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E-Pharmacy regulations in India: Past, present, and future

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ABSTRACT

The advent of digitalization has taken India by storm and the pharma sector is also not left behind. The trend of purchasing medicine online is increasing and so is the number of e-pharmacy start-ups. E- Pharmacies are recent entrants in the Indian e-commerce industry and receiving attention from the government as well as global investors from the past three years. The Ministry of Health and Family Welfare, Government of India has published draft rules on 28th August 2018, with the heading "Sale of drugs by e-pharmacy" to bring e-pharmacies within the scope of Drug and Cosmetics Rules, 1945 by making amendments in it which currently does not distinguish between online and brick and mortar pharmacies. It aims to regulate online sale of quality medicines pan India through e-pharmacies registered under Central Drugs Standard Control Organisation (CDSCO), India's apex drug regulator and central licensing authority, where all records are maintained as per rules laid down. The confidentiality of patient details have to be maintained and cannot be disclosed to anyone one under any circumstances other than the central or state government as the case may be. The sale of tranquillizers, narcotic and psychotropic substances and Schedule X drugs are not permitted through e- pharmacies. The dawn of 2019 is expected to bring a brighter future for a fully legitimate and professionally managed E- Pharmacies in India.

Keywords— E- Pharmacy, Online sale, Registration, Regulations in India

1. INTRODUCTION

E-Commerce has become a booming industry in India today, with the neck to neck competition among global and domestic giants fighting to gain a major market share. Among the multiple e-commerce segments, the one which has the tremendous potential to conquer a major space is the online sale of medicines or the E- Pharmacies. The trend of purchasing medicine online is increasing and so is the number of e-pharmacy start-ups. The Indian online pharmacy growth is fuelled with the increasing Indian population suffering from lifestyle disorders and chronic indications like Diabetes, hypertension, Dyslipidaemia, asthma, cancer etc., leading to increasing demand for therapeutics.

The growth of Indian e- pharmacy market is propelled by a surge on the internet by Government initiative of Digital India campaign and the competition among various data providers which has brought down the cost of internet use and made it affordable for everyone, which was once considered a luxury. According to surveys, with about 580 million internet users, India is ranked the second largest online market just behind China [1]. Despite being the recent entrants in the Indian e-commerce industry, E- Pharmacies are receiving attention from the government as well as global investors [2].

E- Pharmacy market potential is worth over a billion dollar with more than 80 start-ups operational in various states of India. According to studies, the Indian pharmaceutical market is the 3rd largest in terms of volume and 13th largest in terms of value globally [3]. Currently, there are approximately 8.5 lakh retail pharmacies across the country which is able to meet only about 60% of the customer demands. At present online pharmacies contributes to only 1% of the total demand.

The online sale of medicine is slowly gaining momentum in the e-commerce industry and an impressive penetration rate in both rural and urban regions of the country. Many entrepreneurs and investors are interested to be part of this rapidly growing market. Recent laws regarding the regulation of online pharmacy have led to investments and huge funding in start-ups and ventures entering this segment in India. This opens a new avenue for e-pharmacies to exploit this lucrative sector.

2.E-PHARMACY REGULATIONS IN INDIA

The laws governing Pharmacies in India is derived from the Drug and Cosmetics Act, 1940, Drugs and cosmetics rules, 1945, Pharmacy Act 1948, Pharmacy Practice Regulations, 2015 etc. Since most of these acts were framed much before the computer era, it does not differentiate between brick and mortar and online pharmacies. So, amendments are to be made to bring e-

pharmacies within the scope of the Drug and cosmetics rules, 1945. E- Pharmacies come under the purview of Information Technology Act, 2000 also.

2.1 Acts and Regulations

Drugs and Cosmetics Act, 1940

Section 18(c)– This section entails a prohibition on manufacture and sale of the drugs which are not licenced. According to section 18 (c) of the act, read along with rule 65, for the sale of drugs, only a licensed retailer is entitled to sell and that too only upon the prescription of a doctor for the drug.

