



**Report of Sub-Committee constituted by the Drugs
Consultative Committee to examine the issue of
regulating the sale of drugs over internet under the
Drugs and Cosmetics Rules, 1945**

Date:

Table of Contents

Sr. No.	Description	Page No.
1	Introduction	4
	1.1 Deliberations in the 48th DCC meeting regarding sale of drugs over internet	4
	1.2 Terms of reference of the sub-committee	7
2	Background	8
	2.1 Current Drug Regulatory Regime in the country	8
	2.2 Indian Pharmaceutical Industry	10
3	Technology Adoption and Trend of e-commerce	14
	3.1 E-Pharmacy	14
	3.2 Models of e-Pharmacy	15
	3.3 Benefits of e-Pharmacy model	18
	3.4 Technology	19
	3.5 Pharmacy Retail Store	19
4	Summary of the views of the Stakeholders	20

	Industry association perspective	21
	4.1 Industry association perspective	26
	4.2 Professional association perspective	27
	4.3 Trade association perspective	30
	4.4 Regulatory association perspective	31
	4.5 Consumer association perspective	31
	4.6 Other Government agencies perspective	32
	4.7 Other representations and suggestions received	32
	4.8 Summary of suggestions	32
5	Scenario in other countries	38
	5.1 United Kingdom	38
	5.2 USA	44
	5.3 Brazil	46
	5.4 Canada	46
	5.5 China	46
	5.6 Australia	47
6	Recommendations	48

7	Annexure	53
	Annexure: 1 Order constituting the sub-committee	53
	Annexure 2: Representations and suggestions received	54
	Annexure 3: E-prescription & E Pharmacy (Proposed model)	71
	Annexure 4: Draft Rules for amendment of Drugs and Cosmetics Rules, 1945	76

1.0 Introduction

Drugs Consultative Committee (DCC) is a statutory body constituted under Section 7 of the Drugs and Cosmetics Act, 1940 (herein after referred as Act). The main objective of the committee is to secure uniformity throughout the Country in the administration of the Act. In the 48th meeting of the DCC, the issue of clandestine export and sale of medicines via internet by certain web portals in the country in violation of the provisions of the Act was deliberated.

1.1 Deliberations in the 48th DCC meeting regarding sale of drugs over internet:

Instances have come to notice that many of the websites are selling medicines to national and international consumers via internet without valid prescription or sale bills in violations of the provisions of the Drugs and Cosmetics Rules, 1945. Many such portals have come into existence and selling drugs. There is every likelihood that spurious or habit forming drug may be sold online by undisclosed persons as there is no specific check on the modus operandi followed by online websites. It was desired that suitable laws are needed to be framed to regulate the sale of drugs over internet. The issue of distribution of medicines by the intermediaries through internet was deliberated by the Drugs Technical Advisory Board (DTAB) in its 69th meeting held on 22.04.2015 and it gave the following recommendations.

“The members opined that the drugs are different from the normal merchandise and the manufacture and sale of drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. Sale of drugs is a licenced activity and the sale is required to be carried out at the licenced premises, under the supervision of a qualified pharmacist and in compliance to the provisions prescribed under the Drugs and Cosmetics Rules, 1945. Online sales in contravention to the provisions of the said Act and rules should not be permitted.”

The Government of India had received representation from various trade associations, Member of Parliament, and other associations against online sale of drugs in the country and requested for stopping the indiscriminate over the internet drug trade and to frame suitable laws to protect the people of the country.

Government of India had also received representations from various online pharmacy service providers requesting for introduction of specific provisions for online sale of drugs in the country as are available in many developed countries so that legitimate online sale is permitted in the country. It was also stated that Internationally USFDA permits online pharmacies but the pharmacy must be domicile within the US and registered with the Drug Enforcement Administration (DEA) to dispense controlled substances and compliant to the FDA regulations. The pharmacy must comply with the States specific rules also. The list of such pharmacies is available on the State data base. Such regulated

online pharmacies are required to conform to the following provisions.

- Require a valid prescription
- Provides physical address and telephone number in the USA.
- Pharmacy is licensed by the state board of pharmacy in the State where it is operating.
- Has a State licensed pharmacist to answer the questions of the consumers.
- The pharmacy cannot dispense medications that are not approved by the FDA.

The regulatory agencies like USFDA, MHRA etc are however, concerned with clandestine trade by the fake or illegal pharmacies. The USFDA in partnership with other Federal and International agencies are taking actions against websites that sell potentially dangerous, unapproved prescription drugs to US consumers.

In India at present there are no specific laws in respect of regulating the sale of drugs over internet. Specific provisions may be required 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 thereunder. The DCC deliberated the matter for having an integrated policy for regulating the sale of drugs via internet and amendments

required, if any, under the Drugs and Cosmetics Rules, 1945 for the purpose.

The DCC after detailed deliberations felt that it would be difficult to deny the advent of new technologies leading to the development of E-commerce. There has to be an open minded approach to the matter. There is no denying fact that the ease of procurement of drugs through internet will drive the purchasers to look towards such sites irrespective of the fact at whether these are legal or illegal. The issue was required to be examined in detail. The *modus operandi* has however to be within the parameters of the provisions available under the Drugs and Cosmetics Rules, 1945 and the supply chains to be maintained to preserve the quality of the drug till it reaches the consumers. The DCC constituted a sub-committee consisting of the following members to examine the issue of sale of drugs on the internet in the light of practices being followed in the developed countries where such provisions are available for e-pharmacies, while taking care the risks and concerns related to such sales.

1. Shri Harshdeep Kamble, Commissioner , FDA, Maharashtra -
Chairman
2. Shri Raghuram Bhandary, Drugs Controller, Karnataka
3. Shri H. Mahapatra, Drugs Controller, Odisha
4. Shri Atul Kumar Nasa, Assistant Drugs Controller, Delhi

5. Shri Salim A, Veljee, Director, Food & Drugs Admin.-Goa
6. Shri Pankaj Agarwal, State Licensing Authority, Madhya Pradesh
7. Dr. Eswara Reddy, Joint Drugs Controller, CDSCO, HQ

1.2 Terms of reference of the sub-committee:

1. The sub-committee shall examine the issue of sale of drugs via internet i.e. E-pharmacies in the light of practices followed in this regard in the developed countries.
2. The sub-committee shall consider the concerns and risks involved in the sale of drugs over the internet to the consumers.
3. The sub-committee shall consider and recommend changes that will be required under the Drugs and Cosmetics Rules, 1945 to ensure that only legitimate sale of drugs is permitted through internet while taking care the safeguard required to plug its misuse.
4. The sub-committee shall furnish its report in three months.

A copy of the order constituting the sub-committee is at Annexure 1.

2.0 Background

The Indian health care sector, structured in three tiers viz., primary, secondary, and tertiary, is characterized by the presence of several distinct systems of health care delivery such as the government, not-for-profit, charitable organizations, corporate hospitals, and smaller private clinics.

2.1 Current Drug Regulatory Regime in the country

2.1.1 Drugs and Cosmetics Act, 1940 and Rules, 1945

One of the main interventions of the Central Government and State Government, to achieve its Public Health objectives, is to ensure that drugs available to the public are safe, efficacious and conforms to prescribed quality standards. Regulatory control over the quality, safety and efficacy of drugs in the country is exercised through a central legislation called the Drugs and Cosmetics Act, 1940 and the Rules made there under. The quality of the Drugs, Medical Devices and Cosmetics imported, manufactured and sold in the country is regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. The Act provides for the regulatory control over these products imported in to the country by the Central Government while their manufacture, sale and distribution are primarily regulated by the State Drug Control Authorities appointed by the State Governments.

The sale, distribution, offer for sale, etc. are regulated under the

provisions of Drugs and Cosmetic Act, 1945 and Drugs and Cosmetic Rules, 1945. The State Drugs Controllers are the licensing authorities for premises dealing in retail or wholesale or distribution of drugs. The drug is required to be dispensed to the patient through retail sale premises on the prescription of a registered medical practitioner (RMP), for drugs specified under Schedule H, H1 and X, by the registered Pharmacist.

As per the available information, there are more than 8 lakh of pharmacies in India. The supply chain comprises of carrying and forwarding agents, distributors, stockists, wholesalers and retailers.

The sale of Drugs has to be conducted as per the conditions of the licence under the provisions of the Drugs and Cosmetics Rules, 1945 issued for this purpose. The Licence is granted in Form 20 & 21 subject to the compliance of the conditions for grant or renewal, by the applicant. At present the specific provisions pertaining to the sale of drugs over internet have not been introduced, hence currently the sale of drugs are required to be in compliance of the prevailing provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945.

