## – Review Article –

# Online pharmacy or e-pharmacy: A blessing or a curse? Sudipta Dev\*

\*Former Dy. Drugs Controller, CDSCO and Former Technical Advisor, Indian Pharmacopoeia Commission, India

#### **Abstract**

It has seen tremendous growth in the field of online purchase and affordable mobile data packages. Online Pharmacy is an internet-based vendor that sells medicines to customers on orders through mail, or online pharmacy web portals. There are different margins for each type of product, such as profit margins for generic medicines, OTC (over-the-counter) medicines, branded and prescription products. A prescription for medicines ordered is mandatory (except OTC products) must be verified and certified by the registered pharmacist before delivery with issue of a cash memo in detail about the medicines. Selling medicines to minors, banned drugs for curbing the illegal and clandestine trade of medicines through the websites is on its peak. Awareness about online purchase of medicines through a cautionary approach by the consumer/patient is fundamental to better patient management and avoidance of the ill consequences of self-medication. Present review is on the discussions of an adequate and effective legislation and oversight mechanism in place on the activities in this field to protect the consumers from the potential ill effects.

Keywords: online medicine, e-Pharmacy, illicit online medication, Scheduled medicines, fake medicines

#### Introduction

India has seen tremendous growth in the field of online purchase of FMCG (Fast Moving Consumer Goods) and CPG (Consumer Packaged Goods), electronics, apparels, household appliances and furniture, groceries and even perishable products like fruits & vegetables, fish, dairy and meat products, thanks to the exponential growth of information technology, internet penetration, computers, smart mobile phones apps and affordable mobile data packages. Nowadays, we routinely carry out banking, travel bookings, and pay utility bills and taxes, studies and many other activities through internet, Wi-Fi and mobile phones. Moreover, Covid Pandemic situation over last two years has forced the population globally to work at home, study at home and even purchase at home, sans the hassles of visiting market places and risking infection. Many consumers now prefer e-commerce for its advantages over brick and mortar stores as it offers variety, choice and price comparison of products that best suits them. Needless to say, we are witnessing a profound consumer interest these days to buy medical, healthcare and wellness products through the online mode for such products, which includes the sale of prescription and non-prescription medicines and other medical and healthcare products as well. Fuelling the fire are a number of online retails pharmacies like Netmed, 1mg, Pharmeasy,

Medlife, Apollo Pharmacy and others offering such products at the convenience of your online order and home delivery. Many consumers now prefer such business portals over the neighborhood brick and mortar chemist shops. Online retailers have reportedly captured about 4% market share. Although the concept of online pharmacies and online sale of medicines has been in vogue worldwide for more than two decades, Indian consumers too have begun using these online services in the recent times. While online pharmacies could be a blessing for consumers, these have acquired a not-so-commendable reputation due to various reasons, the primary of which is the unregulated manner of functioning, which may lead to other serious consequences. Thus, a holistic view is to be taken with the prevailing Indian legal and regulatory law, vis-a-vis the issue about the online pharmacies or e-pharmacies, which needs to be assessed for its pros and cons, regulation mechanism and its future effect on the healthcare system as prevailing in India.

> \*Mail id for correspondence sdey1410@gmail.com Received 26 September 2022 Revised 12 October 2022 Accepted 13 October 2022 PHARMAWAVE 2022; 15:27-33.

#### What is Online Pharmacy or E-Pharmacy?

An "Online Pharmacy" or "E-Pharmacy" is an internet-based vendor that sells medicines (includes both legitimate and illegitimate pharmacies), independent internet-only sites, online branches of "brick-and-mortar" pharmacies and sites representing partnership among pharmacies. They operate over the Internet and send packages to customers on orders through mail, or online pharmacy web portals.

