



## STATUS OF E-PHARMACIES IN INDIA: A REVIEW

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### Abstract

In the recent years, with the revolutionary advancement in the internet services have fueled the online purchasing practices of various commodities. Online purchase of medicine is also increasing consistently due to introduction of various online pharmacies in India. These online drug stores provide the people with various advantages like home delivery of medicines, huge discounts and lucrative offers. Despite these benefits to the customers the safety concerns related to these E-stores are also on rise. For instance, the medicine quality, irrational dispensing, lack of supervision are the prime concerns arisen from these e-pharmacies. However, this trend with proper regulations is quite popular in western world but it has been recently adopted in India. So, in this review article we have discussed the various factors affecting this practice in India population. Although, E-pharmacies are providing the convenience for the patients to buy medicines but still they are lacking proper regulation for their operations. For this purpose the national guidelines are required to be framed by the regulatory agencies in order to ensure the rational use of drugs.

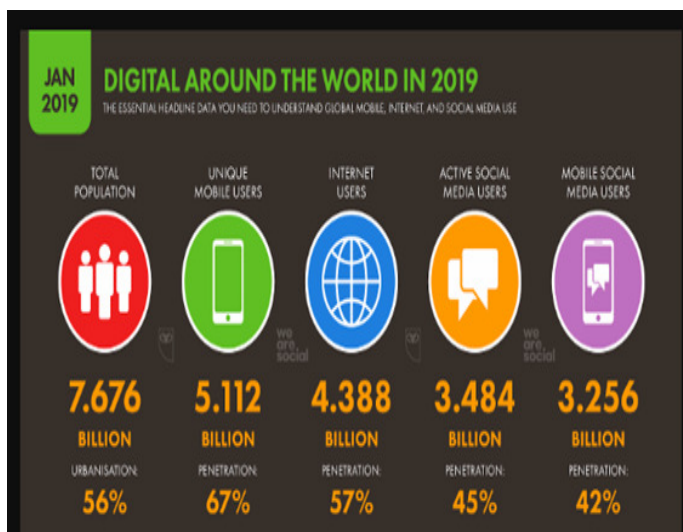
**Keywords** : Online purchase, E-Pharmacy, E-stores, Regulatory agencies.

### Introduction

In India the internet usage has been significantly increased over the period of recent years. It has been estimated from the recent figures that more than half a billion of Indian people are now connected with this service (Patel *et al.*, 2011). In this technological era, there is also a sharp increase in online purchasing of any goods like garments, hardware, furniture, staple, and so forth. Due to this innovation the services of distant to distant shopping outlets now have come to under one roof from where we could easily purchase the item of our need. Hence, in this burgeoning trend of online shopping, how could be our field of pharma remain uninfluenced? Online drug purchase has also become a common practice among the Indian patients because introduction of various online retail stores in India. (Fig. 1)

Emergence of e-pharmacies has significantly transformed the aspects of doctor and patient relationship involving diagnosis, prescription generation & filling. These modern shops have enabled the patients to buy their medicines online after bypassing the safety standards those are provided by the traditional offline method of dispensing & prescription filling. This rapidly growing sector has bombarded the online market with more than 35000 online pharmacies across the globe in a short span of time. Despite offering an ease of medicine buying, this unconstrained expansion of e-pharmacies has also raised a number of safety concerns for the patients because of irrational dispensing without prescription and violation of the regulatory guidelines by these e-sellers of medicines. Due to this advent, most of the pharma companies are expanding their business in this sector. For instance, CVS has become the leading e-pharmacy worldwide and it also acquired many other small online pharmacies (Mackey *et al.*, 2016). E-drug stores market is of \$18 billion and likely to grow up to \$55 billion by 2020. This sector has flourished the most in recent five years (Sahay *et al.*, 2016).

India has become the hub for the various health concerns like rapidly growing & uncontrolled infections, cardiovascular diseases, diabetes, arthritis, various types of malignancies and so on. These issues has put the patients on a long term drug treatment plans so this was the high time for e-drug store model to flourish radically (Patel *et al.*, 2011). However, despite a sharp rise in this trend, there are no regulatory guidelines for this recently adopted practice in Indian market. Medicines are not similar to the other items those can be purchased from anywhere because of their safety as well as efficacy concerns (Priyanka *et al.*, 2016). In India depending upon the nature of stocks & distribution patterns the E-pharmacy models can be broadly classified into following categories (Fig. 2) (Mackey *et al.*, 2016).



