

## **The Regulation of Online Pharmacies (E-Pharmacy): The need for proper policy with combined efforts of Central and State Regulators**

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While the power of the internet has proved a terrific boon for consumers seeking bargains and otherwise inaccessible products, pharmacy is one online sector where the benefits are mixed. E-pharmacies can be a game changer in delivering affordable medicines to all by increasing competition, driving costs down and helping to deliver drugs in remote areas.

During 2013, in China 45.8% of the population, in USA, 84.2% of the population and in Australia 83% of the population are found to be using internet. As of 2014, India was the third-largest online market with more than 167.2 million internet users, ranked only behind China and the United States and declaring itself as a market not to be ignored on the global stage. India's internet usage has registered 17% growth in first 6 months of 2015 as per IAMAI report. Of the millions of internet users in India, 38 percent of those who use the internet at home or work come from the 25-34 age brackets, a percentage which was higher than any other age group surveyed. Furthermore, men dominated internet usage with 61 percent to women's 39 percent. This statistic is important to start the discussion as you would observe that we must consider the reach it has and the manner it will grow, especially amongst the youngsters of our country, who we cannot ignore and allow them to access a tool, which will undermine their safety and health. If we fail to build the safety net around the consumers prior to sale of medicines on the internet in India, we would undermine the rights of our citizens on safety, efficacy and quality health.

At any given time, globally, there are approximately 50,000 active online drug sellers worldwide, and most of them are illegal online drug sellers [Source: Legit Script, LLC; generally consistent with the findings of WHO and National Association of Boards of Pharmacies (NABP)]. The largest illegal online drug sellers can generate between \$1 million and \$2.5 million in sales each month. [Source: MIT's Technology Review; University of California San Diego (2011)]

Drugs are not just any other commodity that can either be sold or brought like any common merchandise. These are highly potent and their misuse or disuse could have serious consequences for human health, both for the person who consume them and in the longer run for the humanity at large. However, all drugs are not alike. At the same time, online sale of drugs, if properly regulated, has the potential to affect public health positively. There is, therefore, a need to leverage the technological advancements in e-marketing, ease of doing business and benefits of online sale of

medicines to the patients. Keeping the fact that adopting technology should not pose risk to human health and any ill-effect of online sale of medicines could have irreversible effect and hence the approach has to be cautious.

The prerequisite for an online market could be the existence of robust system viz. Central portal / clouds, common Apps for patients, physicians, pharmacies, intermediary etc. Such a system will need to be developed and tested for it to be successful. Eleven percent (158 of 269) of those using the Internet for health care information indicated that they had used the Internet instead of seeing or speaking with their doctors. These respondents had also used the Internet for a variety of medical topics. However, compared to all respondents, a greater percentage indicated using the Internet for second opinions (69% vs 41%) and for information on complementary or alternative medicine (83% vs 41%). The two most common reasons respondents gave for using the Internet instead of their providers were that it was “more convenient to get ‘on-line’ advice” and “less expensive to get advice ‘on-line.’” Of these 29 patients, several respondents wrote in additional reasons for using the Internet instead of their doctor. These included: “wanted to see if my problem warranted seeing my doctor,” “doctor wasn't open to discussion of my suggestions,” “little faith in doctors,” “not sure doctor understands my concerns,” and “want more of an education on topic than doctor has time to give.”

From a consumer's point of view, online pharmacies seem to offer much potential value, although not necessarily on price. For housebound patients, the option of ordering medication from home and having it delivered to the door is obvious. For those living in remote areas, and consumers who are short of time and for whom reaching the pharmacy is difficult, ordering online has obvious advantages. There are also those seeking personal products that prefer anonymity. However, there are scams and spam emails offering medicines at very cheap prices or without the need for prescriptions, that can cause financial and health problems. The reality is that, for an increasing number of people, given population ageing and the rise in chronic illness, online pharmacies will likely become an ever more favoured option.

Wherever possible it is preferable for consumers to obtain their prescription medicines at a traditional pharmacy, particularly when the prescription is for a new drug or for a serious condition. Even for over-the-counter products, it is wise to buy from a pharmacy to hear of any safety advice first-hand. The proliferation of online pharmacy prescription services, and now online medical consultation services, points to another dilemma that seems set to become more prevalent. That is, the growing number of remote health assessments made possible by internet and telehealth where the doctor, pharmacist or other practitioner is not seeing the patient in person. It seems that

circumstances, including time and commercial pressures, are combining to make these virtual consultations ever more frequent.

