

E-pharmacies Regulation in India: Bringing New Dimensions to Pharma Sector

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Abstract

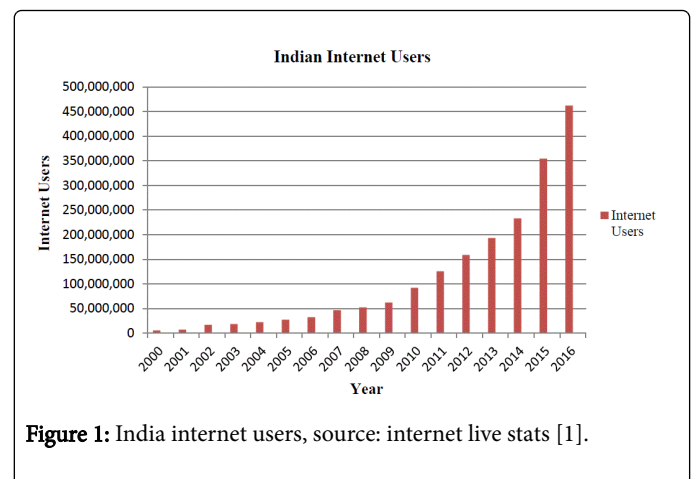
Buying drugs/medicines online is the latest trend amongst the Indian patients and consumers. With this increasing trend of buying medicines online, number of online pharmacies also increase. But there is lack of proper regulatory checks and balances for exercising regulatory control over e-pharmacies. This eventually leads to flourishing of e-pharmacies like mushrooms. There are several other factors also which fuel the gearing up of e-pharmacies like increased number of netizens, long term illness patients and increased chronic diseases. As we all know India is the country of youngsters and they are spending more and more time on internet through mobile or computer. Due to the advancement of technology, access of drugs through Internet is very easy for common man. Numbers of internet users in India have been increased continuously since 2000. This is the high time for the e-pharmacy model to grow with the drastically increasing netizens, smart phone users and patients. E-pharmacies business is growing very fast in India although its mechanism of regulation is not decided yet. The success of the model is not guaranteed in shaky and cloudy regulatory regime but its graph is going higher day by day. There is lack of proper and clear laws for e-pharmacies. The laws governing Pharmacies in India are derived from Drugs and Cosmetics Act, 1940; Drugs and Cosmetics Rules, 1945; Pharmacy Act, 1948; Indian Medical Act, 1956 and Code of Ethics Regulations, 2002 etc. E-pharmacies come under the purview of the Drugs and Cosmetics Act, 1940 and the Information Technology Act, 2000. But current Drugs and Cosmetics Act, 1940 doesn't distinguish between online and offline pharmacies. It seems e-pharmacies may not abide by these regulations and bypass them. Regulatory authorities finds it difficult to control, monitor and track sell of drugs via internet as there is lack of clear guidelines in India regarding the same. E-pharmacy may be proved as dangerous trend in future if not regulated properly.

Keywords: E-pharmacy; Online pharmacy; Internet pharmacy; Web pharmacy; Cyber pharmacy; Regulation; Regulatory issues; India

Introduction

Now-a-days we witness a phase transition of buying pattern of any goods, clothes, electronics, furniture, grocery, etc. With the advent of technology, offline shopping switches to online mode. Buying anything online is in fashion. Then how could be our field of pharma stay untouched of this? Buying drugs/medicines online is the latest trend amongst the Indian patients and consumers. With this increasing trend of buying medicines online, number of online pharmacies also increase. But there is lack of proper regulatory checks and balances for exercising regulatory control over e-pharmacies. This eventually leads to flourishing of e-pharmacies like mushrooms. There are several other factors also which fuel the gearing up of e-pharmacies like increased number of netizens, long term illness patients and increased chronic diseases.

Numbers of internet users in India have been increased continuously since 2000 (Figure 1).



As per Ken market research's report [1] internet penetration (% of Population) was 0.5% in 2000 and reached to 34.8% in 2016 (estimate for July 1, 2016) [1]. From figure it is easily interpreted that a step upward curve in the number of net users is seen since the last few years. Same way share of smart phone users increased continuously (Figure 2). Reliance Jio scheme will add more number of smart phone users in India. Now move towards chronic diseases to establish connection with e-pharmacies growth. As per Patel et al. [2] chronic

diseases (e.g., cardiovascular diseases, mental health disorders, diabetes, cancer, etc.) and injuries are the leading causes of death and disability in India [2]. There is also widespread presence of some lifestyle disorders (e.g., pain, obesity, stress, dyslipidemia, diabetes, hypertension and some cancers, etc.). Day-by-day chronic diseases and long term illness patients are increasing in India. Thus one can say this is the high time for the e-pharmacy model to grow with the drastically increasing netizens, smart phone users and patients.