**Fig. 1** : Global internet use pattern (Simon, 2019).

**Table 1:** Models of E-Pharmacy (Shailendra *et al.*, 2018, IPA Regulations & Guidelines).

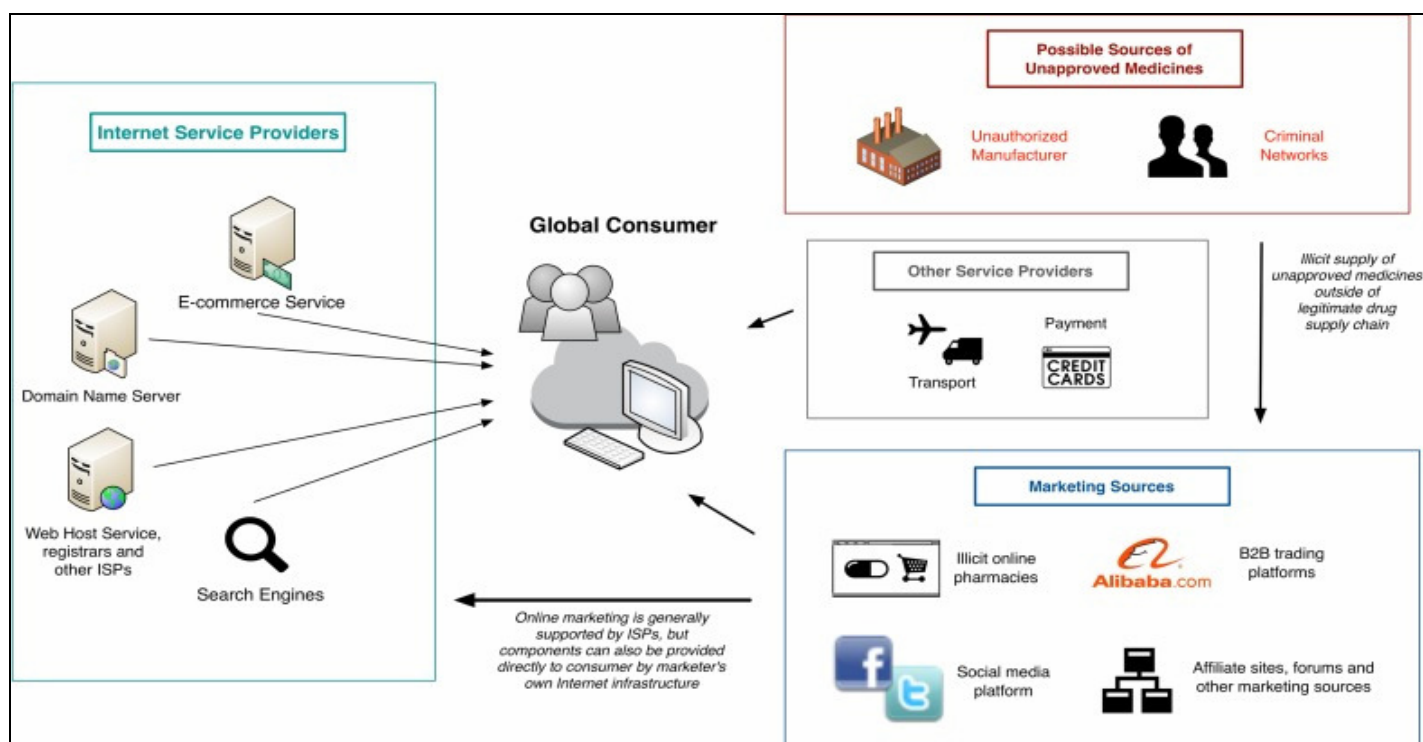
Model	Characteristics
Inventory-based E-pharmacy Model	This is operated on the e-pharmacy platform. Drug inventory & services are self-owned & there is no third party involvement.
Marketplace-based E-pharmacy Model	Stockiest as well as pharmaceutical retailers are on the same platform in this model. Internet connects the consumers which serves a common platform between two.
Generic E-commerce Model	This most advanced model for e-pharmacies has designed completely on the digital platform where all the items are sold under the one roof. This includes the sale as well as distribution of medicines.
Organized E-pharmacy	This is a market place model which service provider for all the nearby pharmacy retailers.
Non Organized E-pharmacy	Medicines sale is not regulated. Sometimes, prescription for the ordered drugs is not validated. Therefore, authenticity & reliability of drugs sold by these types of models is very less.

Mainly the online pharmacies can be classified into three types: first type include the mail order medicine stores and traditional drug stores. In this type the drugs are directly dispensed to the patients after receiving the prescription. In the second type, the medicines are provided to the patients without physical examination by a physician. There is no face to face interaction between patient, doctor or pharmacist. Patients just need to fill an online form for the diagnosis that will be evaluated by the physician for prescription generation. Third type of model includes the drug dispensing without a prescription. Except first the other two types are not licenced form the regulatory authorities therefore they raise the safety concerns (Constance *et al.*, 2004). Apart from this here are some e-pharmacy models being operated (Table 1).