Section 27– The section entails the punishment or penalty in regard to manufacturing and sale of drugs in the form of monetary fine or imprisonment.

Section 10– It is an act prohibiting the import of substandard quality drugs which may be adulterated, misbranded or spurious. It also prohibits the import of drugs which by any means of device or design or statement claims to alleviate any disease or cure as they may be unsafe, fake or mislabelled.

As per the Drugs and Cosmetics Act 1940, clear guidelines have been mentioned on the sale of Schedule H and Schedule X drugs that is restrictive drugs which retailers can sell only on the basis of prescriptions by a registered medical doctor. Schedule X drugs comprise psychotropic and narcotic agents. These are the drugs which have higher chances of abuse and addiction. Moreover, they require proper storage and dispensing records. The prescription for them is also required to be in duplicate, a copy of which is retained by the pharmacy as a record for 2 years.

Drugs and Cosmetics Rules, 1945

The *Rule 65* of the Drugs and Cosmetics Rules 1945 states that drugs can be sold under the supervision of a registered pharmacist only. It also involves signing and stamping of the bill by the respective doctor and the pharmacist involved. It also states about the procedure to be executed by the medical stores while selling the prescription drugs which is to be duly given by the registered medical practitioner for the sale of H1 drugs. Schedule H1 drugs are required to be maintained or listed in a separate register along with the details of patient, doctor and name of the drug and its quantity when sold as mandated for a licensed pharmacist. Such records are to be kept for three years and should be open in front of regulatory authorities.

Schedule H1 comprises habit-forming painkillers; sleep inducing anti-anxiety drugs and potent antibiotics. They are also liable to have special labelling with symbol Rx mentioned in red at the top corner of the label along with a red bordered warning box mentioning– “Intake of this preparation is dangerous unless advised by the medical practitioner. The drug is not to be sold without the prescription of a registered medical practitioner in retail.”

The objective of putting antibiotics in Schedule H1 was to shun the indiscriminate use of antibiotics owing to the rising incidence of multidrug-resistant bacteria. Easy access through online mode would defeat the purpose.

Pharmacy Act, 1948

As per the subsection 1 of section 42 of Indian Pharmacy Act 1948, it is stated that “no person other than registered pharmacist shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner.” Subsection 2 of section 42 also states, “ whoever contravenes the provisions said above shall be punished with imprisonment for a term extending up to six months, or with fine not exceeding rupees one thousand or with both.”

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Rules, 1955

The Drug and Magic Remedies (Objectionable Advertisement) Act and Rules prohibits publication of any advertisement of any drug which suggests or are calculated to lead to the use of that drug for diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the schedule annexed to these rules.[4]

Section 3 of this act refers to Prohibition of advertisement of certain drugs for the treatment of certain diseases and disorders.

Section 4 of this act refers to Prohibition of Misleading Advertisement relating to drugs.

Indian Medical Council Act, 1956 and code of ethics regulations, 2002

Regulation 7.14 of MCI Code of Ethics, 2002, does not allow a registered medical practitioner to disclose the secrets of a patient that he/she may have learnt in the exercise of his/her profession. Regulations clearly specify that not only doctors but pharmacists too have a role in ethical dispensing of prescription medicines.

Pharmacy Practice Regulations, 2015

Pharmacy Practice Regulation, 2015 was enforced by the Pharmacy Council of India to regulate Pharmacy practices in India. As per this rules Dispensing of Drugs should be carried by the Qualified Registered Pharmacists only. Renting of Registration Certificated to Pharmacy owners is strictly prohibited. Along with dispensing services pharmacists should provide their professional services like patients counselling, Adverse drug reactions reporting, Primary Care to all uncomplicated simple illnesses. For this purpose, a separate area should be arranged within the Pharmacy.

An electronic prescription from a registered medical practitioner is considered valid as per this rule. *Regulation 2 (j)* defines “*Prescription*” as written or electronic direction from a Registered Medical Practitioner or licenced practitioners such as Dentist etc to Pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to the patient[5].