As we all know India is the country of youngsters and they are spending more and more time on internet through mobile or computer. Due to the advancement of technology, access of drugs through Internet is very easy for common man. Same way delivery of desired drugs at desired place (at doorstep) is possible with this. The driving forces for popularity of e-pharmacies are time saving, money saving, 24/7 access, transparency, convenience, etc. A number of challenging factors like cost, quality, availability, services, legality, low e-tailing penetration and high drugstores/pharmacies market penetration, etc. will decide the success of e-pharmacies. We expect better and quicker services from e-pharmacies and at the same time, we don't want to compromise with quality and safety of drugs.

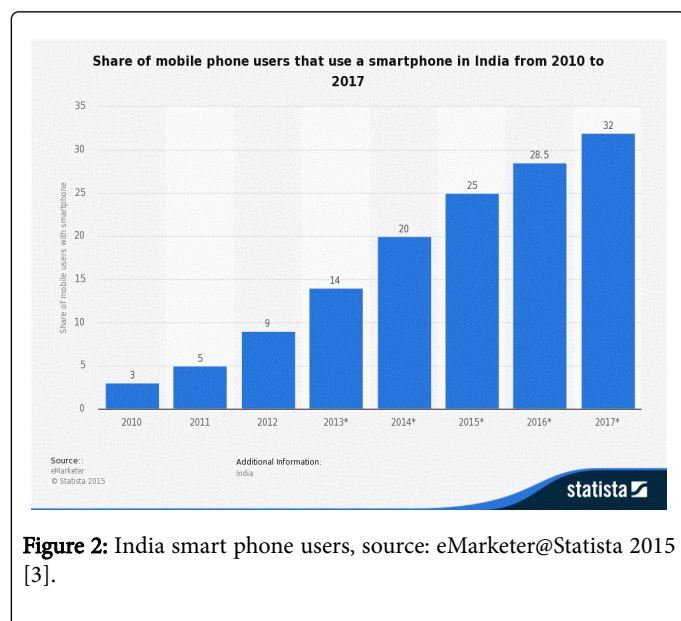


Figure 2: India smart phone users, source: eMarketer@Statista 2015 [3].

There is a vast difference between the sale of common consumer goods and drugs/medicines. Patients or consumer are not in a state to select a drug of his/her choice; which is possible in case of other goods. Basically there is no much more difference between the online and offline pharmacies. Both models pose similarities in operations but most noted difference between the two is the delivery of drugs to the end users. Online stores are operated via the internet in contrast to the offline stores. Three types of models of e-pharmacies exist in India-organized, non-organized and illegal.

Models of E-pharmacy

Organized e-pharmacy

There are two models which operate in this category.

- The market place model, where a technology company connects neighbourhood licensed pharmacies to the end user;

- The inventory based model, where e-pharmacy is the online service of an offline licensed pharmacy.

Non-organized e-pharmacy

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

Illegal international trade through e-pharmacy

In this model, drugs are shipped across the international borders without any prescription and approval from the concerned authorities. This is generally used to order cheaper version of drugs like Viagra [4].

E-pharmacies market is \$18 billion and will grow to \$55 billion by 2020. Industry experts estimate the market to be generating 3,000-4,000 orders on a daily basis [5]. Remarkable growth has been observed during the last five years. Investors are willing to fund the e-pharmacies because they knew this model is potential enough to revolutionize the pharmaceutical industry. This model shows promised and prominent growth in the Indian market when there is condition of recession across the globe.