Some websites may also misuse patients' personal and financial information, infect their computers with viruses, may sell their information to other illicit websites and Internet scams, and charge them for products they never ordered or received and explain that legitimate online pharmacies always require a doctor's prescription, have a pharmacist available who can answer any doubts of patient, are licensed with the concerned drug regulatory in the state where they operate, and have privacy and security policies that are easy to find and understand.

While many internet pharmacies sell prescription drugs only with a prescription, some do not require a pre-written prescription. In some countries, this is because prescriptions are not required. Some customers order drugs from such pharmacies to avoid the cost and inconvenience of visiting a doctor or to obtain medications their doctors were unwilling to prescribe. People living in the United States and other countries where prescription medications are very expensive may turn to online pharmacies to save money. Many of the reputable websites employ their own in-house physicians to review the medication request and write a prescription accordingly. Some websites offer medications without a prescription or a doctor review. This practice has been criticized as potentially dangerous, especially by those who feel that only doctors can reliably assess contraindications, risk / benefit ratios, and the suitability of a medication for a specific individual.

It appears that electronic prescriptions should be valid especially in the light of the Section 4 and Section 5 of IT Act, 2008 read with Pharmacy Practice Regulations of 2015 declared by Pharmacy Council of India in January 2015. In these regulations, "Prescription" is defined by regulation 2 (j) as 'means a written or electronic direction from a Registered Medical Practitioner.....'. 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 online pharmacies has been questioned.

Online pharmacies, especially those that are inventory led and dispense on their own, have the potential to bridge the healthcare gap. Health services management is a growing field, especially with technology adoption. Records management and lab results are all moving to electronic platforms and hospitals need to hire administrators to handle the data. Active leadership roles by physicians, innovative human resource strategies and a strong organizational culture can bridge the talent gap in healthcare.

E-pharmacy is a part of the Digital India campaign because from e-governance to e-learning, the idea of the movement is to transform the country into a digitally-empowered society. Currently, there are about 50 online pharmacy start-ups in India, revolutionizing the way business is done, in an

industry that has been traditionally resistant to change. Leading e-pharmacies are evolving into holistic healthcare hubs that offer access to comprehensive information and medical e-consultation services. India has a dismal ratio of 0.7 doctors and 1.5 nurses per 1,000 people as against the WHO ideal average of 2.5 each of doctors and nurses per 1,000 people which reflects the immense human resource challenge. Therefore the challenge for E-pharmacies becomes tougher when hiring fresh graduates as their growth aspirations are high and it takes twice the effort to train and engage them.

The business model of online pharmacies is making the process of purchasing medicines not only more convenient, economical, organized and transparent. Whether it's insisting on valid doctor's prescription for disbursing certain drugs, or even maintaining documentation of every transaction, digitalization of data is streamlining the distribution system. Over a period of time, the consumer medical database could be useful in planning public health policies,

As per the reports, the government is working on a policy that will ensure a level playing field for e-pharmacies vis-à-vis traditional retailers. The medicines have to be sold or taken against prescriptions especially those mentioned in Schedule H, H1, X and G appended to Drugs and Cosmetics Rules, 1945 and this definitely addresses the issue of self-medication via prescription drugs. Of course, it is necessary to emphasize on last mile delivery and associated complications is an obvious miss as along with it arises factors such as endorsing the prescription, among others.

There are two major issues as far as online pharmacy is concerned i.e. the one with regard to the type of prescription to be honoured and other one with regard to mode of delivery that is whether home delivery in person or by post or by courier. The reality is with the advent of technology consumers and patients today expect convenience and the ability to access medication in privacy and in the manner they feel comfortable rather than driven by laws and regulations. This is evident from the present practices adopted by the consumers to encourage illegal sale through telephone and the internet, even if it is a grey area as per our existing laws. The law enforcers are unable to check the menace of prescription medicines sold in India over the counter, with exceptions in few States. It is no secret that this convenience also comes with the added advantage of boosting the economy and creating thousands of new job opportunities for the unemployed or the under-employed.

Indian Internet Pharmacies are currently practicing the model where they are dispensing based on scanned or image of Prescription and this can be a serious threat to patient safety and rights of consumers. Unauthenticated scanned prescriptions can lead to several risks and safety issues, which are the major challenges before us such as risk of self-medication, risk of drug abuse, risk of black marketing, risk of not taking any responsibility, risk of proper authentication and also risk of image of Indian drug regulators.

