Emergence of E-Pharmacies and their Regulation in India

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ABSTRACT

Buying behaviour towards pharmaceutical products is changing day by day in present scenario. Now a days online marketing for drugs oblige medicine is increasing effectively. The global e-pharmacy market has been increased around to US $9.3 millions. To cope up with this current developing trend e-prescribing technology frame work has also been introduced in the market. E-pharmacy may be beneficial if we may ensure the regulation of it properly.

In today scenario purchasing or buying the drug or Medicine online has become the new trend amongst the consumers and patients. By changing in the behavior of the buying medicine number of e-pharmacies increased. Today buying the medicine through online has become the fashion. But there is lack of proper regulatory control over the e-pharmacies. This gap give the chance to grow e-pharmacies like mushrooms. There is also some other factors which are gearing up the e-pharmacies like increased chronic diseases misusage of medicine and improper treatments.

Number of the internet users has also increased as number of the smart phone users also increase. In which Reliance Jio has played a important role of increase smart phone users numbers. In India the chronic disease and lifestyle disease patients are increasing thus its a high time for e-pharmacies to grow up in India and the same way drastic increase in internet phone users. Because of the increasing of mobile or internet access the medicine information and their delivery to our doorstep become easier.

There is only five factors which increase the populary of the e-pharmacy.

(a) Time Saving
(b) Money Saving
(c) 24 × 7 access.
(d) Transparency.
(e) Convenience.

Apart from these the low cost, Good Quality of drug, with in frame of time delivery, availability, legality, service become success factor of any e-pharmacy.

WHAT IS E-PHARMACY

E-Pharmacies are the online platform from where customer or patient can buy the medicine without having to go or visit brick-and-mortar pharmacies.

According to the Transparency Market Research, the global e-pharmacy market was around US $9.3 Billion in 2014 and it is estimated to grow at GAGR at 17.7% to reach a valuation of US$ 128 Billion by 2013.

In India although the E-pharmacy is initial stage but has the much potential to be a very large Industry segment in the coming future. Currently many e-pharmacy players like such as Zigy, Netmeds, IMG, Mchemist, Medidart Medlife, Pharmacasy, Savemydeds and Save on Medicals etc.

Model of e-pharmacies

(i) The Organized e-pharmacy

There are two model which operate in this category.

(a) One is a market place model where a technology company neighborhood licensed pharmacies to the end user.

(b) Second one is an inventory based model where E-pharmacy is online service of an offline licensed pharmacy.

(ii) Unrecognized e-Pharmacy:

In this model prescription medicines are ordered without any validated prescription. There is no any check of genuineness of order due to absence of the qualified pharmacists. Here no audit is the major concern.
(iii) Illegal International trade through E-pharmacy

Medicines or Drugs are being shipped across the international borders without any prescription and approval from the concerned authorities.

Type of Medicines

Drugs can be classified by many ways. As per our Indian system drugs are categories in allopathic, Homeopathic, Ayurvedic Unani, and Siddha drugs. They can also be classified in two level of control i.e. prescription drug and other is over the counter drug (OTC). On the basis of natural or origin-synthetic it could be natural drugs and phytopharmaceuticals. Drugs could also be classified as miscellaneously like personal care drug, Ethical drug, Orphan drug, Generic drug lie style drug, Diagnostic drug, Neutral- ceuticals etc. All type of drug come under the see of online E-pharmacy.

The biggest problem in today modern time related with existence of e-pharmacies are misuse of medicine, additions, drug abuse, CMS depressants, etc. Doctors should pay special attention when they prescribe these type of the medicines as well as the fix dose combination. There is a conflict between online pharmacies and offline pharmacy. Because they have threat that E-pharmacies can finish the platform of offline retailers.

Apart from these doctor’s writing is also concern which can solved by e-prescription. Due to availability of drug online it is win-win situation from customer as he can compare the price of medicine and find the best price and select from where (e-pharmacy) he can purchase.

e-Prescribing is a technology framework that allows physician and other medical practitioners to write and send prescriptions to a participating pharmacy electronically instead of using hand written or faxed note or calling prescriptions.