Types of Medicines

Drugs could be classified by various ways. As per Indian system of Medicines-Ayurvedic drugs, Siddha drugs, Unani drugs, Homoeopathic drugs and allopathic drugs. It can be also classified by level of control-Prescription drugs and over-the-counter drugs. Based on nature of origin-synthetic or natural (Herbal drugs, Phytopharmaceuticals, Biotechnology products). Drugs could be miscellaneously classified-Orphan drugs, Ethical drugs, Generic drugs, Lifestyle drugs, Diagnostics, Neutraceuticals, Personal Care Products, etc. All type of drugs should be brought under the regulatory scanner being sold online than only emphasis on allopathic drugs. The main concerns linked to e-pharmacies in modern medicines are chances of drug abuse, misuse, resistance, addiction due to pain killers, CNS depressants, etc. So, doctors need to check whether the drug being prescribed is as per patients' requirement or not? Special precautions should be taken in case of fixed dose combination.

There is wave of opposition for e-pharmacies in India by offline pharmacists. But unfortunately they are also not practising well their functions. Offline pharmacists don't check prescription properly and retain 1 copy of prescription. Sometimes they deliver and sell medicines without prescription. Even otherwise how much control over prescription in case of offline pharmacies? As per rules one registered pharmacist is required to run pharmacy. But many pharmacies run by incompetent staff and owner. One pharmacist serve at more than one pharmacy store or sell licence to other pharmacy stores for money. All these could be solved in case of e-pharmacies as transparency is there. The problem of doctor's bad handwriting could be solved by e-prescription. Online model could be proved as much more beneficiary to patients. Very expensive products like Biological products used for cancer. If drugs are available online, then commission is less and patient gets benefit. Patients can do comparative evaluation in e-pharmacy to find cheaper drugs. Patients can choose e-pharmacy which gives cheaper drugs.

Before discussing about e-pharmacies regulation, let's have a look at some basic fundamentals which help to understand regulatory mechanism easily.

E-pharmacies

The application of internet to access drugs and diagnostics which begin early in advent of info age has matured into portals or virtual drugs stores popularly known as "internet pharmacy". The advent of internet pharmacy and access of drugs and diagnostics is gaining popularity due to cost effectiveness, high speed delivery to door step of patients [6]. It is also known as Online Pharmacy, Internet Pharmacy, Web Pharmacy or Cyber Pharmacy.

E-prescribing or electronic prescribing is a technology framework that allows physicians and other medical practitioners to write and send prescriptions to a participating pharmacy electronically instead of using handwritten or faxed notes or calling in prescriptions [7].

E-commerce or electronic commerce is the buying and selling of goods and services, or the transmitting of funds or data, over an electronic network, primarily the internet. These business transactions occur either as business-to-business, business-to-consumer, consumer-to-consumer or consumer-to-business. The terms e-commerce and e-business are often used interchangeably. The term e-tail is also sometimes used in reference to transactional processes for online shopping [8]. Interaction between communication systems, data management systems and security, which because of them exchange commercial information in relation to the sale products or services, will be available, so the definition, the main components of electronic commerce are: Communication systems, data management systems and security [9].

Overview of e-pharmacies regulation in India

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

The laws governing Pharmacies in India are derived from Drugs and Cosmetics Act, 1940; Drugs and Cosmetics Rules, 1945; Pharmacy Act, 1948; Indian Medical Act, 1956 and Code of Ethics Regulations, 2002, etc. These all laws were written before the era of computer has been started. So, basically there are no laws related to internet and e-commerce. The Information Technology Act, 2000 governs all activities and issues related to internet. When e-pharmacies regulation is concerned, there is lack of accurately and unambiguously stated laws and clear-cut guidelines to regulate, control and monitor e-pharmacies. For ensuring efficient and legitimate running of e-pharmacies, it is a need of the hour to make hassle free rules for e-pharmacies.

E-pharmacies come under the purview of the Drugs and Cosmetics Act, 1940 and the Information Technology Act, 2000. But current Drugs and Cosmetics Act, 1940 doesn't distinguish between online and offline pharmacies. So amendments are required to Drugs and

Cosmetics Act, 1940 to bring e-pharmacies within the scope of Drugs and Cosmetics Act, 1940.

E-pharmacy players make interpretation of laws and rules as per their convenience for taking advantage for their business when there is uncertainty on the applicability of these laws to this model. It seems that online players do not abide to these regulations and try to bypass them. There is a big misconception of believing that rules applied for offline pharmacies could be easily applied to the online pharmacies too. This may lead to dangerous consequences and may be proved as dangerous trend in future. There are not clear provisions regarding sale of drugs from internet, it seems very difficult to control, monitor and track sell of drugs through e-pharmacies.