The existing rules are binding on whoever by himself or by any other person on behalf indulge in sell, distribute, stock, exhibit or offer for sale of any drugs. Therefore any drug which is to be sold by brick and mortar outlets or by online thorough web portals have to abide by the existing provisions of the Drugs and Cosmetics Act, 1940 and Rules 1945.

2.1.2 Information Technology Act, 2000 and Rules

The section 81 of the Information Technology Act, 2000 provides that the provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force. Therefore, the sale or offer for sale or exhibit for sale of drugs through electronic media or internet or web portals or mobile application will also be governed by Information Technology Act, 2000.

As per section 3 of IT Act 2000, the authentication of electronic records can be done by affixing digital signature. The methodology thereof has been specified in the said section. As per section 3(a), the electronic signature or electronic authentication technique shall be reliable and as specified in the second schedule of the said Act. The electronic governance have been provided in the section 4, 5, 6, 6(a), 7, 7(a), 8, 9, 10 & 10(a).

The relevant definitions provided under Section 2 of the IT Act, 2000 are reproduced as below:

"data" means a representation of information, knowledge, facts, concepts or instructions which are being prepared or have been prepared in a formalised manner, and is intended to be processed, is being processed or has been processed in a computer system or computer network, and may be in any form (including computer printouts magnetic or optical storage media, punched cards, punched tapes) or stored internally in the memory of the computer;

"digital signature" means authentication of any electronic record by a subscriber by means of an electronic method or procedure in accordance with the provisions of section 3;

"electronic record" means data, record or data generated, image or sound stored, received or sent in an electronic form or micro film or computer generated micro fiche;

"intermediary" with respect to any particular electronic message means any person who on behalf of another person receives, stores or transmits that message or provides any service with respect to that message;

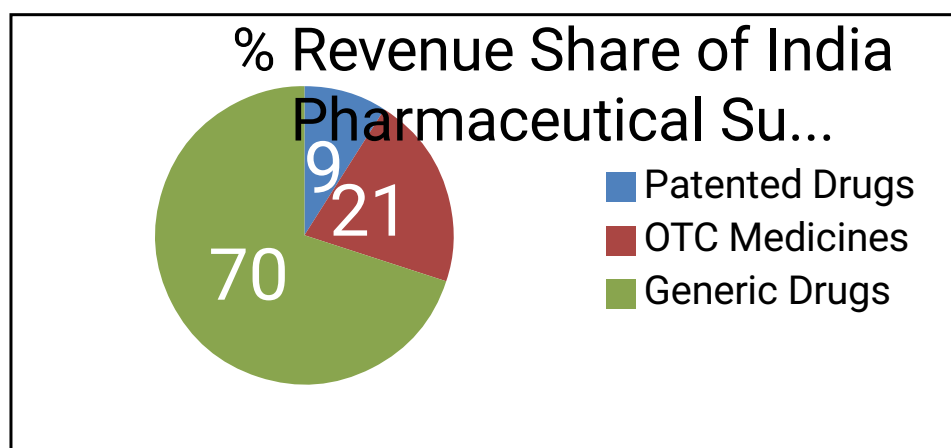
2.2 Indian Pharmaceutical Industry

Indian Pharmaceutical Industry is one of the most vibrant sectors of Indian economy. It has been growing at the rate of 11-12%. It is the 3rd largest in the world by volume and 10th in value. The total size of the Indian Pharmaceutical Industry is about Rs 2 lakh crore out of which exports account for nearly 55%, out of which 29% to USA, 23% to EU, and the rest is the size of the domestic market. Drugs produced in the country are exported to more than 200 countries of the world. The country meets on its own 95% of its domestic demands through indigenous production covering almost all therapeutic categories and imports only a few high technology products. Vaccines and bio-pharma products are exported to about 150 countries. This growth is primarily

driven by high burden of disease, good economic growth leading to higher disposable incomes, improvements in healthcare infrastructure, and improved healthcare financing, to name a few. India is expected to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size by the end of 2020.

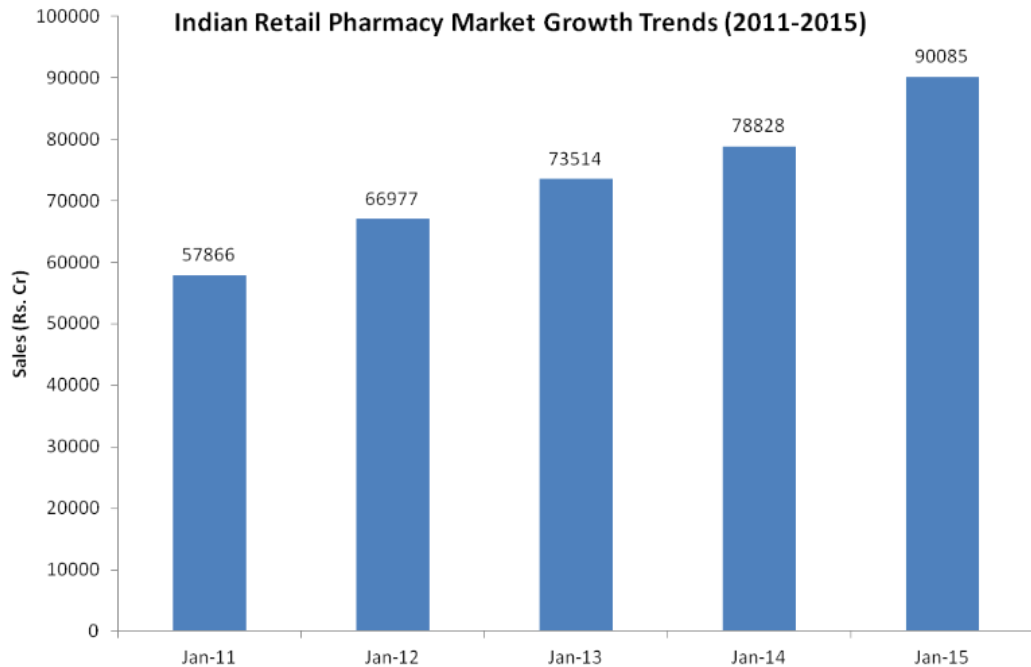
2.2.1 Retail Pharma Markets:

The retail Pharma market in India is currently at a promising stage with its three broad segments of branded generic drugs, non-prescription drugs and patented products. Branded generic drugs form the largest segment of the Indian pharmaceutical sector, with around 70% market share in terms of revenue. Non-prescription medicines and patented drugs constitute 21% and 9%, respectively.



The domestic pharma retail market, valued around INR 98,000 Crore (2015), is primarily driven by the anti-infective market at 15.17%, cardiac drugs market at 12.47%, gastrointestinal drugs market at 11.75%, vitamins / minerals / nutrients market at 8.78%, and anti-diabetic market

at 8.13%.



The pharmacy industry is widely fragmented throughout the country. There are around 8,50,000 licensed drug sale premises existing in the Country.

2.2.2 Challenges of Retail Pharmacy

2.2.2.1 Sustainability of retail pharmacy:

Due to increased competition, rising maintenance costs, increased expenditures on human resources and price control, the sustainability of the retail pharmacy industry has become non-viable. This industry could sustain by adopting technology, which would increase productivity and provide value-added services to consumers.

2.2.2.2 Drug Abuse:

Sale of drugs without prescription, thereby leading to drug abuse.

2.2.2.3 Spurious/adulterated medicines:

Sale of spurious/adulterated medicines increase risk of adverse effects.

2.2.2.4 Documentation / Tracking:

Sale of drugs to the patient without bill may lead to traceability and recall problems

2.2.2.5 Poor Inventory Management:

Not feasible for a single pharmacy to store wide range of products, which forces consumers to visit multiple pharmacies for procuring all the medicines.

The solution for challenges is to adopt latest technologies and models practices in other countries.

3.0 Technology Adoption and Trend of e-commerce

Internet users in India in 2014 were 226.3 million and expected to be 411.1 millions in 2018. Global ecommerce market is estimated at Rs 89 Lakh Crores or 5.9 % of the global retail industry and is expected to reach Rs 168.5 Lakh Crores or 8.8 % global retail industry by 2018. According to some reports, retail market size in India was estimated at Rs 57 Lakh Crores in 2012 and the Indian retail industry is expected to reach Rs 256 Lakh Crores by 2022. India is also expected to become the 3rd largest retail market in the world, after USA and China, by 2022.

Technology development and its adoption for ease of business is continuously changing trend in every field. Similarly adoption of computers, different application software was obvious change in the field of practice in medicine and Pharmaceuticals also. Current trend is e-commerce websites, platforms, aggregators, facilitators, etc. Various companies, etailers have started offering medicines by web based application via websites and mobile applications.