#### Motive of Online Pharmacy business as a profit generating module

This kind of business modules promise to be a healthy profit generator for business organizations. It is estimated that Retail Pharmacy and Medical Store business profit margin is approximately 16-22% at branded medicines and 20-50% at generic medicine. Along with margins, they also get benefits of scheme and offers provided by companies. Profit margins of retail medical shops range from 5% to 30%. There are different margins for each type of product, such as profit margins for generic medicines, OTC (over-the-counter) medicines, branded and prescription products. Some discounts are provided to the buyers. It is important to note that this trade still offers one of the highest profit margin among any industry in the market today. Moreover, a chemist shop sells many other products like medical devices, nutraceuticals, baby care products, baby foods, cosmetics, family planning products, personal hygiene products, even Ayurvedic/Unani medicines having varying profit margins. That is why this business module has attracted some very big business houses. In India it started with some small individual pharmacies like, Netmed, Medlife, Pharmeasy, 1mg etc. Now it has been reported that Tata has taken over 1mg, Reliance has taken over Netmed, Amazon is negotiating with Apollo Pharmacy, Pharmeasy and Medlife have joined together. This indicates that big e-commerce houses have found an attractive business and profit opportunity in online or epharmacy.

#### **Present status of relevant Indian Regulation**

In India, at present, there are no specific laws/provisions in force, in respect regulating the sale of drugs over internet. Laws for E-commerce are ill-defined and subject to varied interpretations. Online pharmacies in India shall come under the ambit of various laws such as the Information Technology Act, 2000, the Drug and Cosmetics Act, 1940, Drugs Rules, 1945; The Pharmacy Act, 1948; The Indian Medical Act, 1956, Narcotic Drugs and Psychotropic Substances Act etc. Many of these, including the Drugs and Magic Remedies Act 1958, which regulate drug advertisements, were written when use of computers and internet was not exist. As per the present Indian laws, medicines can be sold only by a registered pharmacy that has a retail license having a physical storage facility and a Publication of Draft E-Pharmacy Rules and its salient registered pharmacist supervising the sale. A prescription for medicines ordered is mandatory, except for sale of over-thecounter (OTC) products. All the medicines must be verified Based on such recommendations, Central Govt. published GSR

India directly to the customers abroad is highly regulated. Furthermore, no provision exists to recognize the prescription written by a doctor who is not registered in India. Schedule H, H1 and X medicines cannot be sold to customer without prescription and it is imperative to maintain customer records including name of the patient, doctor, and address for every such medicine sold by the pharmacy. Selling medicines to minors (under age 18), banned drugs, and selling at a cost higher than the maximum retail price are prohibited.

The situation called for specific provisions for curbing the illegal and clandestine trade of medicines through the websites while permitting legitimate online sale by the pharmacies registered for the purpose and dispensing drugs in compliance to the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under.

#### **Sub-Committee** Report **Drugs** Consultative Committee (DCC)

This Committee, constituted by the Central Drugs Standard Control Organization (CDSCO), Govt. of India advocated that properly regulated online sale of drugs has the potential to positively impact public health by leveraging the technological advancements in e-marketing, ease of doing business, benefiting patients of online sale and minimizing risks. The Committee recommended amendment of Drugs and Cosmetics Rules, 1945 to create a National Portal as a nodal platform for transacting and monitoring online sale of drugs and defining a mechanism to register e-pharmacy. It advocated setting up of robust systems like central portal/clouds, common apps for all stakeholders like patients, physicians, pharmacies, epharmacies, etc. with some geographical supply restrictions for effective administrative control that would also restrict the entry of prohibited and spurious medicines, ensure effective recall of drugs and better pharmacovigilance. Online sale of drugs may be permitted either on e-prescriptions or verified scanned copy of the prescription, in compliance with provisions of IT Act, 2000 and rules. Some other recommendations are exclusion of narcotic and psychotropic drugs, tranquilizers, habit forming drugs and Schedule X drugs which are prone for abuse or misuse, creation of database of medical practitioners and pharmacies, data integrity, patient's identity and safety through Aadhar Link, patient counseling, track and trace, audit trail to follow up any misuse, prevention of data theft and monitoring any Adverse Drugs Reaction (ADR). A mandatory registry of internet pharmacies/websites should be linked to the National portal in order to verify its authenticity. Product advertisements of the Scheduled drugs shall be prohibited on the electronic media. All the provisions proposed for the online sale of drugs will also be applicable to non-prescription drugs also, except for the compliance of requirements of actual prescription before the pharmacist [1-3].