**Advantages of Online Pharmacies:** The foremost advantage that online pharmacies provide is lower prices. The lower prices are facilitated through the absence of many operating costs associated with traditional brick and mortar sites, which include building costs, property taxes, and labor and employee training costs. Online pharmacies also provide consumers the ability to comparison shop for drug price and availability.

Additionally, online pharmacies are extremely convenient. For example, elderly consumers who do not drive or who do not live in close proximity to a pharmacy can have medication delivered to their home. Ordering on the web is also time-efficient in that consumers can save their medical and pharmacological profiles online. This feature permits the ease of refilling prescriptions in a matter of minutes, which can be delivered directly to the patient's home or be picked up from a local site.

Using online pharmacies affords consumers with more privacy than the traditional doctor or pharmacy visit. Many websites allow consumers to participate in a virtual consultation where they can input their respective symptoms and conditions and receive a diagnosis with accompanying patient information. Sites such as these are therefore popular because of their high degree of privacy since patients can forego face-to-face examinations or visits to the pharmacist that can be embarrassing and uncomfortable.

Electronic prescription is the futuristic model of drug dispensing. Electronic Rx (E-Rx) is created by the doctor using software and it is electronically signed. It helps in doctor and pharmacy integration, prevents misinterpretation, avoids errors of reading the hand writing of doctors while dispensing. It stalls batch number and wrong expiry mismatch. It helps in easy moving of refills from one pharmacy to another as per customer choice with prescription (Rx) validity clearly known to the new pharmacy,

E-Prescription (e-Rx) gives FDA a much cleaner and better long term records than manual keeping. FDA can demand complete copy of Rx records on its own server if needed. The regulatory authority can view the entire end-to-end movement of Rx from prescribing to dispensing.

Besides, E-Rx setup modernizes overall healthcare establishment in the country and creates environment for only serious players which would also reduce healthcare costs tremendously while at the same time increasing patient safety.

E-prescription is a clear win-win for the regulator, government, patients, doctors, pharmacists and chemist shops. The concept is already in vogue in the US as 'VIPPS' program. The new EU regulation mandates online pharmacies to display the related logo which was enforced from July 1, 2015. It automatically presses for registering with the MHRA (Medicines and Healthcare

Products Regulatory Agency) and displays the same in all the web-pages which confirms that the seller is a registered online pharmacy.

**Disadvantages of Online Pharmacies:** In many respects, the benefits that online pharmacies offer are outweighed by the existing and potential damages they can cause to an individual's health and to society as a whole.

The ability to access prescription drugs without a confirmed face-to-face physician consultation creates a large risk of misdiagnosis which, in turn, results in the wrong prescription being dispensed.

Online pharmacies also provide a relatively effortless way for drug abusers and addicts to acquire prescription drugs. Furthermore, many web sites are breaking consumer protection laws by representing that certified doctors are offering their medical opinions and prescribing drugs when, in reality, a computer database is deciding the appropriate drug or remedy. The biggest risk that online pharmacies pose is to the patient's health.

Fabricated scanned prescription may cause legal implications for the doctor who's Rx has been copied. Scanned Rx including signatures can be easily copied using any editing software and leads to abuse and multiple dispensing,

Further, consumers face an increased health risk when they purchase prescription drugs from online pharmacies based in some other places. Many websites market products which are classified as vitamins, herbs, or dietary supplements as legitimate prescription drugs. In other instances, drugs that can only be purchased with a prescription such as those of antibiotics, habit forming, psychotropic etc., can be purchased without prescription from online pharmacy.

Appearance, dosages and even product names can differ. Another major issue with the increased use of online pharmacies is its simplicity of ordering prescription drugs thereby permitting children and drug abusers to acquire non-prescribed medication easily.

**Types of Online Pharmacies:** Globally, the online pharmacy industry can be categorized into three major classifications. The first and most legitimate type of online pharmacy is the one that operates similarly to a traditional "brick and mortar" pharmacy. These types of online pharmacies most resemble the long existing mail order pharmacies. These pharmacies follow the regulations by employing Registered Pharmacists and they also require the consumer to obtain a prescription that is written by a RMP after an examination or consultation. Subsequently, the consumer has the option of having the physician phone, fax, or mail the respective prescription to the online pharmacy. After the pharmacy has received the prescription, the standard practice is to verify it with the physician and Registered Pharmacist and thereafter it will decide to dispense the prescribed drugs.