These players considered medicines, pharmaceuticals as fast moving consumer goods (FMCG) or a commodity, the purchase of which can be decided by the consumers directly. It has not been appreciated that the drugs are basically chemicals and have side effects, hence usually required to be taken on prescription of a Registered Medical Practitioner or to be used under medical supervision.

3.1 E-Pharmacy

e-Pharmacies are online platforms where consumers can purchase medicines without having to visit brick-and-mortar pharmacies. This makes the process more convenient for consumers and has resulted in a rising demand for the model across the world. In addition, increasing utilization of e-Prescriptions in the hospitals, globally, it has also led to the growth of this industry.

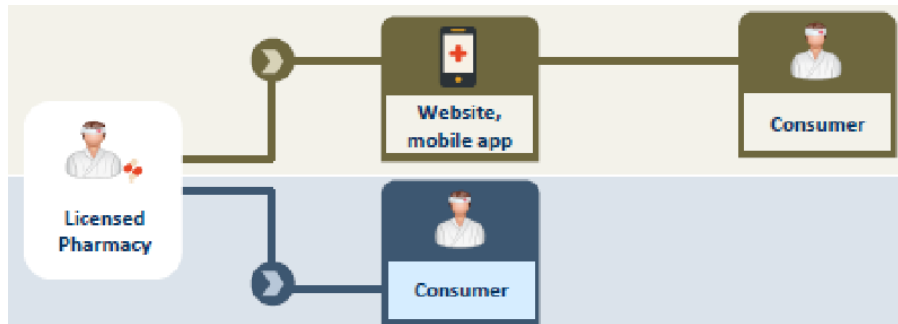
According to Transparency Market Research, the global e-Pharmacy market was around US \$29.3 Billion in 2014 and is estimated to grow at a CAGR of 17.7% to reach a valuation of US \$128 Billion by 2023. The global e-Pharmacy market is currently led by North America and Europe. However, the major opportunity for the global e-Pharmacy market lies in the vast unmet needs of the developing Asia Pacific market. According to a Boston Consulting Group report released in April 2016, the e-Pharmacy market in China was around US \$1.1 Billion in 2014 and is on an upturn.

Currently, e-Pharmacy is at its nascent stage in India, but like other categories, it may grow in the near future. Factors driving the demand include rising number of people with unmet medical needs due to large population and increasing penetration of the Internet in both urban and rural India. It is expected that the e-Pharmacy model could account for 5-15% of the total pharma sales in India, largely by enhancing adherence and access to the medicines for a lot of under-served population.

3.2 Models of e-Pharmacy

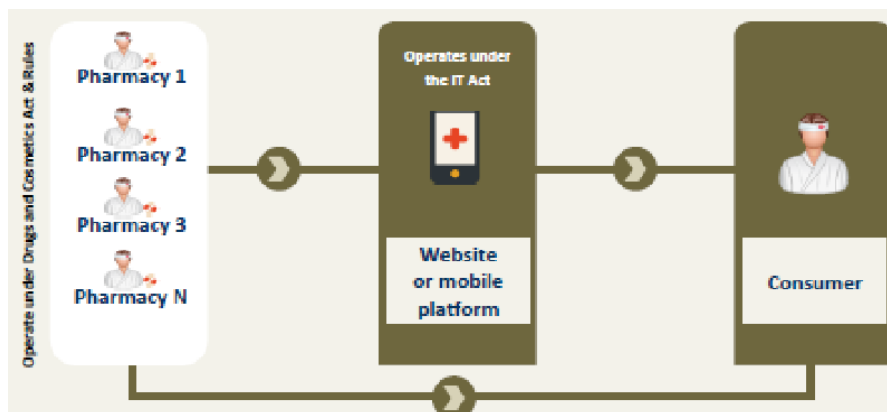
3.2.1 Inventory based: Inventory-based model of e-Commerce

means an activity where the inventory of goods and services is owned by the e-Commerce entity and is sold to customers directly.



3.2.2 Marketplace based: Marketplace-based model of

e-Commerce means providing of an information technology platform by an e-Commerce entity on a digital and electronic network to act as intermediary between a buyer and a seller.



It is has been brought to the notice of the committee that there are different models operating in the market which can be summarized as follows.

1. Offer, exhibit for sale drugs on the websites, mobile application.

Consumers search for the medicine select them, make payment online or cash on delivery and the drugs are delivered at their door steps. Steps involved are;

- a. Display of product on website
- b. Choose the product
- c. Order
- d. Order sent to the medical stores
- e. Medical stores packs the parcel
- f. Sends it by courier
- g. Courier company through delivery boy delivers to the customer
- h. Payment by cash or by card/ net banking

This activity is in contravention of the provisions of Drugs & Cosmetics Act 1940 and Rules thereunder as it is done without a license as required under the said Act.

2. Scanned image or photo copy of prescriptions are uploaded on the mobile application, website. These images are transmitted to the license medical stores, which in turn delivers medicine at door step personally or by courier. The prescriptions are verified or not verified at the time delivery. Steps followed are;

- a. Display of product name on website

- b. Choose the product
- c. Order
- d. Upload the scanned copy of the prescription
- e. Order sent to the medical stores
- f. Medical stores packs the parcel
- g. Sends it by delivery boy
- h. Verifies the prescription, stamps it
- i. Payment by cash or by card/ net banking

This activity is also in contravention of the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder even though the supply of drugs is made through a licenses but the offer for sale of drugs by the mobile application or website is without license. Also the sale on scanned copy of prescription is not in accordance with the provisions of rule 65 of Drugs & Cosmetics Rules 1940. Also it is compliance with the provision of Information Technology Act 2000 and other relevant rules notified under the said IT Act 2000.

3. Doctors prepare prescription on their electronic gadget and transmit it to pharmacy and licensed pharmacy dispenses the medicines against the same. Process in short is;
 - a. Medical Practitioner writes a prescription / eprescription
 - b. Directly transmits it to medical stores with a copy to the customer

- c. Medical stores packs the parcel
- d. Sends it by delivery boy
- e. Verifies the prescription, stamps it
- f. Payment by cash or by card/ net banking

This activity is in contravention of the provisions of Drugs & Cosmetics Act 1940 and Rules there under even though the supply of drugs is made through a licenses but the offer for sale of drugs by the mobile application or website is without license. Also the sale on scanned copy of prescription is not in accordance with the provisions of rule 65 of Drugs & Cosmetics Rules 1940. Also it is compliance with the provision of Information Technology Act 2000 and other relevant rules notified under the said IT Act 2000.

3.3 Benefits of e-Pharmacy model:

- E-Pharmacy improves consumer convenience and access.
- Its most important benefit is for chronic elderly patients living in nuclear families, and patients who are not in a condition to go out to find a pharmacy.
- E-Pharmacy also offers competitive pricing which thereby enables less affluent people to afford medicines.
- There are a lot of technology advancements that are coming up in the form of applications which help in bringing price transparency, create awareness, find an appropriate healthcare service provider,

medicine reminders, and pregnancy alerts to the consumers.

- e-Pharmacy models are well aligned to address key known issues in pharmacy retail for tracking authenticity, traceability of medicine, abuse prevention, addressing consumption of drugs without prescription and value added services for consumer empowerment in healthcare.
- It also increases entrepreneurship.

An e-Pharmacy model is required to have two operating components for dispensing prescription medicines:

3.4 Technology:

- Web-based and/or mobile-based application for consumers to upload the scanned copy of their prescriptions and place requests for medicines.
- Order that is received is verified and checked by a registered pharmacist.
- The registered pharmacist forwards the verified prescriptions to the pharmacy store from where the medicines are dispensed.
- The web or mobile-based platform to be governed under the IT Act 2000 and only act as a platform to facilitate connection between consumer and pharmacy store.

3.5 Pharmacy Retail Store:

- The registered pharmacist at the store verifies the prescriptions

before dispensing.

- The medicines are dispensed from a licensed premise to the patient or patient's relative (Patient's agent).
- An invoice with batch number of the medicines dispensed, expiry date, name and address of the pharmacy with signature of the registered pharmacist/(s) is issued online.
- The pharmacy store to be operated under the oversight of the Drugs and Cosmetics Act & Rules and need to comply with all the requirements of the act, as it does for its normal business.

4.0 Summary of the views of the Stakeholders

In the 1st meeting of the sub-committee, the members discussed and deliberated online sale of medicine with respect to present provisions of the Act and Rules, pros and cons of present (brick and mortar) delivery system and Internet based/mobile/technology based delivery system, legal implications, impact on customers and health care, practices followed in developed countries, best suitable model for India, etc.

The committee made following observations:

- a. Committee will have to be cautious while suggesting any recommendations on this issue as it will impact public health directly and affect health care delivery system.