## features

and certified by the registered pharmacist before delivery with 817(E), dated 28 Aug. 2018, titled "Sale of Drugs By Eissue of a cash memo in detail about the medicines. However, Pharmacy" (It was termed by Govt. as E-Pharmacy instead of there is an ambiguity regarding shipping of medicines from one more commonly used Online Pharmacy) to be in the then state to another and whether a pharmacy is allowed to collect existing Drugs and Cosmetics Rules 1945 [1,3]. There are money before delivery of medicines. Exporting medicines from requirements of registration of e-pharmacies and other conditions and requirements for operating the same in the The requirements of registration of e-pharmacies, proposed draft rules. Draft rules for e-pharmacies sought to define the online sale of medicines, what an e-prescription means and what type of licenses online firms would need to get from regulators to operate. It proposed to allow e-pharmacies to get a central license to operate from the country's apex drug regulator CDSCO, which could be used to allow it to operate across the country. It also proposed to define e-pharmacies in a facilities and number of pharmacists to be provided within the way that would allow them to distribute, sell and stock medicines. The proposed regulations prohibit sale of narcotic and psychotropic drugs, tranquilizers, habit forming drugs and Schedule X drugs. So far, the Govt. has not yet finally notified this Rule. At present, it is under consideration by a group of senior Ministers of Govt. of India [4].

#### Comments on the proposed rule

There is no clarity of the mode of business to be adopted by epharmacies or online pharmacies in the present draft rule. The procurement and warehousing storage practices to be adopted by e-pharmacies or online pharmacies have not been clarified. Would they work as a conduit between the patient and a physical chemist as aggregator/ procurer or receive order and supply through their own supply chain? It is not feasible to assess any possible deterioration of the drugs due to faulty storage conditions at online pharmacies or their suppliers. Although they are insisting on the uploading of a scanned copy of the prescription of any online sale of a prescription drug, however, possibilities of manipulation of scanned copies for procuring habit forming or other prescription drugs for misuse cannot be ruled out.

What kind of prescription and form (hard copy or soft copy on smart phone) should be acceptable to both brick and mortar chemists as well as online pharmacy portals? Whether submission of a scanned copy or photo of the hard copy signed prescription stored in a mobile phone or computer may be accepted? Whether the remote medical consultation on the illness and e-prescription generated by a physician without physically examining the patient can be an adequate alternative to a normal prescription or satisfy the medical ethics? What is the misuse and manipulation potential on it, as a few cases of irrational and doubtful online prescriptions have come to the surface already? Else, can we insist on an electronic/digital signature of the prescriber, for its authenticity, which can be accessed and verified by a physical chemist by a printout as well as e-pharmacy portal through some kind of authorization key? However, this would require huge infrastructural set up with respect to requisite software across the prescriber, the chemists and the e-pharmacies. As there are different levels of software awareness and inadequate infrastructure in many cities and villages, private doctors, Govt. and private hospitals, dispensaries and health centres located in far-flung and interior areas of the country, pan India acceptance may be a challenge. However, within a particular system of healthcare network like CGHS Dispensaries, the electronic prescription generated on a computer are stored for reference and accessed by the pharmacists for dispensing using their specific software within organization. How to rope in the private practitioners/hospitals/dispensaries and health centres in an franchise-led hybrid (offline/online) — depending on the way area within this type of uniform prescribing/e-prescribing the supply chain is structured. Start-up companies like system is the challenge.

conditionality to maintain, sale and distribution procedure etc. have been given in the proposed rule. However, there is no clarity as to who could be eligible to apply for registration of epharmacy any person or any licensed chemist/or wholesaler, who has adequate drug storage facility, set up and Regd. Pharmacists? There is no mention of area requirement and premises. An e-pharmacy may work 24 hours and need more than one pharmacist.

Form 21AA, shall be the registration certificate to distribute and sell, stock or exhibit or offer for sale drugs through epharmacy. Thus, stock issue becomes very important as it requires special storage arrangements for different drugs. In case they do not store drugs, the storage word has to be removed from the form.

If the e-pharmacies do not store the drugs, whether they would procure the items from a licensed retail chemist(s) or a wholesaler (s), it appears that they would have to enroll many such chemists having adequate drug storage infrastructure. What would be the criteria for selecting and enrolling such traders?

