies as there is no violation of existing laws including the Drugs and Cosmetics Act 1940 as well Information Technology (IT) Act.2000.<sup>4</sup>

### **MADRAS COURT –**

“Rule 67-I of the proposed rules contains definition clauses defining 'e-pharmacy', 'e-pharmacy portal', 'Central Licensing Authority', 'prescription' and 'sale by way of e-pharmacy'. Rule 67-J mandates the registration of e-pharmacy, while Rules 67-L and 67-M specify the application for registration and conditions of registration respectively. According to Rule 67-Q, the registration issued to any person shall remain valid for a period of three years, which can be renewed under Rule 67-R. Rule 67-N provides for granting registration. Rule 67-K speaks about the disclosure of information generated through e-pharmacy portal. Rule 67-O empowers the Central Licensing Authority to depute officers for periodic inspection. Rule 67-P lays down procedure for distribution or sale of drugs through e-Pharmacy. Prohibition of advertisement of drugs is imposed under Rule 67-S. Rule 67-T empowers the Central Licensing Authority to suspend or cancel the registration with provisions to appeal and deemed cancellation. Rule 67-U and 67-V deal with complaint redressal mechanism and monitoring of e-pharmacies. These provisions are intended to regulate the on-line trade of drugs and cosmetics and to prevent abuse of drugs.”<sup>5</sup>

The court further observed: “In this case also, though there is a statute, the regulatory rules are yet to be notified, in the wake of advancement of technology. Unless the legislation keeps pace with the technology, the commerce based on technology has to lag behind. While the draft rules are published in the Gazette, they are yet to be notified. Once it is notified, there is bound to be disagreement between law makers, drug companies, on-line traders and finally the consumers. In the absence of any Central or State Government legislation or rules, on-line sale of prescription drugs could hardly be curbed<sup>6</sup>.”

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<sup>4</sup> Cdsco.nic.in,  
[http://www.cdsco.nic.in/writereaddata/2018\\_08\\_28\\_Draft%20GSR%20817\(E\)\\_Sale%20of%20Drugs%20by%20E-Pharmacy.pdf](http://www.cdsco.nic.in/writereaddata/2018_08_28_Draft%20GSR%20817(E)_Sale%20of%20Drugs%20by%20E-Pharmacy.pdf) (last visited Apr 11, 2019)

<sup>5</sup> Practo Technologies (P) Ltd. v. Tamil Nadu Chemists and Druggists Assn., 2018 SCC OnLine Mad 3577, Order dated 20-12-2018

<sup>6</sup> Madras HC Restrains Online Sale Of Medicines Till Rules Are Notified [Read Order] Livelaw.in,  
<https://www.livelaw.in/madras-hc-restrains-online-sale-of-medicines-till-rules-are-notified-read-order/> (last visited Apr 11, 2019)

### THE DELHI HIGH COURT:

The industries of e- pharmacies have spread without any check and balances. Seeing the exigencies of the situation, the Delhi High Court has directed the Union Government and the Government of Delhi to ban the selling of medicines through online platform. The petition filed by a dermatologist named Zaheer Ahmad drew the attention towards the illegal sale of the drugs online. Since, the easy availability of drugs on the online platform increases the chances of drug abuse among the youth and put the life of people at stake and affects their right to a safe and healthy life enshrined in article 21 of the Constitution<sup>7</sup>.

A sub-committee was formed, the **Drug Consultative Committee** which analyzed the risk involved in the online selling of medicines and submitted its report on 30/09/2016. The reports noted some key issues which were need to be addressed urgently. Some of those serious concerns were:

- Need of cyber experts to counter the rampant increase in fake and illegal online pharmaceutical companies who could monitor such concerns.
- The scanned copies of prescription lack authenticity under Drugs and Cosmetic Act. One prescription can be uploaded to two different e- pharmacies sites leading to drug abuse because there is no such stamping system on the prescription.
- It increases the chances of self-medication among the people.
- The sale of online medicines may lead to create an unhealthy competition among the companies which would result in selling of below standard medicines and disposing of expired medicines.
- As we all know medicines are to be delivered to an adult, the home delivery of medicines may lead to the delivery of the medicines to minor.
- Transportation and storage of medicines to be delivered have to be in accordance with proper guidelines otherwise medicines may lose its sensitivity and potency.