Overview of e-pharmacies in India

Netmeds is a trusted since 1914 with excellence, expertise and experience in pharma. It is a trusted online medicine partner for more than a million loyal customers. It is India’s most convenient online pharmacy. Netmeds.com India ki pharmacy is bought by Dadha & company one of the most trusted pharmacies with over 100 years experience in dispensing quality medicines. Customer can buy or send medicines from any corner of the country with a just a few clicks of the mouse Netmeds.com offer fast online access to medicines with convenient home delivery. At netmeds.com they provide wide range of medicines listed under various categories they offer a one stop shop like OTC products, wellness products, vitamins, diet or fitness supplements, herbal product pain reliever diabetic care kits, baby or mother care products, beauty care, and surgical supplies customer can upload and send their Rx through email, fax, whatsapp.

1MG is an e-commerce healthcare based company based in gur’gaon India. The company was founded in 2012 as healthkart plus, a subsidiary of healthkart by the key people prashant Tandon, Sameer Maleshwari, Gaurav Agarwal and vikas Chauhan in April 2015, and Healthkart plus converted into as 1MG. 1Mg deals in online marketplace for medicines, besides facilitating medical appointments and diagnostic test bookings. 1 MG also has done acquisition on Jun 2015 1 MG acquired online homeopathic drug store home buy and rebranded as 1mg aysh on July 2016 1mg Acquired med an online diagnostic image processing aggregation. On December 2016, acquired Mumbai based medi Angels, a online consult platform for undisclosed sum. 1mg.com provide broad range of wintercare, fitness & supplements, diabetes, medical devices, personal care, health conditions, ayurveda and homeopathy. On 1mg the patient or customer can upload his Rx and get the medicine on door step. It also have 1mg app for mobile users.

Medlife is an online pharmacy which provide the wide range of healthcare products customer can easily download his prescription to send and get medicine customer can also call in 1860-1234-1234 they also provide discount on medicines.

Pharma Easy startup was started by dharmil spreth in 2015. Now it is a leading medical and healthcare app in India, which connect consumers with local pharmacies and
diagnostic centers DHARMIL’S key areas to handle customer experience and also helms the operation and marketing division of the company.

PharmaEasy is based on Mumbai Maharashtra. PharmaEasy provide the wide range of the products include personal care, herbal care & Ayurveda healthcare, food & nutrition, sexual wellness, diabetic care and medical supplies & equipment PharmaEasy is a one stop solution to affordable healthcare services. Buying medicine online is a sure to become easier and more convenient than ever. Free home delivery, amazing discounts available within almost categories, no minimum order and easy return policy on all medications. There is no other option that provide affordable and convenient services in the realm of online medicine delivery.

Dgmedicine is a India’s 1st online wholesale rate pharmacy. It is an ISO 9001:2015 certified pharmacy based at Aligarh known as har ghar ki pharmacy for online order customer can go on his website dgmedicine.com or download app.

OVERVIEW OF E-PHARMACIES REGULATION IN INDIA
If we see the current scenario of the e-pharmacies regulation then it can be understand by the given below diagram:

Regulatory power

Central Government State Government

Responsible lisencing of drug import

Responsible for manufacturing, sale & distribution of drug

Central Government is responsible for licensing of drug import and state government is responsible for manufacturing, sales and distribution of drug. Central government regulate control over drug by New Delhi based Central Drug control organization headed by Drug controller Central India where the State authorities’ exercises regulatory control over drugs by state based Drugs control Administration readed by the state drug controllers. Every State has its own drug control administration.

Central Government State Government

DCGI State Drug Control

Central Drug Control Organization headed by Drug Control Administration

Controller General India

In India pharmacies governing law came from below:
(a) Drugs and Cosmetic Act, 1940
(b) Drugs and Cosmetic Rules, 1945
(c) Pharmacy Act, 1948
(d) Indian Medical Act, 1956
(e) Code of Ethics Regulation 2002 etc.

If you see then you will find that these laws are derived before the era of Internet. So it can also be say no law as today era is digitize or digital. The only Information Technology Act 2000 governs are activities and internet related issues. When the regulation concern come regarding e-pharmacies then there is no clear cut law, rule and control over the e-pharmacies. E-pharmacies come actually under the Drugs and cosmetic Act, 1940 and Information Technology Act, 2000 but Drugs and cosmetic Act, 1940 not able to distinguish between online or offline pharmacies. So area of improvement and amendments are very important in Acts to bring e-pharmacies under it.