#### Defining e-Prescription in the proposed rule

So far, prescription has not been defined under the Drugs Rules, 1945 and it requires some deliberations for clarity. Except OTC Medicines, most drugs are prescription drugs which are first prescribed by a qualified Registered Medical Practitioner in hard copy, signed and stamped by him. According to the existing rules, one has to produce such a prescription to a Chemist in order to get the prescribed medicines. The proposed E-Pharmacy Rule defines: "prescription" means an instruction from a Registered Medical Practitioner to a patient, written by hand or any electronic mode duly signed, to dispense a drug and quantity of drug to a patient. However, in the Pharmacy Practice Regulations 2015, the prescription has been defined as follows: "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."Besides, the types and contents of prescriptions have been stipulated in the said Regulation. A prescription should contain Prescriber's office information, Patient information, Date, Rx Symbol, Medication prescribed, Dispensing directions to Pharmacist, Directions for patient, Prescriber's signature and Registration No. etc. There has to be a synergy between both the regulations with respect to the definition and contents of an e-prescription.

How online Pharmacies operate at present?

Unlike the US, where the top three pharmaceutical distributors have a 90 per cent share in the market, India's is a fragmented market with over 8 lakh pharmacies — this gives online pharmacies an opportunity to capture their space without opposing large traditional retailers. Currently, companies in the Indian e-Pharmacy space mainly operate three business models marketplace, inventory-led hybrid (offline/online) and Netmeds, Medlife, Tata1mg, etc. as well as traditional chemists

such as Apollo Pharmacy have been operating e-pharmacies of the purchaser, there are similar and several advantages of ethrough their portals and offering prescription drugs upon uploading the scanned copy of the prescription with doctors' signature and stamp besides, details of the drug and patient. It is not clear how they are procuring drugs, whether they have a licensed warehouse or wholesale/retail license to procure and dispense drugs. Most of them are acting as an aggregator/ facilitator of orders for chemist shops, procuring medicine and supplying them to consumers through the locality-based chemists linked on their supply chains. They also take some amount of service charge as overhead cost.

#### Opposition of E-Pharmacy Rules by the Chemists and Wholesalers' Associations

Considering that online pharmacies or e-pharmacies currently are not regulated, their operations are constantly met with very strong opposition lobbies of brick and mortar chemists. Government of India has received representation from some traders' associations like All India Organization of Chemists & Druggists (AIOCD), Mumbai; Chemists & Druggist Associations of Tamil Nadu and Karnataka; Indian Pharmacist Association, Delhi; Indian Medical Association against online sale of drugs. They requested for stopping the indiscriminate internet drug trade and pressed for suitable laws to protect the people of the country. It was pointed out that Hon'ble Delhi; Mumbai & Chennai High Courts have given the orders to stop illegal online sales in various petitions filed in respective courts. It was alleged that such practices may increase the high chances of entry of spurious/fake medicines in the channel. There are several press releases about the online sales of drugs like MTP kits (used for abortion), habit forming medicines and narcotic (NDPS) drugs on unverified prescriptions are also reported being sold by online players. They also pointed that the print media and electronic media several times released on the reported cases of illegal online sales of medicines and its impact. Unethical practices are adopted by online players like offering huge discount from the pocket by burning their own capital; hence the survival of local small players is in danger. Recently the Hon'ble Gujarat High Court issued notice on a writ petition seeking prohibition of online sale of medicines and scheduled drugs and directed the concerned drug regulatory and other authorities of the Centre and State to file appropriate affidavits dealing with all the contentions made by the Petitioner.

Federation of Gujarat State Chemist and Druggists Association (FGCDA), comprising of more than 27000 chemists will soon launch an app containing details of all medical stores across the state for doorstep delivery at competitive prices. Regular customers shall install the application with pre-filled details and upload prescription, which will be directed to the same nearby pharmacy from where they have been buying the drugs. The customer will be assured about the genuineness of the product as well as better services given their lifestyle. If the first chemist does not have the stock of the particular medicine, the order will go to an alternate nearby chemist who has the

#### Advantages of an Online Pharmacy/E-Pharmacy

Likewise, the convenience and popularity of other e-commerce

pharmacy. We may take a comprehensive look on these issues which are noted below.