The second type of online pharmacy is more appealing to consumers because it offers consumers both physician services and pharmacist services. Initially, the consumer will fill out a medical questionnaire which provides the online doctor with the patient's health profile, current medications, and a medical history. Based on this information the online doctor will determine the patient's medical condition and prescribe a medication accordingly. Following the diagnosis, the patient can purchase the prescribed medication from the website. Some websites may charge for both the consultation and for the medication while others may solely charge for the medication. These types of pharmacies not only prove to be more convenient but also provide a higher degree of privacy appreciated by many consumers.

The final type of online pharmacy is classified as a "rogue" pharmacy. The lawmakers continue the battle to shut down these websites because they pose the highest risk to a patient's health. Lawmakers are extremely concerned with such rogue pharmacies because they essentially allow consumers to purchase prescription drugs without a physician's consultation and a valid prescription. Consumers simply have to log on to the site and fill out an order form requesting their choice of prescription drugs and quantity. These sites are popular for obtaining "lifestyle" drugs such as Viagra, whose prescriptions many consumers are hesitant and embarrassed to solicit from their physicians.

Considering all the above and coming back to our country's main law related to medicines i.e. as per Drugs & Cosmetics Act, 1940 and Rules 1945 and IT Act, 2008 read with Pharmacy Regulations, 2015. It is not possible to get uploaded the required medicines especially prescription drugs on any website directly from patient or customer and then dispense.

Though the existing rules are sufficient to carry out legally and ethically online sales of medicines except that some provisions are to be made in the rules with regard to delivery of medicines / devices which can be covered in the recently announced guidelines by CDSCO on Good Distribution Practices, the major problem faced are that of not marking on the prescription about its dispensing by majority of brick & mortar retailers and physical presence of pharmacists in the retail outlet at the time of sale of medicines especially in big cities which may be due to weak regulation for whatsoever reasons.

However if Govt. considers Online sale of medicines (Online Pharmacies) is that of permitting the customer / patient to upload any medicines on a website of so called market place business people following steps may be considered keeping importance of safety of patient health.

- While finding solutions public awareness is to be considered as an important tool and priority for combating illegal online drug sellers, including by raising awareness with the consumers, healthcare professionals, government officials and regulators, and the Internet

commerce companies that advertise and facilitate online sales of medicines which may turn out as of spurious and NSQ product;

- Though “Online sale” is one of the mode of sales activities it has to be recognized under Drugs & Cosmetics Act, 1940 and rules there under probably by amending the said law suitably;
- Online Pharmacy or it’s concept has to be defined in the Drugs and Cosmetics Act and suitable punishment clauses are to be included for any violations;
- Fixing the validity period for prescription;
- Define “OTC (Over the counter) drugs” whose sale can be done without prescription and without supervision of pharmacist. Once “OTC drugs” is defined list out such drugs [*In the UK, GSL medicines are those that can be sold with reasonable safety without the supervision of a pharmacist, enabling supermarket sales*]. Allow only such OTC drugs to get uploaded by patient / customer on the approved websites for the purpose;
- Define or recognize such “Intermediaries” under D & C Act fixing their role and responsibility and also suitable punishment clauses for any violations by such functionaries. Similarly other terminologies are to be defined like Delivery, Internet commerce companies, Authenticate, Authentication of Product History, Centralized Performance Database, Collaborative Pharmacy Practice, Collaborative Pharmacy Practice Agreement, Digital Signature, Distribute or Distribution, Electronic Signature, Emergency Prescription Drug Order, External Entities, Fine/Civil Penalty, Health Care Entity, Health Information, Mobile Pharmacy, Non-Prescription Drug, Nonresident Pharmacy, Pedigree, Pharmacist, Pharmacist Care, Prescription Drug, Prescription Drug Order, Protected Health Information, Public Health Emergency, Quality Self-Audit, Significant Adverse Drug Reaction, Temporary Pharmacy Facility (*these have been defined under Model Act of NABP of VIPPs of USA which can be viewed at website <http://www.nabp.net/publications/model-act/>*);
- Such websites should have Retail License from respective State Licensing Authority to get identified who is running and then they should get registered with CDSCO for which requisite fees may be fixed and may be made to renew every year [*Since 1 July 2015, any online seller of medicines based in Europe needs to be registered with their respective national regulator and display a common European logo. In the UK, medicine retailers must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA), similarly in USA, VIPP system is existing*];
- At present most of retailers are not following Rule 65 (11) (c) of D & C Rules, 1945 with regard to stamping the prescription for having dispensed which has to be properly mandated and may be considered for severe punishment for its violation;