Taking the advantages of the weakness and loophole of e-pharmacies law player take advantage of that and not abide the regulation of law and drive the things in favour of their business advantages. There is a big confusion of believing that rules applied for offline pharmacies could be easily applied to be online pharmacies also. It is a dangerous move towards the future of e-pharmacies regulation. There is no clear cut provision to sell the drugs through internet and very difficult to internet and very difficult to control, monitor and tracking sell of drugs through e-pharmacies.

PHARMACIES ACTS AND RULES
Drugs and Cosmetic Act, 1940
Section 18(c) of the drug and cosmetic Act prohibits manufacture and sale of any drug without a license. As per
the section 18(c) of Drugs and Cosmetic Act, 1940 to be read with Rule 65, only a licensed retailer in entitled for the sale of drugs and that too on the basis of doctor’s prescription only.

As per the Section 27 of drugs and cosmetic act has provision for the penalty for manufacture, sale etc. of the drugs in the form of imprisonment and monetary line. It is crystal clear in states in subsection “b (ii) without a valid license as required under clause (c) of Section 18”.10

As per Section 10 of the Drugs and Cosmetic Act prohibit import of any drug which is not of Standard quality, spurious drug or adulterated any misbranded or any drug for require a license for import. It also not allow import of “any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to are or alleviate any disease.” The imported medicines may be unsafe mislabelled and fake.

The drug and cosmetic Act, 1940 and drugs and cosmetic Rules, 1945 have a very clear cut rule or guidelines regarding schedule H and schedule X drugs which are ‘restrictive drugs’ and can be sold only on the prescription of a registered medication doctor or practitioner. If we see schedule X drugs includes narcotics and psychotropic substances with these drug the rate of addiction and drug abuse are higher. These drug requires the storage and dispensing records. The prescription has to be in duplicate one copy of which is to be retained by the licensed pharmacist for two years.

Drugs and Cosmetic Rules, 1945

This drug and cosmetic Rules 1945 stipulated sale of the drug under the supervision of the pharmacist which put his sign on the bills and stamping on the prescription by the pharmacist and doctor under this act it prescribe the procedure to be adopt to sell the medicine from the medical stores even selling of prescription drugs and under which the prescription from the registered medical practitioner is necessary for sale of schedule H drugs under the Act. Under Schedule H1 of the Drugs and cosmetic Rules 1945 it is mandate a licensed pharmacist should have the separate register in which he will keep records of patients name drug name and Quantity for three years and can be check by the regulatory authorities time to time.

Schedule H1 drugs include the mainly potent antibiotics, habit forming pain killers and anti-anxiety drugs that induce sleep. Schedule H1 drugs also having the special labelling with the symbol Rx in red clearly shown let top corner of the label and a box have a warning with red border—”It is dangerous to take this preparation except in accordance with the medical advice. It should not to be sold without the prescription of Registered Medical Priscriptioner.”

Indian Medical Council Act, 1956 and Code of ethics regulation, 2002:

1. As per the regulation 5.3 of the MCI Code of Ethics states that doctor and pharmacist should work together. But if e-pharmacies are allowed then this relationship will be lost.

2. As per the Regulation 6.4 of MCI code of ethics it prohibits from giving and taking any rebates or commissions e-pharmacies provide the rebet to the doctors to provide prescriptions on the basis of online information that has been filled by the patient on this way doctor will be vulnerable to malpractice suits.

3. As per the Regulation 7.14 of MCI Code of Ethics 2002, it does not allow a registered Medical practitioner to open or disclose the secrets of a patient that he/she may have been learnt in the exercise of his/her profession. Declaration given to doctors at the time of registration states: I will respect the secrets which are confined in me.

4. In giving right ethical drug to patient is not only responsibility of the doctor but pharmacist also.

5. As per regulation 1.9 of MCI code of the Medical Ethics Regulations, 2002 requires all doctors should follow the national law that regulate their practices. Neither doctor nor pharmacist should help each other to escape these laws.

As per regulation 7.19 of MCI code of Medical Ethics Regulation, 2002 it does not allow doctors to use touts or agents for procuring patients. So pharmacist should not participate in such type of activity.