#### Convenience:

Online or e-pharmacies are convenient and advantageous to all, more so to the people with disabilities or really severe conditions that restrict movement, and those placed in remote locations with access difficulty. They don't have to leave their homes to visit local pharmacies for medication. They can log in to the internet, look for a legitimate e-pharmacy and then proceed to buy their drugs to be home delivered. They also get unlimited access to professional healthcare givers any time of the day.

Private and Confidential: Any information that you provide online is usually discreet. Online pharmacies guarantee your anonymity. This is particularly helpful to people who find it hard to expose themselves or speak face to face with doctors or pharmacists. It is also helpful to people who feel as if they have very embarrassing or apparent shameful conditions such as erectile dysfunction, skin infections, hemorrhoids, STDs, hair loss, obesity, contraception, gynaecological issues etc. They can order their products online without the shame of feeling judged.

#### Range of choices:

Online pharmacies offer a great variety of options. They usually have larger stocks of drugs than a physical pharmacy store. Therefore, you are almost guaranteed to find easily whatever drug you are looking for. In case you do not find your preferred drug of choice, they provide you with related products for you to choose from. Also, there are so many online pharmacy websites giving you the freedom to use any that you wish to.

#### Time and money saving on commutation:

You can save a lot of hassles, time and money by using epharmacy. People with remote locations, disabilities, senior citizens and those with busy schedules find this advantageous. In just a matter of minutes, you can log in to the internet, head over to an e-pharmacy website and buy any prescription medicine that you want. It takes less time and effort than travelling to your local pharmacy and having to wait in line for your medicine.

#### Affordability:

Online pharmacies having approved warehouses have changed the value chain. There are no middlemen present and the pharmacies usually source the drugs directly from manufacturers. They also have fewer expenses and thus their drugs are considerably cheaper than those in local pharmacies. They also do offer discounted prices for any products purchased in bulk or popularly.

#### Bigger role of online purchasing of medical products during movement restrictions due to Covid Pandemic:

The medical supply chains of distributors, wholesalers and retail chemists were always open during the Covid Pandemic. However, owing to Govt. imposed lockdown enforced to prevent spread of the Pandemic, many people opted for online mode for purchase of daily needs as well as their medical portals, supply various consumer products to the home comfort supplies. Even regular chemists also resorted to the doorstep delivery of medicines of the patients or at the hospital wards, Privacy not Guaranteed: based on a photo/soft copy of the prescription. As a result, the Some of these online e-pharmacy sites are not legitimate. Some importance and role of online pharmacy in providing prompt healthcare for the community during the emergency need has got a tremendous boost.

In a nutshell, online pharmacies offer better pricing than offline stores, increased access, lower transaction and product costs, convenience and greater anonymity for consumers. They offer accessibility to people with limited mobility and people in Late Delivery: remote areas. These provide medialerts (personalized medicine Delivery for some of the drugs can take a few days which can reminder service), discounts, doorstep delivery within a short time, and validation of prescription through licensed pharmacists.

#### Disadvantages of an E-Pharmacv

While online pharmacies could be a boon for consumers, these have acquired a not-so-commendable reputation due to various reasons, the primary of which is the unregulated manner of functioning. Some of them are elaborated here.

#### **Unlicensed Pharmacies:**

There is a probability of dealing with an unlicensed pharmacy. The internet has paved way for so many great inventions but it has also created a loophole for some rogue criminals to exploit. Therefore, before even using an e-pharmacy, make sure it is a legitimate site. You can use pharmacy review sites to find out if the online pharmacy you are using is approved by the regulatory body. A legitimate site usually asks for a doctor's prescription before they can even process your order. Sites that offer to sell you prescription drugs without a doctor's prescription are unlicensed.

#### Risk of Spurious, Sub-standard and Fake Drugs:

There is also a probability of being compelled to buy spurious, sub-standard and fake drugs through online mode as you cannot check before and compare the product with your own eyes as purchasing from a chemist shop. Purchase of medicines from unauthorized online pharmacies or those concealing their physical address increase the risk of being supplied illegal, unregistered, falsified and substandard medical products. Returning the product may not be easy. Fake drugs should not be taken lightly as their effects on the body can be potentially harmful. One should try as much as possible to avoid foreign sites; they often sell contaminated or outdated drugs at very attractive prices.