- b. The export of medicines to the consumers abroad and import of drugs for personal use, through internet, should be out of the purview of the mandate of the committee.
- c. Various models of e-pharmacy followed in India shall be appraised.
- d. Actions to be taken in case of non-compliances found during the online sale of medicines shall be proposed.
- e. The terms such as Internet Pharmacy, Online Pharmacy, E-prescriptions, Electronic business platform, etc., should be defined, after due diligence.
- f. Experts in mobile technology and information technology may be called so as to understand legal provisions and future trends in this field.
- g. All the concerned stakeholders may be invited to present their view to the sub-committee.
- h. The suggestions may also be invited from public to present their views. Permission for online sale of medicines, if permitted the adequate safeguard to restrain the malpractices such as delivery of wrong medicine, fake prescriptions, fake customers etc. should be provide.
- i. The provisions of I.T. Act shall be taken into consideration while deciding any methodology.
- j. Proper tack and trace mechanism up to the consumer level from the manufacturing site should be provided. The existing

mechanism in case of tracking Narcotic Drugs or Psychotropic substances should be studied.

- k. Negative list or list of prohibited items for the purpose of online sale of drugs may be decided.
- l. Need to establish National portal and all transaction may be routed through this URL or a single gateway.
- m. The provisions and facilities such as Digital signatures, e-sign, Digital Locker used for verification, authentication of the users, documents may be examined for this purpose.

4.1 Industry association perspective

4.1.1 Federation of Indian Chambers of Commerce & Industry (FICCI)

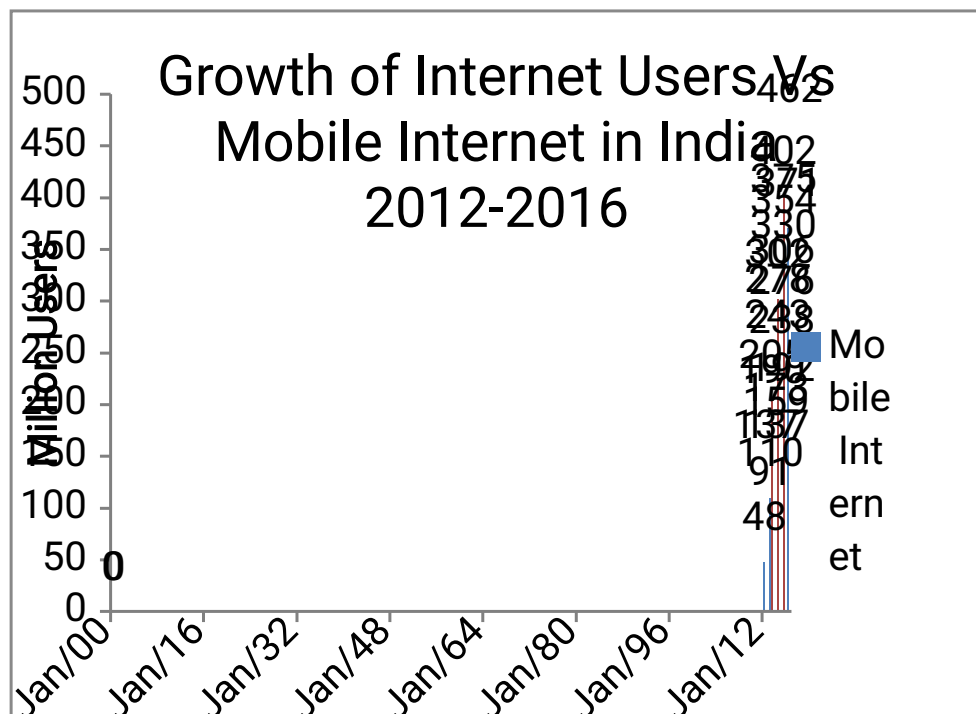
gave a detailed presentation on advantages of this mode of sale and also advocated that the market place and electronic platforms are in line with the provisions of the Information Technology Act, 2000 and Pharmacy Practice Regulation 2015. They also reiterated that the sale of medicines through online mode do not violate prevailing provisions of the Act.

4.1.1.1 Key Drivers of Digital Transformation:

India is one of the fastest growing Internet markets in the world. The number of Internet users in India rose from approximately 300 million in December 2014 to around 402

million by December 2015, making India the third-largest Internet user base in the world. This number is further likely to increase to around 462 million by June 2016, according to the “Internet in India 2015” report released by the IAMAI and IMRB International.

There is an enormous surge in the number of mobile Internet users in India due to increasing adoption of smartphones. The country is estimated to have around 371 million mobile Internet users by June 2016, according to the latest report, “Mobile Internet in India 2016”, released by the IAMAI.

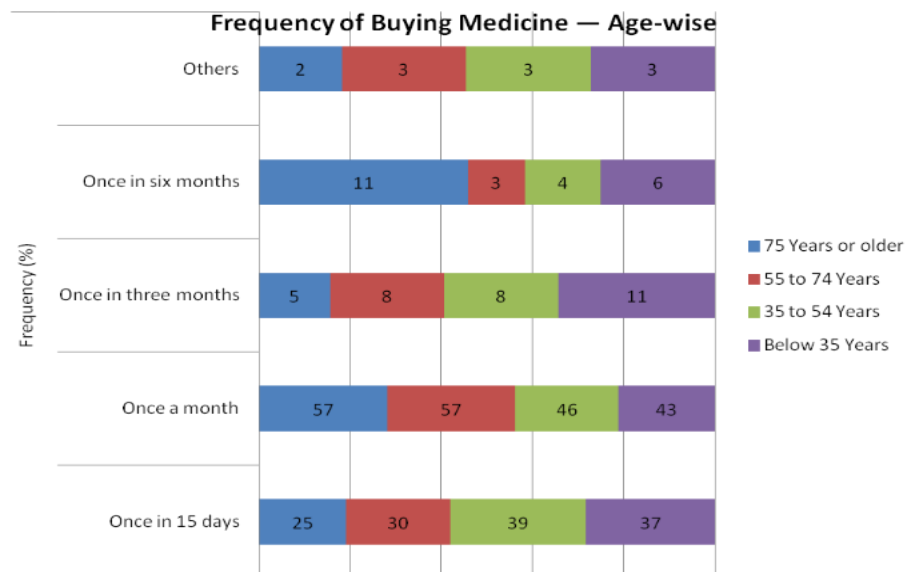
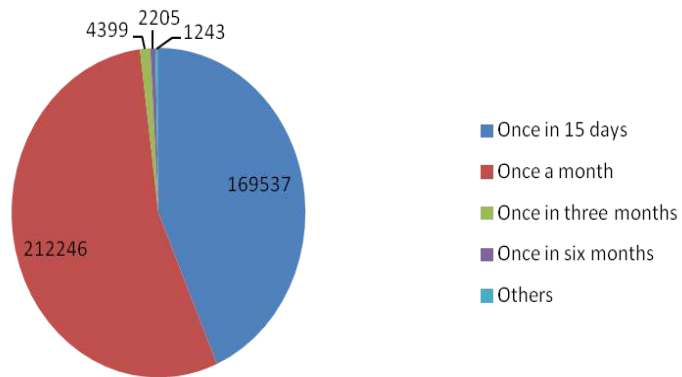


4.1.1.2 Frequency of Buying Medicine

The survey findings revealed that a considerable share of the respondents tend to buy medicine either once in a month (46%) or once in 15 days (37%). Some of the respondents reported that they buy medicines as and when needed or prescribed by their respective doctors. Furthermore, it would be required to understand the effect of the different parameters on the medicine-buying frequency of consumers to get a detailed insight on the same.

As analyzed, the frequency of buying medicines changed significantly for different age groups. It can be observed from the chart that instances of buying medicines once in 15 days decreases with increase in age. On the other hand, instances of buying medicines once in a month increases with increasing age as far as the sample respondents are concerned. In simple words, with increase in age, consumers tend to have more planned purchases of medicines.