### Pharmacy Regulations & Guidelines in India

In 1945 the drugs & cosmetics rule was formulated for the proper import, production, channelization & sale of drugs & cosmetic products in the country. This act was legislated prior to the internet invention, so it is devoid of the

guidelines for online sale of medicines. Due to emergence of the various issues related to sale of online drugs in India, Drugs Controller General India (DCGI) communicated a circular on December 30, 2015 which explained that the rules & guidelines are the same for conventional as well as the online sale of the drugs. After this the Ministry of Health and Family Welfare published a draft amendment to the D & C act, 1945 on August 28, 2018. This amendment was focused on the laws & eligibility criteria for the sale of online medicines by the various E-pharmacies across the country (Suneeth *et al.*, 2019). Drug regulation in is divided into state & centre governments. Centre government controls the drug import licencing through a central body called Central Drugs Control Organisation (CDSCO). On the other hand state government holds the charge for manufacture, sale & distribution of drugs. Till now there are no devoted e-pharmacy regulatory laws or guidelines in India. These are being operated only under the common IT laws and other pharmacy laws framed for traditional drug stores. Here is the law that governs the overall drug operations across the country (Table 2) (Prashanti *et al.*, 2017).

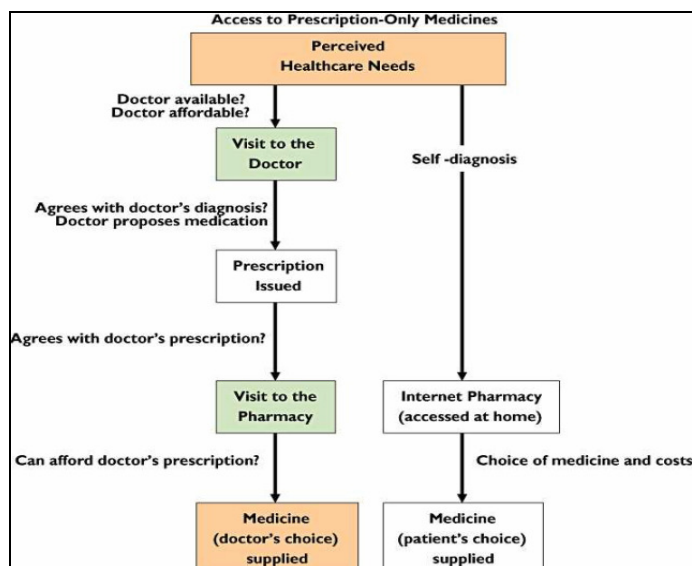
**Fig. 2:** Internet ecosystem explaining the functioning of online pharmacies (Mackey *et al.*, 2016).

**Table 2:** Different laws governing the drug operations in India (Verma *et al.*, 2015).

CDSCO	It provides the general information & implements the drug regulations & requirements in India.
NPPA	National Pharmaceutical Pricing Authority (NPPA), Government of India generally controls the drug prices in India.
Drug & Cosmetic Act, 1940	This act was formulated in 1940 and various drug operations like manufacture, distribution & sale are governed by this act.
Schedule M	This schedule contains the recommended manufacturing requirements like space, materials & equipment standards for drug manufacturing.
Schedule T	This Schedule of the Drug & Cosmetic Act describes GMP specifications for manufacture of alternative medicines like Ayurvedic, Siddha and Unani medicines.
Schedule Y	This is particularly dedicated to requirements for conduct of clinical research studies in India.
GCP guidelines	Together with DCGI & ICMR, the Ministry of Health has formulated these guidelines for maintaining good standards while conduct of clinical trials in the country.
The Pharmacy Act, 1948	This act was formulated in 1948 in order to regulate the pharmacy profession in India.
The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954	This act particularly focuses on the drug advertisements. It prevents the any type of false claim through the advertisements.
Indian Patent Act 1970	For protection of the filled patents in India.
The Narcotic Drugs and Psychotropic Substances Act, 1985	This act governs the operations related with The narcotic drugs and psycho active substances.
Drug Prices Control Order 1995	Controlling prices for consumers.
India joined Paris Cooperation Treaty 1999	The implementation of product patent.
Patent Amendment Act 2005	It contain the for Black Box Application provision
Clinical Trial Registry-India 2007	This law states that a CRO must be registered before start of enrolment process of patients.
Pharmacovigilance Program of India (PvPI) 2010	Assurance of drugs safety for Indian patients.