## Not receiving what is ordered:

This issue is common for online purchase of other consumer packaged goods. Often, we have found the apparel or footwear supplied differed from the size or specification you ordered. Moreover, you do not know if medicine is degraded due to inappropriate storage at supplier site or expired potency but illegally relabelled to have valid shelf life. Returning the product may not be easy.

#### **Hidden Costs:**

Some sites may contain hidden costs such as shipping fees, ordering and processing fees, consultation fees, etc. Be sure to find out what costs are covered by the site and which ones are Drugs Control or Regulatory Authority as soon as possible. self-covered.

of them may ask for personal and financial information which they may end up selling. Some of the sites don't have proper security measures and thus are prone to hackers. There are chances for misuse of personal data and bank card. SPAM mail advertising medicines may contain hidden software which can compromise your computer and privacy.

be unfortunate if you need urgent medication urgently. For urgent medication needs, it is better to visit local health care provider or pharmacy to minimize risks of getting worse.

## **Product quality and integrity issues:**

There may be product quality and integrity issues like no guarantee that the product supplied will be the same original, where the product was manufactured or how it was stored, degradation and loss of effectiveness supplier is authorized or qualified to dispense medical products, it is appropriate for you, or may react with other medicines you are taking [5].

Advice to consumers

In order to curb any fraudulent practices, there should be consumer awareness regarding the need to verify the authenticity of the service provider as well as the product, and to avoid sites that sell drugs without a legal prescription. Some general advices and cautions to the consumers are elaborated

- Do not respond to SPAM email advertising medicines.
- Look for a verification logo or certificate and check it out for authenticity.
- Look for spelling mistakes and poor grammar.

Beware of websites that do not display a physical address or landline or offering prescription only medicines without a prescription or suspiciously low- priced products or"2 for 1" offers.

On receipt of medicines that you have purchased on line consumers should check the following:

Have you received exactly the medicine you ordered and is it the correct dosage? Is the packaging in good condition, clean, with a patient information leaflet and in the language in which it was advertised?

- Does the medicine look, feel and smell as it should?
- If security seals are present are they intact with no sign of tampering?
- Does any Customs declaration or postal label declare the contents as medicines?(for supply from overseas)
- Does the batch number and expiry date on the primary internal packaging match the batch number and expiry date on the secondary (external) packaging?

If you have any doubts concerning a medical product you have purchased, or have suffered an adverse reaction having used a medical product purchased on line you should seek the advice of a qualified healthcare professional and report the incident to your Drugs Control or Regulatory Authority as soon your

#### International scenario for online selling practices

Let us have a look at the online selling practices of medical products adopted by different countries. In many countries it is legal to purchase medicines and medical products from properly authorized on-line pharmacies, with a prescription where necessary. However, it is estimated that globally more than 5 lakhs websites are selling drugs through online pharmacies and there are websites in the dark web selling narcotics and other drugs.

#### The European Union (EU)

It is possible for patients to buy medicines online from online retailers registered with the national competent authorities in the EU Member States, to reduce the risk of buying substandard or falsified medicines. The European Commission has introduced a common logo that appears on the websites of these registered retailers [6].

#### **United States of America**

US FDA permits online pharmacies which domicile with the US and registered with the Drug Enforcement Administration (DEA) to dispense control substances and compliant to the FDA regulations. The pharmacy is licensed by the state board of pharmacy and must have a licensed pharmacist and required to comply with the state specific rules. They cannot dispense medications that are not approved by the FDA.

Overseas online or mail order pharmacies delivering medicines to USA, are regulated by the federal laws of the U.S. There are stiff penalty provisions, to purchase controlled substances from an overseas pharmacy. Any package containing prescription drugs may be seized by U.S. Customs and Border Protection and may be eventually returned to the sender if the addressee does not respond and provide proof like a valid prescription. Online prescriptions are not recognized by FDA. For a prescription to be valid there must be a face-to-face relationship between the patient and the prescriber. Travelers bringing small quantities of controlled substances in or out of the country in person but not by mail are exempted provided the importation of drug or device does not pose an unreasonable risk to the individual or public health. It is also illegal to import nonapproved drugs, except under certain circumstances.