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<sup>7</sup> Zaheer Ahmed v. Union of India

The unregulated sale of medicine online will increase the risk of spurious, misbranded and substandard drugs being sold. Some drugs have psychotropic substance and can be easily ordered on the internet for the criminal activities or drug abuse. Making strict laws on this issue is the need of the hour.

**ONLINE PHARMACIES OR E- PHARMACIES ARE ILLEGAL. IT CAN  
BE UNDERSTOOD BY VARIOUS REPORTS OF GOVERNMENT  
DEPARTMENTS AND SEVERAL EXISTING LAWS**

The Food and Drug Administration Department of the State of Maharashtra prepared a report against e- pharmacies. The report derived some important things which is as follows;

- a) The report found online sale of medicines in violation with section 18 (c) of the Drugs & Cosmetic Act, 1940 as selling was without any requisite licensees.
- b) The scheduled drugs which need to be supplied on the prescription of specialized practitioners such as pediatrician, Gynecologist, Psychiatrists, Nephrologists etc. are supplied either directly or indirectly by the unqualified practitioners.
- c) There is every possibility of selling of medicine on an old or fabricated prescription. It was noticed that in some cases drugs were sold on changed prescription, which was not uploaded by the consumer. Even it was noticed that, on the prescription of veterinary doctors, drugs were supplied for humans.

Presently, a number of laws have been violated, keeping aside the safety and security of the people. Some of them are:

- The Rule 64 of D&C Rules, 1946 says that “*license to sell medicines will be granted inter alia only if the authority is satisfied that the premises are adequate equipped with proper storage and accommodation for preserving the properties of Drugs and the person incharge is capable and competent enough to handle preservation and distribution of drugs*”.
- The *Pharmacy Act, 1948* was enacted to control the profession of pharmacy and to prohibit any person other than a registered pharmacist from dispensing medicines to a patient. Rule

65(2) of the *Drugs and Cosmetic Rules, 1945* and Rule 9.1 of the *Pharmacy Practice Regulation, 2015* require that “**prescription medicines shall be dispensed only or under the personal supervision of a registered pharmacist**”.

- The Drugs and Cosmetic Rules, 1945 and Pharmacy Regulations of 2015 mandates that the prescribed medicines must be given to the patient or its care taker but online delivery does not ensure such safety.
- The role of pharmacist is not only confined to hand over the medicines but at the same time counsel the patient and makes them understand about the medicines. These guidelines are provided in Rule 9 of Pharmacy Regulation, 2015.

There is huge techno- legal requirement to combat the illegalities associated with the e-pharmacies. These companies lack privacy, data protection, encryption, cyber law due diligence, cloud computing etc.

In the time when the government is going to bring strict regulations to govern the online sale of medicines called e-pharmacies and courts are giving differing judgments against the running of such pharmacies mentioning decades-old drug laws, a consolidation phase has begun in the world of expanding e-pharmacies in India.

Chennai based *Netmeds.com*, one of the largest e-pharmacies with claims of more than 3.7 million customers in over 610 cities and towns, on Monday acquired health-tech start-up *KiViHealth*, a clinic management platform providing cloud-based AI-powered tools for doctor-patient interaction, in a cash and stock deal<sup>8</sup>.

KiViHealth offers a "digital prescription pad" tool, which allows doctors to generate digital prescriptions, with an end to end clinic management solution app that provides facilities like appointment booking module and patient engagement tool along with billing/invoicing solutions.

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<sup>8</sup> <https://www.businesstoday.in/sectors/pharma/indian-e-pharmacies-on-consolidation-mode/story/331366.html>, last visited on 10/04/2019

## **CONCLUSION**

E-Pharmacy is one of the leading platforms that could fill the gap and act like a bridge between the growing population and their medical demands. It fulfills the needs and demands of customers at affordable price and gives easy access of medicines to the consumers at their doorstep with just a click away. Moreover, the concept will provide the consumers wider options about buying the accurate medicine and it will also help the customers to get its prescribed medicine even if medicine is not available in one store. There is an urgent need to encourage this developing sector with the right set of policies, laws and regulations in order to deliver the benefits to the consumers. As one of the major issues of the Government has been to provide quality health facilities to its growing population, therefore e-Pharmacy can serve as a best tool to achieve the goal because today a large number of people are having access to internet .