Drug and Magic Remedies Act (Objectionable Advertisement) 1954

Under this Act mentions a list of ailments for which advertising is not permitted. It also stop or prohibits false or misleading advertisement that marking wrong claim. As the Indian population is going rapidly so population move exposed to advertising for prescription drugs despite legal prohibitions.

- **Section 3:** Prohibition of Advertisement of Certain Drugs for Treatment of certain disease and disorders.
- **Section 4:** Prohibition of Misleading Advertisement Relation to Drug.
Narcotic Drugs and Psychotropic substances Act, 1985
There is the chances of misuse of unmonitored and uncontrolled sale of narcotic drug which is listed under the Narcotic Drug and Psychotropic substances Act, 1985

Pharmacy Act 1984
According to the subsection 1 of the Section 42 of Indian Pharmacy Act 1948, “no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner.”

Section 42(2) also states, “Whoever contravenes the provisions of sub section (1) shall be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupee or with both.”

Information Technology Act, 2000
The information technology Act 2000 stipulate some of the legal issues pertaining to the online dealings but it is silent on the aspect of e-pharmacy. Because of this illegal e-pharmacies have been increasing in India. In India there is no any specific legislation data privacy yet. The law which is deal with date protection or privacy in India are Section 43-A of the Information Technology Act, 2000. Information technology Rules 2011.

There is many doubtful creating Indian law which nor have clear meaning whether a pharmacy is allowed to take money prior to delivery of Medicines. Certain provisions of the law mandate, money to be collected from the customer only after medicine are physically handed over to the customer.

Pharmacy Practice Regulation, 2015
It appears that electronic prescriptions should be valid especially in the light of the pharmacy Practice regulations of 2015 as per declared by the pharmacy council of India in January 2015.

In these regulation the “Prescription” is defined by 2(j) “Prescription” means a written or electronic direction from a Registered Medical Practitioner or other property licensed practitioners such as Dentist Veterinarian, etc. to a Pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to patient. On the basis of existing regulations it appears that existing regulations it appears that a scanned copy of prescription will be considered as a valid prescription. But when the electronic prescriptions can be used to buy medicine from e-pharmacies has been Questioned. Apart from that existing regulations scanned copy of prescription will be considered as a valid prescription.

Distribution Services:
The drug distribution is currently regulated at State level by the heath department for detecting such cases and taking Action. As per the FDA officials, there is need of proper regulatory mechanism for e-pharmacy which will help to control illegal practices of irrational use of drugs through self-medication, more so, as it has become a global phenomenon.

Techno-legal Requirement:
Online pharmacies operating in India are abided to follow certain techno legal requirement of Indian laws which they fail to follow like Privacy Data protection, Encryption, cyber laws due diligence, cloud computing and Internet Intermediary obligations.

Due to not proper knowledge of cyber law and diligence requirements and Internet intermediary liabilities some e-pharmacies stores, websites and Individuals breach the provisions of Information Technology Act, 2000.

E-pharmacies assuming that offline medico legal requirement can be used for the same online requirements which actually misbelieving as both have different legalities and array of questions. Strictly follow up of an adherence to compliance with Indian laws is required for successful operation of any e-pharmacy.

Government Approach towards these issues
The sale of Medicines through e-pharmacies has been banned by the Drug controller General of India on 30th December 2015. The DCGI has keep eye on the online sale of Medicines to control or stop breaching rules and regulations. Therefore all the e-pharmacies operating in India are the under regulatory scanner.

Federation of India chambers of Commerce and Industry (FICCI) has been appointed as nodal agency by the drugs controller General of India to consolidate and frame guidelines for online sales of medicines through e-commerce channels in June, 2015. To oppose the central Government move to regularise the online sales of medicine the Ace Indian Organization of Chemists and Druggists (AIOCD) went on one day’s strick in October, 2015.

Indian Medical Association (IMA) wrote a white paper which shows strong oppose of e-pharmacies Traditional pharmacies also oppose the online drug pharmacies model. Authorities are working to make a model in which they can fill the gap of traditional Pharmacies and provide new opportunities to the patients specially who are old. Model would be served as a platform to bridge the gap of existing offline pharmacies and connect the patients with existing offline pharmacies.
Highlights of Federation of India chambers of Commerce and Industry (FICCI)

In current e-pharmacies law there are lots of the gap in e-pharmacy model. If it will go continue then e-pharmacies may be proved as dangerous trend in future. A sub committee is ready to release a Report of recommendation to regulate e-pharmacies after extensive deliberations with experts industry persons and stake holders. As per S. Esware Reddy (joint Drugs controller-CDSCO), “This Report will mainly accept online pharmacies only with respect to e-prescriptions.”