International Clandestine Trade by Fake or Illegal Pharmacies The regulatory agencies like US FDA, UK MHRA, etc. are however, concerned with clandestine trade by the fake or illegal pharmacies and are taking actions against websites that sell potentially dangerous, unapproved prescription drugs to consumers. The Interpol, an International Police Organization for Police Cooperation and Crime Control, has also initiated the Operation PANGEA, for tackling the online sale of counterfeit and illegal medicines in several countries resulting in investigation and seizures, and highlighting the dangers of buying medicines online. Moreover, the issue has become more complicated globally due to Covid Pandemic situation. Criminals cashed in on the huge global demand for drugs meant for treatment of Covid-19, personal protection and

fake or substandard sanitizers were reported in India. Even injecting spurious Covid vaccines have come to light. Interpol has even issued warning about fake offers of online Covid vaccines rather than National Provider. In some countries, clandestine and criminal operators operating through Darknet (Internet content and website not searchable by standard search engines like Google, mostly operated for illegal operations and trafficking of narcotics) sold online medications like treatments Remdisivir, and ineffective Hydroxychloroquine, various purported Covid-19 antidotes and sera, and even offered to sell and ship oxygen ventilators [7,8].

#### The way forward

The Central Government is very keen to bring about the laws/amendments to the Drugs Rules 1945 regarding functioning and regulation on online or e-pharmacies as evident by the draft rules published after a lot of due deliberations with many stakeholders having both pro and opposing views. It is felt that there is no going back on the implementations of epharmacy regulations, having checks and balances so as to protect and safeguard the interests of the patients and general public.

Purchase of a medicinal product is very different from purchasing any consumer goods through online portals where the consumer himself decides what to purchase. However, choice of a medicinal product cannot be decided by the consumer/patient (except for OTC medicines), but is based on the medication prescribed by a physician. This calls for a different dimension and vardstick for adopting an online business module from that of other consumer goods.

We have seen the practices adopted by different countries for online selling of medicines. It is felt that best practices adopted by different countries need to be adopted keeping in view the Indian situation.

Not only The Drugs Rules, amendments may be needed in The Pharmacy Act 1948 [2], Pharmacy Practice Regulations Act 2015, Indian Medical Act 1956, Code of Ethics Regulations 2002 and Drugs and Magic Remedies (Objectionable Advertisements) Act. 1954.

Brick and mortar chemists and their distributor chains are apprehensive and fearful about imminent loss of their livelihood after the advent of the e-pharmacies. Moreover, the news of big business houses like Tatas, Reliance and Amazon entering into the business has upset the chemists much more. These big houses can directly negotiate and obtain bulk discounts from the manufacturers' sans middlemen, thus enabling them to offer the products at a discounted price than the retail chemists who purchase in small quantities through existing supply chain. There is a dire need to alleviate their fear and apprehension before any such rule is notified and put into effect.

The advantages and disadvantages/risk factors of online pharmacy have been elaborated above. They appear to be more convenient than the traditional physical pharmacies. The pros of online pharmacies may tend to outweigh the cons for many people. Both types of business modules can co-exist together for the benefit of consumers, just like other consumer products. hygiene products due to the pandemic. They were quick to However, it is still necessary to verify whether the online target these new customers who were forced to move online for pharmacy site one is using is legitimate or not. It would be an medical needs. Several instances of selling spurious life-saving unfortunate occurrence to lose a loved one for not taking extra Covid-19 drugs like Remdisivir, Faviflu, steroids etc. as well as precaution. A particular logo issued by the Licensing Authority

website to indicate its legitimacy may be useful.

If a bar-coding or any OR code is made mandatory on the medical products sold in the domestic market, we may have an assurance about its authenticity whether it is sold through chemists or online/e-pharmacies.

There is an advantage to restrict online pharmacies to operate within a geographical territory (States/UTs wise) or Zone wise of Central Drugs Standards Control Organization (CDSCO) for better management.

Considering the very different nature and areas of regulatory activities undertaken by CDSCO, the enforcement part of the epharmacies may be entrusted with States/UTs Drugs Regulatory Authorities through suitable amendments for the reason that they carry out licensing and enforcement of sale licenses within their territories and are experienced to handle such matters.

The Registered online or e-pharmacies should be made to declare the details of names, addresses and other details of their existing vendors/suppliers on their websites time to time, in order to keep a vigil on their compliance to the Drugs and Cosmetics Act and Drugs Rules. On demand by the regulatory authority, they shall provide any such details of records of drugs procured, stored, sold, prescriptions etc.