- At present the ground reality is that in most of bigger cities pharmacists are not found to be present at retail outlet during business hours;
- There is no proper infrastructure i.e. required number drugs inspector (DI) posts in most of the states except few states like Maharashtra, Gujarat, Uttaranchal, AP, TN etc. The ideal situation will be for every 250-300 sales outlets one DI and for every 30-40 Manufacturing units one DI is required;
- Govt. Analyst should be able to give the test and analysis report within 15 days of receiving it except in case of animal test, Microbiology or sterility test where it can be given within 45 days otherwise the purpose will not serve since the sale is not prohibited after drawing drug for test;
- In case of prescription drugs or drugs other than OTC drugs following points may be considered further:
  - Rule 65(10) mentions about the prescription's model i.e. Prescription should be in writing and be signed by the person giving it with his usual signature and be dated by him; whereas Section 4 of IT Act 2008 recognises first portion i.e. "in writing" if it is made available in "Electronic Form"; similarly Section 5 of IT Act 2008 recognises the second portion i.e. "and be signed" if it is "in electronic signature" of prescriber,
  - Prescription has to be recognized only if it is in physical form or online form i.e. electronic form with electronic signature as defined under IT Act, 2008 read with Pharmacy Regulations, 2015,
  - Noting on the Prescription Dispenser's name, address and signature (including Registered Pharmacist's name and signature) has to be made compulsorily on the Prescription and if possible suitable punishment clauses may be incorporated for any violation of this.
- Suitable provision may be made under D & C Act / Rules for **Prescription Audit** by a suitable committee comprising the officers from medical field and drug control enforcement and any others with suitable punishment clauses for any violations. This audit is required for verifying even rationality of prescribing various medicines or diagnosis by the prescriber as it involves lot expenditure to the patient;
- Raise public awareness about the risks of illegal online drug sellers and how to purchase medicines safely:
  - Share consumer education videos,
  - Speak publicly about the issue at widely-attended events,

- Educate key stakeholders about the problem and increasing threat,
  - Share news and engagement media, educating journalists about the growing problem,
  - Run a Public Education Campaign National video contest,
  - Invite Alliance for Safe Online Pharmacies (ASOP) to speak with your media, at public events, or with policymakers,
  - Use search engine advertising to share public education messages and tools that facilitate consumer safety Distribute a newsletter with online pharmacy key facts and developments,
- Sale of medicines through online may be restricted to respective Zones or States by fixing the jurisdiction as is done in some of the developed countries;
  - Other allied Acts and rules like DPCO, DMR, and NDPS etc. are also to be considered while framing any guidelines / suggesting amendment to various relevant Acts and Rules;
  - In order to regulate online pharmacies, a National Portal be created, which will be the nodal platform for transacting and monitoring online sale of drugs. It would be necessary to evolve a mechanism to register service providers which do not directly indulge in stocking, exhibiting, distribution for sale and sale of drugs. Since service providers are offering drugs, directly or indirectly or on behalf of others, they need to be regulated under rules as most of drugs are required to be prescribed by the registered medical practitioner, sold through professionals from the licensed premises and require patient counseling;
  - All e-Pharmacies which plan to sell, offer or exhibit for sale medicines over internet, will need to be registered with Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Rules, 1945. No unregistered entity shall be permitted to undertake online sale of medicines;
  - Online sale of drugs may be permitted only on e-prescriptions or electronically generated and electronically signed in compliance with provisions of IT Act, 2000 and other rules under the said Act. Electronic prescriptions are medical prescriptions generated by electronic mode, gadgets, devices which are verifiable, can be printed and transmitted. Integrity and authenticity of prescription is crucial in any online sale of medicines. There is a possibility of misuse of prescription by patient for its multiple use and also chance of issue of prescription by fake doctors. To address these issues, it is recommended to accept only e-prescriptions or electronically generated and electronically signed prescriptions;
  - Critical areas such as validity and verifiability of prescriptions, delivery of medicines, monopolistic practices, technology platform, policy for honoring prescriptions, database of

medical practitioners, pharmacies, data integrity of patients identity and safety, patient counseling, track and trace, linking with Aadhar card and product recalls are need to be taken care at the time of making rules for online pharmacies;

- Delivery of medicines:
  - Pharmacy shall ensure that the medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved,
  - All the e-pharmacies shall follow the Good Distribution Practices (GDP);
- To create the enabling environment for online sale of medicines, the Drugs and Cosmetics Rules, 1945 need to be amended for effective monitoring and proper enforcement of the Act, in achieving its aims and objectives;

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