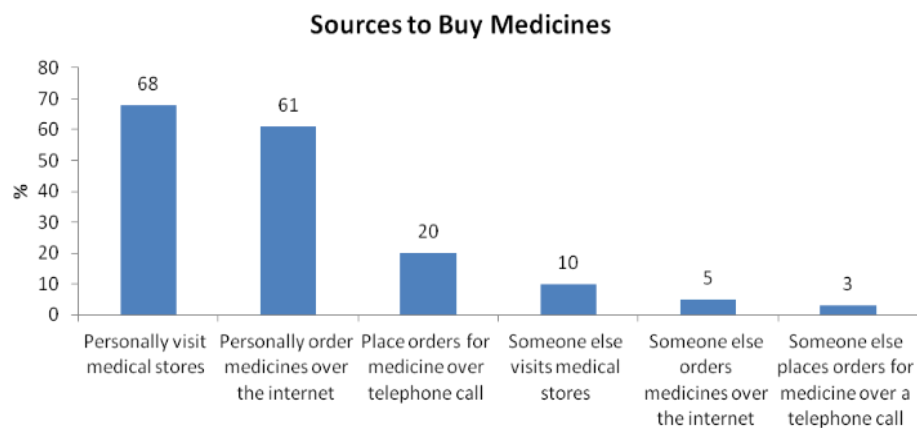
Frequency of Buying Medicine



4.1.1.3 Source of buying medicine:

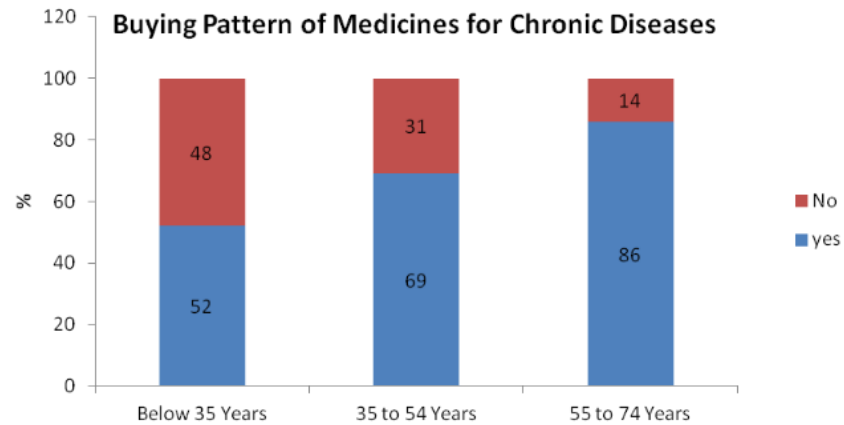
While analyzing the medicine buying behavior of sample consumers, it was observed that majority of them buy medicines on their own. The fact that physical medicine outlets

form the primary source of medicines was reiterated by the findings, which showed that majority (68%) of the surveyed consumers personally visit medical stores, and about 20% of the respondents order medicines over the telephone from such outlets. However, 61% consumers have reported that they resort to online purchase of medicines.



4.1.1.4 Medicines Bought for Chronic Diseases:

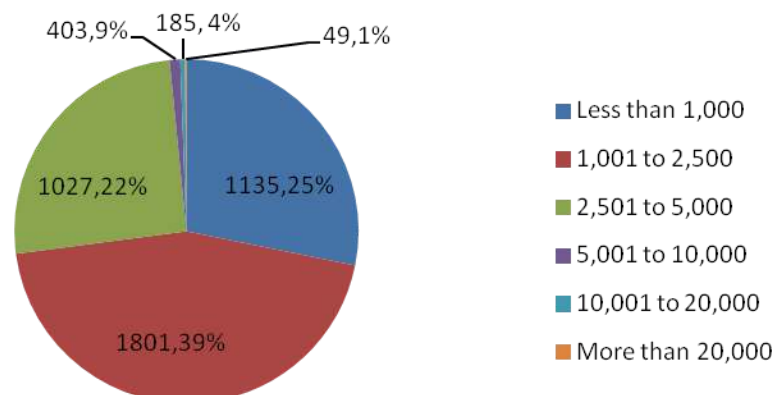
People are expected to be more prone to chronic diseases with age. Evidences of this pattern can be seen in the above exhibit, wherein with increase in age, the frequency of buying medicines for chronic diseases was found to increase among the surveyed consumers. Approximately, 86% of the respondents in the age group of 55-74 years have been buying medicines for chronic diseases.



4.1.1.5 Expenditure on Medicine:

On analyzing the expenditure pattern over medicine by the sample respondents, it was observed that majority (39%) of the surveyed consumers reportedly spent between INR 1,001-2,500 in a month on medicines, followed by 25% and 22% spending less than INR 1,000 and INR 2,501-5,000, respectively. Altogether, the monthly expenditure incurred over medicine by 86% of the respondent consumers is up to INR 5,000.

Monthly Expenditure Incurred Over Medicine (in INR and %)



4.1.2 Indian Pharmaceutical Alliance – IPA stated that the changes in the present statute shall be made to ensure that online pharmacy players shall deliver against every order and should not be selective. It should be mandatory to cater and deliver to the remote and rural areas of the country. They said that this mode of sale will increase the accessibility of the medicines in general.

4.1.3 Indian Drug Manufacturers Association – IDMA, said that this will not affect their members and on contrary it will reduce the prevailing monopolistic practices in the trade of medicines.

4.1.4 Organization of Pharmaceutical Producers of India – OPPI expressed that although online pharmacy have some advantages such as medicines being available at reduced cost, reduced inventory but cautioned on entry of counterfeit and spurious medicines. The system should ensure the traceability of the medicines. They also said due to present hurdles of trade organizations the new launch of products will be faster and less expensive to the members of OPPI. They also expressed fear of substitution, storage conditions, traceability issues.

4.1.5 Confederation of Indian Industry – CII expressed doubts on adherence of the storage conditions by the online pharmacy players and hence suggested that the special products such as vaccines, injectables and other products requiring

special storage conditions should be excluded and prohibited from online sale. Sale of medicines by internet or online pharmacies should be monitored and prescription pads with unique IDs should be supplied by the regulators.

4.2 Professional association perspective

4.2.1 Indian Medical Association – IMA, thrown light on growing instances of self medication and expressed their concern that the sale of medicines over internet will further contribute this menace. They said that IMA is not in favor of encouraging this mode of making availability of medicines. The prescriptions on the electronic platforms should be verifiable.

4.2.2 Pharmacy Council of India brought to the notice of the sub-committee that the Pharmacy Practice Regulations have been made by Pharmacy Council of India, with approval of the Central Government, as powers conferred under Section 10 and 18 of the Pharmacy Act, 1948. While dispensing the medicines whether online or offline, the provisions under these regulations have to be considered. The regulations provide for

- Practice of Pharmacy, Dispensing, Compounding, Distributing, Patient Counseling, etc. These terms have been defined elaborately and Pharmacist is supposed to practice accordingly.
- Prescription has been defined and recognizes written or

electronic forms of it.

- Duties towards the patients have been provided.
- It said that while making recommendations the provisions of these regulations may be considered.

4.2.3 **Indian Pharmaceutical Association** stated that India doesn't have a burning need of online pharmacy as of now. In order to have professional intervention in dealing of drugs, it is always advisable to have brick and mortar pharmacies. Sale of medicines cannot be compared with the general stationery or FMCG commodity, purchase of which cannot be decided by the consumer or patient but has to have intervention of medical practitioner and / or a Pharmacist. It cautioned about the misuse of such sale of medicines through internet and suggested that it should not be allowed. It expressed concern that present government machinery is inadequate to tackle the abuse and consequences. It presented views over the actual need of online pharmacy in India as follows:

- The demand for online pharmacy is more from the business point of view as compared to the need for consumers.
- The existing physical pharmacies are not well regulated & start of online pharmacies can lead to higher violation of Drug & cosmetic Act 1940 & Rules 1945.

4.3 Trade association perspective

4.3.1 **All India organization of Chemist and Druggist Association** gave detailed power point and written presentation before Sub-Committee and out rightly opposed the concept of online sale of medicine. The concerns raised by the associations on online sale of medicines are as below:

- Very few developed countries have adopted the concept of online sale of medicine that too after proper infrastructure, system and adequate law in place.
- Major countries such as France, Japan, Russia, Korea, Italy, China etc. do not permit on line sale of medicines.
- Quoted some incidences of mis-use of sale of drug through online website.
- Some of the websites are offering drugs through internet fraudulently and without verifying the credentials and authenticity of customers, prescriber and prescription.
- Young generation will be spoiled as it can be easily misused and manipulated.
- India has inadequate regulatory machinery and infrastructure to monitor the hazards of online sale of drugs.
- There will be steep rise in spurious and adulterated drugs which may also lead to serious and adverse drugs reaction.
- The storage conditions for the drug may not be followed during the delivery which may lead to deterioration of drugs.

- Online pharmacy will create monopoly which will lead to non-viability of present physical pharmacies, especially in rural areas which will create unavailability of drugs. The monopoly will create unemployment.

4.3.2 Indian Internet Pharmacy Association (IIPA) presented their views regarding their current working model. It gave a detailed presentation on advantages of online mode of sale and also advocated that the market place and electronic platforms are in line with the provisions of the Information Technology Act, 2000 and Pharmacy Practice Regulation 2015. They also reiterated that the sale of medicines does not violate prevailing provisions of the Act. The comments of IIPA on online pharmacy are:

- It is a value addition for all stake holders. Consumers are benefited with ease of access, more convenient method of purchase with availability of discounts. The regulator also is at ease as all transactions are fully tracked and tax can be verified. The pharmacists at pharmacy store are also at benefit as he has access to additional customer base.
- Pharmacy Practice Regulation, 2015, along with the definition of electronic records as per section 2 (t) of the IT Act 2002 and provisions of sections 65 (B) of the Evidence Act, 1872, (admissibility of electronic records) should suffice and not require any specific amendments, just need to be included in Drug and Cosmetic Rules.