Rules and Acts

Drugs and Cosmetics Act, 1940

- Section 18 (c) of the Drugs and Cosmetics Act prohibits manufacture and sale of any drug without a license. As per the Section 18 (c) of Drugs and Cosmetics Act, 1940 to be read with Rule 65, 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 of Drugs and Cosmetics Act has provisions for penalty for manufacture, sale, etc., of drugs in the form of imprisonment and monetary fine. It very clearly states in subsection "b (ii) without a valid licence as required under clause (c) of section 18" [10].
- Section 10 of the Drugs and Cosmetics Act prohibits 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, mislabelled and unsafe.
- The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, have clear guidelines on the sale of Schedule H and Schedule X drugs, which are 'restrictive drugs' and can be sold only on the prescription of a registered medication practitioner. Schedule X drugs include narcotics and psychotropic substances. Chances of drug abuse and addiction are higher with these drugs. They also require meticulous storage and dispensing records. The prescription has to be in duplicate, one copy of which is to be retained by the licensed pharmacist for 2 years.

Drugs and Cosmetics Rules, 1945

- Rule 65 of Drugs and Cosmetics Rules, 1945 stipulates sale of drug under the supervision of a registered pharmacist which also involves signing of the bill and stamping of the prescription by the pharmacist and the doctor. Rule 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 [11].
- Schedule H1 of the Drugs and Cosmetics Rules, 1945 mandates a licensed pharmacist to maintain a separate register for sale of drugs that are specified in Schedule H1 with 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.

Schedule H1 mainly includes potent antibiotics, habit forming painkillers and anti-anxiety drugs that induce sleep.

- 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, in view of the rising incidence of multi-drug resistant bacteria, 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

- Regulation 5.3 of MCI Code of Ethics stipulates that pharmacists and doctors should work together. If e-pharmacies are allowed, then this relationship will be lost.
- Regulation 7.14 of MCI Code of Ethics 2002, also does not allow a registered medical practitioner to disclose the secrets of a patient that he/she may have been learnt in the exercise of his/her profession. Declaration (g) given to doctors at the time of registration states: I will respect the secrets which are confined in me.
- Regulation 6.4 of MCI Code of Ethics prohibits from giving or receiving any rebates or commissions. E-pharmacies may provide rebates and commissions to doctors to provide prescriptions on the basis of online information that has been filled by the patient. This way doctors will be vulnerable to malpractice suits [12].
- Not only doctors, Pharmacists too have a role in ethical dispensing of prescription medicines. Safe and effective use of medicines is a complementary effort and subsequent amendments have some provisions in it that are of relevance to the pharmacists.
- Regulation 1.9 of MCI Code of Medical Ethics Regulations, 2002 requires all doctors to abide by the laws of country that regulate the practice of medicine. Neither the doctor nor the pharmacist should be a party to helping others evade these laws.
- Regulation 7.19 of MCI Code of Medical Ethics Regulations, 2002 does not allow doctors to use touts or agents for procuring patients. So, a pharmacist should not indulge in such activities [13].

Narcotic Drugs and Psychotropic Substances Act, 1985

There is chance of misuse of unmonitored and uncontrolled sale of narcotic drugs listed under the Narcotic Drug and Psychotropic Substances Act, 1985 [14].

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

The Drug and Magic Remedies (Objectionable Advertisement) Act and Rules 1954 mentions a list of ailments for which no advertising is permitted. It also prohibits false or misleading advertisements that end up making wrong claims. Indian population is being increasingly exposed to advertising for prescription drugs despite legal prohibitions [15].

Section 3: Prohibition of Advertisement of Certain Drugs for Treatment of Certain Diseases and Disorders

Section 4: Prohibition of Misleading Advertisements Relating to Drugs [16].

The Pharmacy Act, 1948

According to Subsection 1 of 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 rupees or with both.”

Information Technology Act, 2000

The Information Technology Act 2000 governs some of the legal issues pertaining to online dealings but it is silent on the aspect of e-pharmacy. As a result, illegal e-pharmacies have been increasing in India [17].

There is no legislation specific to data privacy in India as yet. The laws that deal with data protection or privacy in India are Section 43A of the Information Technology Act, 2000 and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011.

There is a proposed Privacy (Protection) Bill, 2013 (“Bill”), which focuses on the protection of personal and sensitive personal data of persons. If passed and enacted, it will override all existing provisions directly or remotely related to privacy under section 3, which provides that “no person shall collect, store, process, disclose or otherwise handle any personal data of another person except in accordance with the provisions of this Act and any rules made thereunder.”