The issue should be deliberated and debated further between all stakeholders such as the Government, legal experts for ecommerce, medical and pharmaceutical professional bodies, healthcare and e-commerce industry and trade representatives, chemist organizations and consumer protection organizations. Regulation in force in different countries may be studied for suitability before adopting some of the provisions in Indian regulations. Some concrete recommendations should be made considering all aspects within an agreed timeline on the proposed e-pharmacy rules for its relevance, implementation, changes or amendments in law and regulation etc [9-13]. Conclusion

There can be no denial that the day has come to adopt the technological advancement and progress of e-commerce in 7. everyday life. Since we are witnessing the tremendous growth of e- commerce for everyday purchases of consumer goods in India; it did not necessarily result in closing down of showrooms and physical stores offering the same products. Both business modules did good business and grew within their socio-economic strata. India has a huge population and heterogeneous socio-economic-geographical set-up with varying living standards. The apprehensions about loss of business the brick and mortar chemists offering medical and 9 healthcare products appears to be more of anxiety and fear about future business scenarios well as vested interest, and may not be based on sound logic. However, there must be an adequate and effective legislation and oversight mechanism in place on the activities in this field to protect the consumers from the potential ill effects.

There are good online pharmacies having well-defined safety and quality benchmarks, patient privacy and security, verifiable physical address and licensed pharmacists on roll. Medical Practitioners should familiarize themselves with a few reputable and legitimate online pharmacies that they may recommend to their patients.

We need to reflect on the today's consumers' interests and inclinations for online pharmacies in order to create a robust

with Registration No. of the e-pharmacy to be displayed on its legal framework, effective supply chain mechanism, keeping away spurious, substandard and falsified products and enhance a symbiotic physician-pharmacist-patient relationship. We also need to prevent any unauthorized and fake prescriptions from clinicians for entering and misusing this channel from illegitimately procuring narcotics, habit-forming drugs and other inappropriate and harmful drugs for non-deserving consumers. These measures, coupled with adequate regulatory framework and effective regulatory monitoring, can help the consumer reap rich benefits of these pharmacies, minimizing the inherent risks involved. Awareness about online purchase of medicines through a cautionary approach by the consumer/patient is fundamental to better patient management and avoidance of the ill consequences of self-medication. The consumers will ultimately decide the future of online or epharmacies with respect to their ability to deliver quality and safe medical and other healthcare products with privacy, convenience and satisfaction.

#### References

- Rules 1945. Drugs https://cdsco.gov.in/opencms/export/sites/CDSCO\_WEB/
  - documents/acts rules/2016DrugsandCosmeticsAct1940Ru les1945.pdf
- Pharmacy Act, https://legislative.gov.in/sites/default/files/A1948-8.pdf
- GSR 817(E), dated 28 Aug. 2018, titled "Sale of Drugs By E-Pharmacy", Minutes of 47<sup>th</sup>, 48<sup>th</sup> and 50<sup>th</sup> DCC, November 2015,
- https://cdsco.gov.in/opencms/opencms/en/Committees/DC
- Desai, C. Online pharmacies: A boon or bane? Indian J Pharmacol. 2016; 48: 615-616.
- Official EU Website of Europesn Medicines Agency, https://www.ema.europa.eu/en
- Interpol Report-Operation Pangea shining a light on pharmaceutical crime,21 November https://www.interpol.int/en/News-and-Events/News/2019/Operation-Pangea-shining-a-light-onpharmaceutical-crime
- Interpol Report- Thousands of fake online pharmacies shut down in Interpol operation, 8 June https://www.occrp.org/en/daily/14611-thousands-of-fakeonline-pharmacies-shut-down-in-interpol-operation
- News item-https://www.livelaw.in, dated 05 July2022.
- 10. Times of India Report dated 05 July, 2022. https://timesofindia.indiatimes.com/archive/year-2022, month-7.cms
- 11. News report 2022, dated July https://www.medicaldialogues.in
- Report-Advantages and disadvantages of E-Pharmacy, https://www.tigahealth.com
- News report of AIDCOC dated 19 July 2022. http://aidcoc.in/trainingacademy.html