Section 43 A, of Information Technology Act, 2000 and Information Technology Rules, 2011, deals with data protection or privacy in India. The act prescribes that when a document is required to be signed under the law, such a document would be deemed to be in compliance with the law only when such information is authenticated through an electronic signature.

2.2 Pathway to legalisation for E- Pharmacy in India

E- Pharmacy refers to the application of the internet to access medicines delivered at doorsteps. Though online pharmacy business started way back in 1999, in India, the online sale of medicine was started by Netmed in 2010. The year 2012 to 2015 saw mushrooming up of more than 50 active e-Pharmacy start-ups expecting to replicate the success of e-commerce giants Flipkart and Snapdeal in India. Unlike other goods sold online, the sale of medicines involved regulatory controls and the same was under constant criticism.

Maharashtra's Food and Drug Administration (FDA) raided the Mumbai office premises of e-commerce giant Snapdeal on 17th April 2015 for allegedly selling prescription drugs online. Despite the raid, Snapdeal continued selling prescription drugs online and an FIR was filed against its CEO and distributors of such drugs by Maharashtra FDA on 1ST May 2015.

Even as Union health ministry has initiated a process to formulate guidelines for an e-commerce marketplace to ensure the safety of consumers, the Drugs Controller General India (DCGI), appointed FICCI as the nodal agency for consolidating the guidelines on 19th June 2015[6]

A Sub-committee to examine the issue of regulating sales of drugs over internet under the Drugs and Cosmetics Act, 1945, was constituted as per the recommendations of 46th meeting of Drugs Consultative Committee (DCC) held on 24.7.2015 and an office memorandum in this regard was released on 11.8.2015, With Dr. Harshdeep Kamble IAS, Commissioner, Maharashtra FDA as Chairman and Dr. S. Eswar Reddy, Joint Drug Controller, CDSCO as Convenor. The subcommittee submitted its detailed report on 30th September 2016.

In July 2016, the Government gave its nod for online pharmacies and Central Drugs Standard Control Organisation issued directions to all state regulators stating, no objections on the online sale of medicines as long as there was no violation of the existing laws, Drugs and Cosmetics Act and Rules and IT Act, 2000.

Major Online Pharmacy players joined hands together and formed the Indian Internet Pharmacy Association, in June 2016. On 21st November 2016, IIPA released the 'Self-Regulation Code of Conduct' for e-pharmacy sector as an attempt to adhere to the highest professional standards and to have proper- safeguards to ensure consumer health and safety. According to the Self-Regulation Code of Conduct, e-pharmacies will process scheduled medicines only against valid copy of prescription (Physical/scanned) of a registered medical practitioner and ensure that no Schedule X and other habit-forming medicines are processed through their platform. The Code of Conduct was released under the ambit of FICCI [7]

The Launch of Goods Service Tax, in July 2017 became a boon to the online pharmacies. GST eliminated the cascading effect of the tax which involved multiple taxes applied on one product. Due to discontinuation of the Central Sales Tax and Interstate transactions between two dealers the conventional Cost and Distribution Model got replaced by supply chain efficiencies and tax became impartial.

On 28th Aug 2018, Ministry of Health and Family Welfare, Government of India has published e- Pharmacy draft rules to amend Drugs and Cosmetics Rules and to regulate the sale of medicines online.

3. E- PHARMACY DRAFT RULE, 28TH AUG, 2018

The Central Government on August 28, 2018, came out with e-Pharmacy draft rules under the Drugs and Cosmetics Act 1945 (the Act). The draft rules are proposed to regulate the sale of medicine through a web portal or e-Pharmacy business in India. It defines "e-pharmacy" as a business of distribution or sale, stock, exhibit or offer for sale of drugs through a web portal or any other electronic mode. The rules also provide for various regulatory processes that would be required to operate the e-Pharmacy business including:

3.1 Registration of E- pharmacy

As per the draft Rule, no person shall distribute or sell, stock, exhibit or offer for sale of drugs through e-pharmacy portal unless registered under Central Licensing Authority in Form 18AA through the online portal of the Central Drugs Standard Control Organization (CDSCO). The applicant also needs to pay an application fee of fifty thousand rupees which shall be accompanied by the application form. Apart from the e-pharmacy registration, the registration holder will have to comply with certain other conditions:

- The e-pharmacy registration holder will have to comply with provisions of Information Technology Act, 2000 (21 of 2000) and Rules made thereunder.
- E-Pharmacy registration holder shall receive the orders for retail sale through the e-pharmacy portal.
- E-Pharmacy registration holder shall arrange or provide the drugs, as per the prescription received from the customer, within the period specified by the e-pharmacy registration holder at the time of placement of the order through the e-pharmacy portal.
- Supply of any drug shall be made against cash or credit memo generated through the e-pharmacy portal and such memos shall be maintained by the registration holder as a record.

- e-Pharmacy registration holder shall have a facility for grievance redressal and customer support of all stakeholders which shall run not less than twelve hours for all seven days of a week, provided, the facility for customer support shall have a registered pharmacist present to answer the queries of customers through such helpline.

The registration issued to any person for e-pharmacy in Form 21AA will remain valid for a period of three years from the date of its issuance and registration will have to be renewed before its expiry.

3.2 Procedure for sale or distribution of drug through e- Pharmacy

On receipt of prescription through e- Pharmacy portal should be verified by a registered pharmacist for patient details, registered medical practitioner and the same has to be recorded in the portal before dispensing. The premises from where the drug is being dispensed should comply with Drugs and Cosmetics Act, 1940. In the case of e-prescription, the same has to be uploaded and kept as a record in the portal.

3.3 Data privacy through the e-pharmacy portal

Data of patient received through e-pharmacy portal shall be kept confidential and not be disclosed to any other person or agency except to the central government or the concerned state government, in case required for public health purposes. The draft also suggests that in no case the data generated or mirrored through the e-pharmacy portal shall be sent by any means, outside India.

3.4 Narcotic and psychotropic drugs sale through e-pharmacy

The e-pharmacy registration holder shall not carry out e-pharmacy activities with the drugs covered under the narcotic and psychotropic categories as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), tranquillizers and other drugs as specified in the Schedule X of Drugs and Cosmetics Rules, 1945.

3.5 Periodic monitoring and inspection of e- Pharmacy

An inspection will be conducted every two years at the premises where the e- Pharmacy transactions are conducted by a team authorised by Central Licensing Authority or team authorised by concerned State Licensing Authority. The data or information of e Pharmacy shall be monitored periodically to ensure compliance with the provisions of the Drugs and Cosmetics Act, 1940, and Rules thereunder by the inspecting authorities. E-pharmacy registration holder is liable for producing prescriptions on the basis of which the drugs have been dispensed for the purpose of transaction audit when asked to do so.

3.6 Advertisement policy

The draft envisages that no e-pharmacy shall advertise any drug on radio or television or internet or print or any other media for any purpose as per the Drugs and Cosmetics Act, 1940.

4. LOOPHOLES IN THE NEW DRAFT RULE

Though the new rule for e- pharmacy is a welcoming step from the government which legalises the online sale of medicines in India, it has some grey areas too. It does not emphasise on recording details like age, gender, address and registration number of the prescriber. The use of a scanned copy of the prescription is allowed, which can lead to over dispensing by use of the same prescription from different e- pharmacy portals. No guidelines on maintenance of storage condition during transportation for retaining the potency of the medicines supplied has found any mention in the new rule.

5. CONCLUSION

The success of e- Pharmacy business depends on the high level of professional ethics with which it manages to fit in the legal framework and make its unique place in the highly booming pharma sector. Patient safety and quality of medicines supplied should be the prime focus of this business which can be attained by involving professional in this area. Though ease of access and delivery at doorsteps are the major attractions of e- Pharmacy but also have a major impact on access to medicine for the geriatric population. The dawn of 2019 is expected to bring a brighter future for a fully legitimate and professionally managed E-Pharmacies in India.

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