There is ambiguity in the Indian law 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 medicines are physically handed over to the customer [18].

Pharmacy Practise Regulations, 2015

It appears that electronic prescriptions should be valid especially in the light of the Pharmacy Practise Regulations of 2015 declared by Pharmacy Council of India in January 2015. In these regulations, “Prescription” is defined by regulation 2. (j) “Prescription” means a written or electronic direction from a Registered Medical Practitioner or other properly 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 a patient.¹² On basis of existing regulations it appears that a scanned copy of prescription will be perfectly considered as a valid prescription. However, whether such electronic prescriptions can be used to buy medicine from e-pharmacies has been questioned [18].

Good Distribution Services

The drug distribution is currently being regulated at the state level by the health departments for detecting such cases and taking action. FDA officials, however, pinpoint that there is a need for a proper regulatory mechanism for e-pharmacy. This will help, according to the drug regulators, in curbing the currently prevalent illegal practice of

irrational use of drugs through self-medication, more so, as it has become a global phenomenon [19].

Techno- legal requirements

Online pharmacies operating in India are abided to follow certain techno legal requirements of Indian laws which they fail to comply with are as below:

- Privacy
- Data protection
- Encryption
- Cyber law due diligence
- Internet intermediary obligations
- Cloud computing [14]

In absence of knowledge of cyber law due diligence requirements and Internet intermediary liabilities some e-pharmacies stores, websites and individuals breach the provisions of Information Technology Act, 2000.

E-pharmacies operate assuming that offline medico-legal requirements can be used for online requirements, which is actually misbelieving as both have different legalities and array of questions. If they follow it will lead to chain of legal consequences and liabilities. Strict adherence to compliance with Indian laws is required for successful operation of any e-pharmacy.

Government's move towards the issue

Sale of medicines through e-pharmacies has been banned by the Drugs Controller General of India (DCGI) on 30th December, 2015. All the drug control administrations of state governments and union territories are informed to take necessary action against the e-pharmacies selling medicines as pending submission of the report prepared by the expert committee to the Centre. The Drugs Controller General of India (DCGI) emphasized to keep eye on the online sale of medicines to stop breaching rules and regulations. Hence all e-pharmacies operating in India are under the regulatory scanner.

Drugs Consultative Committee had constituted a seven-member subcommittee to study the issue of sale of drugs on the internet and associated risks and concerns. Sub-committee review recommendations to formulate guidelines on the use of information technology in e-pharmacy and authorise its legal validity.

Federation of Indian Chambers of Commerce and Industry (FICCI) has been appointed as nodal agency by the Drugs Controller General of India (DCGI) to consolidate and frame guidelines for online sales of medicines through e-commerce channels in June, 2015. To oppose central government's move to regularise sale of medicines through the internet, All India Organisation of Chemists and Druggists (AIOCD) went on one day's strike in October, 2015.

Indian Medical Association (IMA) wrote a white paper which shows that Indian Medical Association (IMA) strongly oppose e-pharmacies. But objection of white paper could be improved if concerned authorities study it in detail and proper steps will be taken. Traditional pharmacies owners also oppose online model. So, concerned authorities should think about existing models interest and benefit while drafting new rules for online model. It would not hurt business of existing model's players. New model will be such that it integrate and augment the business of existing model rather than harming it. It should open horizon of new opportunities for the existing model. Both

models should be operated, worked and regulated in harmonized and synchronised manner. It would be served as a platform to bridge the gaps of existing offline pharmacies and connect the patients with existing offline pharmacies.

Glimpses of federation of Indian chambers of commerce and industry (ficci) report

Earlier there was shaky and cloudy regulatory regime for e-pharmacy model in absence of well-defined laws. If this persists for long time, unregulated e-pharmacy may be proved as dangerous trend in future. To overcome this situation, regulatory authorities have started to frame laws and guidelines for the same. Sub-committee is ready to release a report of recommendations to regulate e-pharmacies after extensive deliberations with experts, industry persons and stake holders. As per S. Eswara Reddy (Joint Drugs Controller-CDSCO), "This report will mainly accept online pharmacies only with respect to e-prescriptions."