- Currently the pharmacies under IIPA are working under framework of regulatory as the web platform is covered by the IT Act, 2000 under the concept of intermediaries and the Pharmacy retail operations are covered under the Drugs and Cosmetics Act.
- Every transaction is recorded and tracked. It can be easily audited and verified that no medicine is being sold without prescription. Dispensation is also done by registered pharmacist and from a licensed pharmacy premises.
- E-pharmacies that are part of IIPA do not sell Schedule X drugs.
- Such model is best studied to enable drug recalls. Such models have records of every transaction with patients' name, address, telephone number and email. They also record batch number, expiry with proper invoice and by a licensed pharmacy.
- There is no compromise on storage conditions as same traditional supply chains are being used for delivery to the last mile.
- Besides giving additional business to pharmacies and distributors, E pharmacies also employ pharmacists directly to work on value added work where they get trained on latest concepts.
- It is recommended that a registry of pharmacies should be made available. A specific logo for identifying the authenticity of online pharmacy which can be displayed on every page of the internet portal and the mobile application.
- It also recommended that online portal should disclose complete transaction details to the licensing authority on request. They

should notify the licensing authority whenever vendor pharmacy is enrolled with the portal. Portal should also disclose the name of dispensing pharmacy prior to dispatch of medicines.

- It is further recommend that the portal must allow users to interact with pharmacists for routine clarification & counseling. Portal should maintain confidentiality of patients record in compliance with provisions of the IT Act read with the RSP rules.

4.4 Regulatory association perspective

All India Drug Control Officer's Confederation – AIDCOC, presented their views as regards to the impact on enforcement and various provisions of different Acts related to the sale of drugs over internet. While elaborating the modus operandi adopted by different players, they urged that this activity should be covered under the Drugs and Cosmetics Act, 1940 and rules 1945 with specific amendments to it.

4.5 Consumer association perspective

4.5.1 Consumer Online Foundation, New Delhi submitted the copy of written representation. While accepting the online pharmacy that the technology advancements are inevitable, but it has to be taken with caution and with certain safeguards. Before recognizing and legalizing online pharmacies following points shall be taken into consideration

- a. Proper education, training, awareness between the stakeholders.
- b. Consumer should be taken in confidence by his education
- c. Measures to avoid abuse.
- d. Use of technology for track and trace shall be made mandatory for the service providers.
- e. Monopolistic practices, unreasonable profiteering, cartelization and discounting shall be monitored.
- f. Shall promote generic medicines.
- g. Shall have powers to block websites in case of default and also should have methodology to block illegal websites.
- h. Scanned prescriptions should not be allowed and the digitally signed or e-signed prescriptions should be verified by the system itself.
- i. Heavy financial penalties should be provided for the defaulters.
- j. All the stakeholders shall be regulated.

4.6 Other Government agencies perspective

4.6.1 National Informatics Centre – NIC, said that the technical and software support of any kind is possible from NIC.

4.6.2 Commissioner of Customs, Mumbai cautioned about misuse of online sale of medicines by narcotic drug mafia. He also said that verification of prescriptions, restricting the fake patients, mis-declared drugs will be a bigger challenge.

4.6.3 State Informatics Officer, National Informatics Centre, Mumbai stated that it is necessary to bring all the stakeholders on one platform which is monitored by Government. He advised that the UID authentication may be used if at all online pharmacy is to be regulated. He expressed concerns over cyber security issues and assurance of actual goods delivery. NIC is competent enough to help if any technology support is needed.

4.7 Other representations and suggestions received

Overall, many responses were received through letters and emails from various individuals, associations, trade bodies, companies from various parts of India. The list of all senders of these responses is attached as Annexure 2.

The respondents have expressed their views in the form of supporting the regulations regarding online pharmacies or in the form a rejecting the proposal for online pharmacies. Some of the respondents have also commented the benefits and concerns regarding sale of drugs via internet while some have suggested amendments in laws to regulate

such practice of sale of drugs.

The details of these responses are summarized further in this report.

4.8 Summary of suggestions

Representations were received from various individuals, associations, trade organizations & companies etc. Some of them supported the sale of drugs through internet while many objected the concept. Some also suggested various amendments to be made in the existing law to help regularize the sale of drugs without harming public health safety.

Respondents like individuals patients expressed their support with the example of ease of access to medicines. Most of the Chemist & Druggist organizations from various parts of India completely oppose the online pharmacies owing to risks involved with sale of controlled medications. Some organizations like Indian Internet Pharmacy Association, FICCI supported the concept if regulated well. They provided benefits of regulated system and also required amendments in the existing law.

The comments received from around 360 respondents in the form of benefits and risks of sale of drugs through internet are summarized below.

As suggested by the stakeholders in support of e-pharmacy, major benefits of online sale of drugs are:

1. Pharmacovigilance: As the supply of medicines to all patient can be tracked and traced, the safety of the drug in the real world setting can be effectively monitored with appropriate follow up measures.
2. Consumer convenience: The consumers are able to order medicines in a convenient manner, from their mobile or computer. This significantly helps patient who are already sick and not in a condition to go out to find a pharmacy.
3. Consumer access: Online pharmacies can aggregate supplies, making otherwise hard to find medicines available to consumers across the country.
4. Consumer education: Online pharmacies have the technology infrastructure to provide value added information to consumers, such as drug interactions, side effects, medicine reminders etc.
5. Consumer savings: The ability to pass on savings to consumers due to lack of front end retail costs as well as inventory. Typically online pharmacies are in position to offer savings in the range of 10% - 15%. Some patients may also benefit from savings in travel costs.
6. Data Records: All medicine purchases can be tracked – effectively reducing the problem of drug abuse and self – medication. Entire audit trail including the name and address of the patient/ physician/ pharmacy are digitally stored and can be tracked easily.
7. Medicine authenticity: With full tracking systems and solid

technology backend, spurious/adulterated medicines can be traced back to the channel/ manufacturer/ supplier thereby making the market a lot more transparent and ensuring authenticity.

8. Medicine adherence: One of the main challenges in medicine adherence is patients running out of medicines. Online pharmacies can have automated reminder systems and methods to call customers to remind them to refill or can even setup an auto refill.
9. Transaction records: Organized online players have systematic records for all transactions.
10. Data analytics: Online pharmacies store and can analyze large amounts of data on consumers across the nation which can be very useful for planning public health policies.
11. Industry sustainability: An online pharmacy model enables existing physical pharmacies to start online operations and serve a broader set of customers, or a network of pharmacies integrating to one platform and accessing a broader customer base while also ensuring that the inventory is consolidated. This would reduce working capital requirements, remove wastage from system and increase margins, making the pharmacy model sustainable and higher value add.
12. Prediction of misuse of drugs: The customer order frequency is recorded along with the name of prescriber. This helps predict potential misuse of drugs.

13. Better employment opportunities for pharmacists: Online pharmacies can bring high quality pharmacists at more attractive pay to interact with the users at the time of sale due to economies of scale.

Apart from these benefits, there are also some alarming risks involved with sale of drugs through internet. They are:

1. Fake and illegal pharmacies: Monitoring of fake and illegal pharmacies could be a challenge and cyber experts need to be employed to tackle such cases.
2. Scanned copy of prescription: The scanned copy of prescription is not considered authentic under D & C Act as well as under IT Act. One prescription can be uploaded two different e-pharmacy sites leading to drug abuse.
3. Multiplicity of dispensing of pharmacies: The prescription once uploaded has no system of stamping as required by D & C Act. Thus, it can lead to multiple dispensing of one prescription as the buyer can upload the same prescription on various portals.
4. Increase of drug addicts: Multiple dispensing of prescription can lead to misuse of drugs and increase the number of drug addicts especially in the youth population.
5. Increase in self-medication: Online sales would promote self-medication and give rise to dangers associated with it, like over or under medication. If the drug is an antibiotic or anti-TB drug, there

are dangers of generating drug resistance due to self medication.