The main focus on e-prescription and recommended a standardized format for these prescriptions. They defined the terms related to online medicine retail, including e-prescription, online pharmacies, and over. The-Counter (OTC) drugs.

In report few reforms are suggested and Apart from this some change in drug rule and a “negative list” which have some specific drugs prohibited to seese to ensure the safe running of online pharmacies. It has suggested integrating AADHAR Number in to the overall e-pharmacy framework to make the retail process more transparent.

Ways to improve regulation
(i) Government should make a common logo for legally operating e-pharmacies to distinguish them from illegal one.
(ii) Make guidelines for online drugs important to be registered and to get licence for the same for regulating body.
(iii) Design a website for checking legality of e-pharmacy.
(iv) Specific and clear cut rules should be made for selling, prescribing, dispensing and delivering prescription drugs through e-pharmacies.
(v) Make guidelines for consumers for safely accessing e-pharmacies and explains how to buy medicines safely from e-pharmacies.

It should be mandatory for e-pharmacies dealing with online drugs importation and re-importation to be registered and to get licence for the same from regulatory body.

As the power of drug regulation is divided between Central Government and State Government so it should be crystal care. E-pharmacies should not use the date generated from online business for commercial purpose. Using public-private tie-ups leveraging characteristics of Internet based technologies and engaging private sector service providers can be the basis of an encyclopedic policy to address this planetary public health. e-pharmacy must establish its server in India as if it is outside the boundaries of India its is difficult to control and regulate it.

Advantages of E-pharmacies
1. E-pharmacies provide time saving Money saving and 24×7 access possible.
2. E-pharmacies play an important roll as they increase convenience, easy accessibility to medicines and Refunds also.
3. E-pharmacies provide Easy comparison of medicines in the terms of cost, increase the consumer information and Privacy and fast distribution.
4. E-pharmacies provide as increased choice as wider verity of medicines are available and it helps to old age people who can not their home.
5. Delivery of the medicines at desired place at desired time or at right place at right time.

Disadvantages of the E-pharmacies
The disadvantages of the E-pharmacies are:
1. The disadvantages of the E-pharmacies may be dry resistance, drug interaction, drug abuse, drug misuse, self medication and chances of misdiagnosis.
2. Purity and quality of drugs not assured Medical privacy is also a big concern.
3. E-pharmacies Encourage direct to consumer advertising of prescription drug which is illegal.
4. Selling of the drugs without prescription through the E-pharmacies which is illegal.
5. Online prescription without consulting doctor and evaporates trust of trio doctor-pharmacist-patient.
7. No control on purchasing of drugs by minors from e-pharmacies.
8. It is very tough to distinguish between legitimate and illegitimate websites for e-pharmacy.
9. It is tough to transport temperature sensitive drug.

Challenges towards E-pharmacies:
If we talk about the challenges towards the E-pharmacies then speed of internet, knowledge of Internet absence of concrete law fore-pharmacies and unclear laws on inter-state transfer of drugs/medicines are the main challenges.

Apart from these few are:
(a) Protection of consumer right.
(b) The lack of security of financial transactions.
(c) Issue of Regulatory control over e-pharmacies operating outside the jurisdiction of India.
CONCLUSION

As per the regulatory authorities it is difficult task to control, manage, monitor the sell of online drug sells and purchase via internet because of the lack of clear cut guidelines in India for e-pharmacies. As the model of e-pharmacy is good and beneficial to all but need to make clear cut rules and regulatory hurdles to make it successful. The misuse of it will create drug addiction, drug resistance, self medication and drug abuse.

E-pharmacy may be proved as beneficially if it regulate properly and may be proved as dangerous trend in future if not regulated properly. So it is important to make rules and policies by government authorities and central government for e-pharmacies also that they can fulfill the gap of market and e-pharmacies can meet out with requirement of customer or patient.

The main purpose of the e-pharmacies would be to provide good quality safety with economical price of drug to patients.

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