They emphasize on e-prescriptions and recommended a standardised format for these prescriptions. They defined terms related to online medicine retail, including e-prescriptions, online pharmacies, and Over-The-Counter (OTC) drugs. The report has suggested amendments to drug rules and a "negative list" which specifies drugs prohibited to sell to ensure the safe running of online pharmacies. It has suggested integrating AADHAR Number into the overall e-pharmacy framework to make the retail process more transparent.

What should do to improve regulation?

Design a website for checking legality of e-pharmacy.

Make guidelines for consumers for safely accessing e-pharmacies and explains how to buy medicines safely from e-pharmacies.

Specific and clear-cut rules should be made for selling, prescribing, dispensing, and delivering prescription drugs through e-pharmacies.

List of illegal and blacklisted e-pharmacies should be provided to help out consumers and stop them using such fake websites.

Government should make a common logo for legally operating e-pharmacies to distinguish them from illegal one.

Make guidelines for online drugs importation and re-importation for legislators and consumers.

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

As the power of drug regulation is distributed between Central and State government, role of Central government and State government should be well defined.

E-pharmacies' should not use the data 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 encyclopaedic policy to address this planetary public health concern.

Government schemes like National Rural Health Mission can aid in promoting proper procedures to acquire drugs, prevent self-medication through campaigns on television, radios and social media [20].

Watch should be kept on importation of banned drugs through e-pharmacies outside India which don't come under Indian jurisdiction.

Each and every activity and transactions made through e-pharmacies must be under regulatory scanner to prevent it from underworld and smuggling.

E-pharmacy must establish its server in India as if it is outside the boundaries of India, it is difficult to control and regulate it.

To ensure efficient running of e-pharmacies great compliance and strict adherence to laws is required. So, regularly check whether e-pharmacies follow it or not.

Advantages

- Time saving
- Money saving
- 24/7 access possible
- Convenience increased
- Easy accessibility to medicines
- Increased availability of medicines
- Refund possible
- Easy comparison of medicines in terms of cost
- Increased consumer information and information exchange
- Privacy
- Fast distribution
- Increased choice as wider variety of medicines available.
- Convenient for some patients and old age people who can't leave their home.
- Delivery of medicines at desired place at desired time possible

Disadvantages

- Chances of drug resistance
- Chances of drug interaction
- Chances of drug abuse
- Chances of drug misuse
- Chances of misdiagnosis
- Promote self-medication
- Purity and quality of drugs not assured
- Financial privacy issues
- Medical privacy is a major concern
- Electronic health records security and privacy concerns
- Easy availability of illegal substances
- Encourage direct to consumer advertising of prescription drugs which is illegal
- Risks associated with online purchasing of drugs
- Sale of drugs without prescription by some e-pharmacies which lead to harmful consequences
- Online prescription without consulting a doctor
- Doctor's prescription may not be honoured
- Doctor- Pharmacist- Patient: This trio trust evaporates
- Affect business of offline pharmacists
- Access to illiterate and poor population difficult
- Authentication of physicians and pharmacist online is unclear
- Labelling and packaging related issues

- Tough to distinguish between legitimate and illegitimate websites for e-pharmacy
- No control on purchasing drugs by minors from e-pharmacies
- Tough to transport temperature sensitive drugs

Challenges

- Absence of concrete laws for e-pharmacies in India
- To take money before delivery of drugs/medicines is questionable
- Selling or shipment of drugs to minors
- Reach of technology driven model to illiterate people due to lack of knowledge about internet
- Speed of internet
- Prescription related issues
- Legality of electronic signature
- Identity and reliability of legal e-pharmacy
- Protection of consumer rights
- Security and confidentiality of information exchanged
- Security of financial transactions
- Regulatory control over e-pharmacies operating outside the jurisdiction of India
- Unclear laws on inter-state transfer of drugs/medicines.
- Drug importation and re-importation issue

Conclusion

Regulatory authorities finds it difficult to control, monitor and track sell of drugs via internet as there is lack of clear-cut guidelines in India for regulating e-pharmacies. Although the model is promising great opportunity for the business, it have some drawbacks also and number of regulatory hurdles in its way of success. It will promote self-medication, drug abuse, drug addiction, drug resistance. It will also encourage patients to self-report the medical history. E-pharmacy may be proved as dangerous trend in future if not regulated properly. Regulatory authorities and government of India should think about existing pharmacy system and pharmacists while framing the rules for e-pharmacies. Patients' safety and quality of drug should paramount whilst framing rules.

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