**E-Pharmacy Model: Pros and Cons**

In this information age the web based drug stores have become a new gateway for the patients to buy their medicines with more convenience & ease. These modern drug stores work on the similar pattern like traditional drug stores. The only difference between the two is the dispensing method of the drugs (Fig. 3). The prime motive behind the introduction of e-Pharmacies was to alleviate the time taken by the patients to visit the doctor and get their prescription signed. They can be assessed by analysing their advantages & disadvantages form various aspects (Joy *et al.*, 2016 and Prashanti *et al.*, 2017).



**Fig 3:** Comparison of dispensing of medicine by internet pharmacy and traditional pharmacy (Anand *et al.*, 2010).

**Advantages:**

- Online purchase is less time consuming
- Discount on drugs which saves the money
- Online pharmacies provide 24 hrs. access
- Offers more convenience
- Provide the refund policy to the customers
- Cost of the medicines can be easily correlated with each other
- It provides the confidentiality to the patient data
- It is quite convenient for geriatricas well as those patients who unable to leave their home.
- Medicines can be delivered at the desired (Davis, 2007, Priyanka *et al.*, 2016).

**Disadvantages**

- In comparison to traditional drug stores more chances of medication opposition
- There are more chances of medication errors
- E-pharmacies are prone to more medication misuse & abuse
- Chances of misdiagnosis
- Online pharmacies are responsible for promoting self-prescription practice
- Quality of medications not guaranteed
- Financial security issues are also associated with online drug stores
- Security of medical records is not guaranteed

- Unlawful substances are easily accessible
- E-pharmacy stores encourage the promotion of physician endorsed drugs which is irrational
- Sometime the drug literature is not provided along with drugs which poses the threat to the safety
- Online dispensing of medicine without counselling by a pharmacist
- Doctor-Pharmacist-Patient: This trio relationship is not developed in this modern pharmacy stores.
- Poor population having no access to internet cannot buy medicines from these web based drug stores.
- Authentication of doctors and pharmacists is not confirmed
- Labelling and bundling related issues
- Minors can easily have access to various harmful drugs which leads to the drug abuse & misuse.
- Medicines can be deteriorated due to transportation & hard climatic conditions (Davis, 2007, Priyanka *et al.*, 2016).

#### Challenges and Difficulties:

- There is no solid law or regulations for e-pharmacies operations in India.
- Less reliability and troublesome in case of advance cash payment for online drug purchase because of transactions issues due to poor internet connections.
- At the cyber pharmacies, it is hard to prevent drug purchase by minors.
- This modern innovative drug model is inaccessible to the reach of uneducated people because they lack the skill required to use internet services.
- Issues arises which involves the Prescription related issues like erroneous prescription; misinterpretation and biased prescribing are common with e-pharmacies.
- Electronic drug operations lack required to be under legal norms which are quite difficult to achieve.
- Quality of the drugs supplied by the cyber pharmacies is also a concern because all the drug operations carried out at the pharmacies are out of your sight.
- It is challenging task to protect shopper rights in web-based drug stores (Chaturvedi *et al.*, 2011, Priyanka *et al.*, 2016).

#### Plan of Action from Government

Due to lack of governing norms for e-pharmacies, they are becoming a loop hole for the pharmaceutical industries. Previously government had banned the e drug sale in India in order to prevent any undesired drug effects. After this, the DGCI appointed Federation of Indian Chambers of Commerce and Industry (FICCI) as a central, governing agency in order to sortall the issues related to e-pharmacy in India.

This move served as an initial step toward designing of regulation framework for e-pharmacies (Verma *et al.*, 2015, Nautiyal *et al.*, 2015). However, a proposed draft plan has formulated by the government to govern the online sale of drugs. Firstly, this draft includes that the e-pharmacy should be located in India if it is providing its services to Indian population. Secondly, no person is entitled to sale, distribute and stock drugs through online stores unless he is registered. They required to be registered with DCGI but state governments hold the right to cancel their registration in case of any malpractices found. Also, e-pharmacies will not sell the drugs comes under category X (Akash *et al.*, 2019). The

motive behind these guidelines is to enhance the safe use of drugs by making their purchase from reliable & authenticated e-stores.

#### Conclusion

Despite the various advantages provided by the e-drug stores, they are more likely to cause the various irrational clinical practices likeself-medication, medicate misuse, chronic drug use and biased prescribing in the clinical sector. These unethical issues will fuel the existence clinical problems like non-compliance, drug resistance, prolong hospitalisation & increase in morbidity&mortality among the patients. So due to rise in popularity of e-pharmacy concept in India, we can expect to see finalisation of proposed norms and some relevant amendments in theexisting laws governing the pharmaceutical operations in India, in the near future.

#### Conflict of Interest

The authors declare that they have no conflict of interests.

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