6. Lack of control over sale of medicines: Sale of psychotropic drugs, which can be easily abused, would increase. So can be the case with diet pills, libido enhancers, and cosmetic fillers and so on. Minors or children can even order controlled medications and can consume without supervision of parent/ guardian.
7. Unhealthy competition: Online pharmacies offer discounts which may attract more customers. This might lead to an unhealthy competition between online pharmacies and physical pharmacies resulting into sale of substandard or spurious drugs.
8. Delivery of drugs: The drugs are supposed to be handed over to an adult. Allowing online pharmacy with home delivery may lead to delivery of medicines in the hands of a minor.
9. Mishandling during transport: The storage conditions during the transport of medicines are not monitored. The sensitive drugs may degrade and result into loss of potency.
10. Interstate transport: There are no specific rules for shipment of medicines from one state to another.
11. Confidentiality of data: Intentionally or unintentionally some may leak the patient information. Personal records of a regular buyer could be leaked and information regarding drugs bought by the customer could be leaked. This would lead to violation of right to privacy of person. This could also lead to risk of receiving

repeated emails and phone calls falsely promoting follow up medications.

12. Insufficient drug inspectors: There are insufficient numbers of drug inspectors in drug control department and it will not be easy to monitor each and every online pharmacy.

13. Requirement of IT Professionals: Expertise of IT professionals will be needed resulting in further burdening the drug control department with high salaries of IT professionals.

On the whole, 368 representations have been received from various stakeholders. Bulk of them is from the Chemists and their associations and individuals.

The category wise representations are tabulated below:

Categories	Total
Gen Public	173
Chemist	45
Chemist Assn	111
NGOs	12
Press	6
Online Traders	4
Online Trade Assn	4

Mfg Co	4
Mfg Assn	4
Regulatory	4
Reg Assn	1
	368

5.0 Scenario in various developed countries:

Presently purchase and sale of medicines over the internet is increasingly being popular worldwide. Some countries have stringent rules and regulations while some countries are still in process to make the framework. However developed countries like Japan, Italy, Ireland, Spain, Korea, Thailand, Turkey and Russia Federal do not permit sale of medicines through online pharmacies.

5.1 United Kingdom:

On request MHRA Regulatory Authorities were kind enough to give brief about the scenario in their country. Sub-Committee hereby expresses gratitude towards their cooperation extended to India in this regard. The summarized note is reproduced herewith as follows;

In 2013, 36 million adults (73%) in Great Britain accessed the Internet every day, with some 21 million households (83%) having Internet access. In the same year it is estimated that 72% of all adults bought goods or services online with an estimated value of £91 billion. This wide penetration of the internet, a well-developed IT infrastructure and high levels of competition between Internet Service Providers (ISP) has created opportunities for both legitimate online suppliers and criminal enterprises selling medicines illegally, to reach a wider proportion of the UK public.

- The innovative criminal has identified that the internet provides:

- Access to consumers and patients on a global marketplace
- Access to business to business (b2b) forums
- The ability for manufacturers and suppliers to communicate across the world
- Advertisement through SPAM e-mail to millions of individuals
- Use of Social Media to promote websites or supply products
- Ability to establish infinite numbers of websites quickly and easily with relative anonymity
- Access to electronic payment systems to facilitate credit card payments
- Use of global mail and courier networks to deliver and track goods
- Use of offshore companies and bank accounts to launder the financial proceeds of crime
- The opportunity to target customers and patients with credit card fraud, identity theft and malicious software

MHRA is aware of the availability of medicines being offered for sale through internet websites and by mail-order. By monitoring the electronic market, the MHRA has established that a vast range of medicines is now available on-line in many countries in the world. There is evidence to show that medicines supplied via the internet may not meet UK standards on safety, quality and efficacy and consequently, may pose a risk to patient health. As MHRA's primary aim is the protection of public health, there are serious concerns regarding the

availability and accessibility of medicines on-line.

There is also evidence to show that counterfeit medicines are available from websites, particularly from countries where there is little or no regulatory control.

Many UK consumers approach the purchase of medical products in much the same way as other lifestyle consumables and fail to realise or acknowledge the dangers posed by using unlicensed or non-prescribed medicines. Additionally consumers buying medical products online expose themselves to a much higher risk of buying falsified medicinal products.

Through the work conducted in partnership with UK Border Force in intercepting parcels of medicines purchased online, it is clear the UK market is broad in its demand with the largest volume being 'lifestyle' medicines for the treatment of issues such as obesity, erectile dysfunction and hair loss. However, whilst smaller in numbers, benzodiazepines (or similar analogues) and medicinal products for pain relief and abortion are also intercepted regularly.

5.1.1 Current UK Position

The UK has three legal classes of authorized medicines:

- General sale list (GSL) medicines are suitable for sale and normal use without supervision or advice from a pharmacist or doctor.

- Pharmacy (P) medicines can only be obtained from a pharmacy and are sold or supplied under the supervision of a pharmacist.
- Prescription only medicines (POM) must be prescribed by an authorised healthcare professional, for example a doctor, dentist, or independent prescriber.

Prescription Only (POM) and Pharmacy (P) medicines may only be legally sold or supplied to the public through registered pharmacy premises, by or under the supervision of a pharmacist. Additionally POM may only be sold or supplied in response to a prescription from an authorised healthcare professional (such as a doctor, dentist, or certain trained nurses and pharmacists). Doctors may also supply medicines direct to patients – for example, where they personally administer a medicine such as a vaccine, or where they are able under specific NHS arrangements to supply prescribed medicines to their patients as part of a NHS dispensing service.

5.1.2 UK Pharmacies and the Internet

A UK registered pharmacy may have a presence on the internet; however the requirements of legislation apply equally to both UK internet pharmacies and bricks-and-mortar premises. POM cannot be advertised directly to the public. These legal controls also apply equally to medicines for human use sold or supplied via the internet or e-mail transactions. Some POMs are "Controlled Drugs" (such as benzodiazepines) and their availability to patients can be subject to

additional control under the Misuse of Drugs Act 1971, which is administered by the Home Office.

These restrictions do not apply to countries outside UK jurisdiction, where medicines may be classified and regulated differently. For example, in the US and other countries some medicines that would be POMs in the UK are available without prescription. Medicines legislation does not prohibit the remote prescribing of POM by a qualified prescriber. However, prescriptions must meet the usual requirements set down in medicines legislation.

5.1.3 The New Mandatory Logo for Selling Medicines Online

The General Pharmaceutical Council (GPhC) operates the Internet Pharmacy Logo which helps members of the public identify if a website is being operated by a legitimate pharmacy in the UK. Currently, this is a voluntary scheme but provisions in the European Falsified Medicines Directive require Member States to introduce national arrangements to register suppliers of 'medicines at a distance' – this not only include pharmacies but also online supermarkets, Amazon etc. This involves the establishment of a national website and the adoption of a common EU logo. All websites supplying medicines at a distance will be required to display the EU logo and provide a hyperlink to the national website of the Member State in which the person offering to sell medicines at a distance is established. These provisions took effect across the EU on 1 July 2015 and the MHRA is responsible for UK registrations. According

to the EU Directive, anybody in the UK selling medicines online to the general public needs to be registered with the MHRA and to be on the MHRA's list of UK registered online retail sellers.

They are also required to display on every page of the website offering medicines for sale, the new European common logo which is registered to the seller. The registered EU logo contains a hyperlink to their entry in the MHRA's list of registered online sellers. Therefore, anybody buying medicines online can check if the website is legitimately registered with the MHRA and will be able to click on the logo, which will take them through to a list of approved sellers.

5.1.4 Registered Person selling through a Third-party Website

If the registered person retails a medicine through a third-party market place website, then the third-party market place service provider must display that registered person's EU Common Logo on every page of their website that offers the registered person's medicine for sale to the public from that service provider's site. A third party market place would include websites like Amazon.

5.1.5 Licensed Medicines in Member States

Under the rules of the new scheme the medicine being offered online must be licensed in the member state where the member of public who buys the medicine is based. The person selling the medicine must be legally entitled to sell medicine to the public in accordance with UK

medicines legislation.

Registered pharmacies can sell general sales list medicine, pharmacy medicine or supply prescription-only medicine that they have dispensed against a prescription. All other general retailers can only sell general sales list products. The penalty for selling medicines online without being registered and not displaying the logo is up to 2 years imprisonment or a fine or both.

5.1.6 Memorandum of Understanding (MOU), Cooperation & Information Sharing and Training

The MHRA Enforcement Group realizes the importance of stakeholders in combating the illegal sale and supply of medicines online. To this end, as illustrated in its enforcement strategy, the MHRA Enforcement Group collaborates and engages with relevant stakeholders to obtain the maximum impact in disrupting the activities of illegal websites selling medicines. In order to facilitate easy and effective exchange and sharing of information as well as assistance in the fight against the illegal sale of medicines online, the MHRA Enforcement Group have established Memorandum of Understanding (MOU) with law enforcement agencies and other stakeholders.

5.1.7 Cyber Security within Internet Governance (CSIG) and Government Advisory Committee (GAC)

The MHRA is represented on the UK Public Safety Working Group

(PSWG) which sits under the general umbrella of GAC under the chairmanship of the Global Internet Governance, Department of Culture Media and Sport (DCMS). High level discussions and recommendations aimed at influencing policies relating to internet security are held. As a result, in the last twelve months DCMS has commenced a project to broaden the scope of engagement on the issues of Cyber Security within internet governance over the next year.

5.1.8 Training and production of Information Material

The MHRA is actively involved in capacity building and training programs and production of material for kindred agencies in the area of pharmaceutical crime; particularly in intelligence gathering and investigation techniques regarding illegal sale and supply of medicines online. Amongst some of the documents produced for kindred agencies and training are 'A guide to Internet Investigations' produced by the MHRA Intelligence Unit in 2013 and 'A Practical Guide for EU Investigations on Falsified Medicines' – co-authored by the MHRA Enforcement Group and INTERPOL, Irish Medicines Board (IMB), International Institute against Counterfeit Medicines (IRACM), French Central Office against Environmental and Health Crime (OCLAESP), Permanent Forum on International Pharmaceutical Crime (PFIPC) and Pharmaceutical Security Institute (PSI). This guide has been translated and available in the following languages: Croatian, Dutch, German, Greek, Hungarian, Latvian, Lithuanian, Polish, Slovak, Slovenian, Spanish and Romanian.

Investigators, Financial Investigators and Intelligence Analysts at MHRA are trained to high standards of investigation techniques and have provided and facilitated bespoke training (as expert trainers) aimed at all aspects of medicines enforcement including Internet and counterfeit cases. Amongst many, some of the Enforcement Group's training partners are INTERPOL, European Police (EUROPOL), Working Group of Enforcement Officers (WGEO), World Health Organisation (WHO), Council of Europe's Counterfeit Training Programme, French CIVIPOL and others.

5.2 USA:

The main features of the regulatory regime in USA are:

- It is permitted in US but the pharmacy must be domiciled within the US.
- Online pharmacies must be registered with the Drug Enforcement Administration (DEA) to dispense 'controlled substances', must be compliant with Federal food, Drug and Cosmetic Act, Federal Controlled Substances Act and cannot dispense medications that are not approved by the FDA.
- Pharmacy must comply with state-specific rules in addition to federal rules.
- An Exchange was created in 2001 with standardize interfaces to allow healthcare providers to send prescriptions to pharmacies electronic thereby eliminating manual errors and enabling easy

monitoring and tracking mechanism for insurance companies.

- Currently, 96% of the pharmacies and 70% of the physicians in the U.S. use Sure Script Exchange. Sure Script processes more than 6 billion transactions each year, including nearly 700 million medication histories, more than 1 billion e-prescriptions and nearly 10 million clinical messages.
- USA has a programme called Verified Internet Pharmacy Practice Sites (VIPPS) certification which is given to pharmacy websites that practice the defined rules and standards set by the VIPPS programme.
- The primary rule being maintaining the sanity of the prescription so as to ensure it is authentic, it cannot be dispensed twice and once dispensed all necessary records are well maintained.
- VIPPS does not allow the pharmacy to dispense based on scanned prescription or an image of prescription.
- E- prescription or original paper prescription is the only allowable form of prescription for a VIPPS pharmacy.
- Patients must have the ability to easily contact online pharmacies should they have questions regarding dosage, drug type and/or adverse effects post-drug usage.
- FDA Guidelines suggest that a legal, regulated 'online pharmacy':
 - Requires a valid prescription

- Provides a physical address in the United States
- Is Licensed by the state board of pharmacy in the state and the state where the pharmacy is operating
- Has a state- licensed pharmacist to answer your question

5.3 Brazil:

The main features of the regulatory regime in Brazil are:

- Pharmacy has to be licensed in Brazil.
- Internet pharmacy must post its ANVISA permit number on its website which provides a link to a searchable database of licensed internet pharmacies.
- They must be open to public, with a pharmacist present during all hours of operation.

5.4 Canada:

The main features of the regulatory regime in Canada are:

- Internet pharmacy must be a brick and mortar pharmacy with a physical street address to dispense drugs over internet.
- There is no national license, it happens at the provincial level.
- Any licensed pharmacy that offers internet services must meet the standards of practice within its own province.

5.5 China:

The main features of the regulatory regime in China are:

- Online pharmacies are mandated to display certification on their websites;
- Customers can check the pharmacy domain name/registration number with the China FDA (CFDA) database.
- Chinese online pharmacies operate on a market-place model and allowed to sell over the counter (OTC) drugs.

5.6 Australia:

Australia allows dispensing on scanned prescription however only if it is sent directly from doctor to pharmacy and with an authentication that can ensure it is indeed the doctor who has sent it.

6 Recommendations

6.1 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.

6.2 In order to minimize the risk and consequential adverse effect, use of technology in case of online sale of medicine may be allowed in a limited way and that too after institutionalizing strict monitoring and supervisory approach. As of now, the supervisory, monitoring and vigilance system are not in place or not upto the standards as required. 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.

Some geographical restrictions for supply of drugs are required for effective administrative control on online sale. Geographical restrictions will ensure proper regulatory control through periodical inspections by local enforcement agency and sampling of medicines sold through online systems. It will also restrict the entry of prohibited items, spurious medicine. Geographical restrictions will help in effective recall of drugs and better pharmacovigilance.

6.3 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.

6.4 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.

6.5 Online Service providers for sale of drugs may be considered as intermediaries as provided in the Information Technology Act, 2000 and the Rules framed there under. It is, therefore, recommended that suitable amendments need to be made in the Drugs and Cosmetics Rules, 1945 in order to define functions and responsibilities of intermediaries.

6.6 Intermediaries shall have at least one licensed pharmacy in each state where they propose to carry out online sale of drugs.

6.7 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.

6.8 Online sale of drugs may be permitted only on e-prescriptions or electronically generated and digitally 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 digitally signed prescriptions.

6.9 The dispensing of drugs be done through the physical pharmacy against valid e-prescription from the Registered Medical Practitioner, duly licensed under part VI of Drugs and Cosmetics Rules, 1945.

6.10 Entire audit trail including the name and address of the patient/ physician/ pharmacy shall be digitally stored to prevent abuse and ensure tracking in case of any adverse events.

6.11 Provision shall be made in the rules for Patients to easily contact, through telephone helpline and email, online pharmacies to clarify any questions regarding dosage, method of administration, contraindications, drug type, adverse effects etc.

6.12 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.

6.13 Detailed system architecture for the Central portal/cloud need to be developed. Some ideas on this are at Annexure 3.

6.14 Drugs not permitted through online pharmacy

As certain categories of drugs viz. the Narcotic and psychotropic drugs, tranquilizers, habit forming drugs and Schedule X drugs are prone for abuse or misuse, such categories may be excluded from sale through online pharmacies.

6.15 Confidentiality of patient information

- Safety of patients is of utmost importance and it is the right of the patient to keep his data confidential.
- The e-pharmacy shall comply with provisions of the IT Act and Rules regarding handling and transfer of any personal information of the patient.
- The consent from the end customer shall be obtained for the provision of delivery services.

6.16 A registry of E-Pharmacies should be made available on the National portal. Information to be available on the website of online pharmacy are as under:

- All E-Pharmacies should provide a link of the National portal on their homepage for verification of its authenticity by the patient/consumer.
- A specific logo for identifying the authenticity of online pharmacy which can be displayed on every page of the internet portal and the mobile application.
- Information regarding name, address, contact details (Phone

number, email ID) of every pharmacy from where dispensing of drugs is undertaken shall be provided on their websites.

- The contact details (email ID, Phone number) of the pharmacist shall be made available to the patient for any clarification/information.
- The details like Name and Address of Pharmacy and its drug licence number shall be made available to the patient/consumer before he confirms the order for medicines on an E-Pharmacy.

6.17 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 be in conformance to Good Distribution Practices (GDP).

6.18 Amendments required in the Drugs and Cosmetic Rules, 1945

- Proposed rules for amendment of Drugs and Cosmetic Rules, 1945 is annexed at Annexure 4.
- Registration with Central Authority shall be mandatory for routing all the transactions through National portal for the online sale of Drugs whether prescription or non-prescription drugs.

- In case of any investigations, Licensing Authorities shall have access to the information of the online Pharmacies.
- Product advertisements of the Scheduled drugs shall be prohibited on the electronic Medias.

7.0 Annexure

Annexure 1: Order constituting the sub-committee

F. No. X-19013/1/2015-DC
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
FDA BHAWAN, KOTLA ROAD, New Delhi.

Dated: the 27 08 2015


OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee to examine the issue of regulating the sale of drugs over internet under the Drugs and Cosmetics Rules, 1945 – reg.

A sub-committee to examine the issue of regulating the sale of drugs over internet under the Drugs and Cosmetics Rules, 1945 was constituted as per recommendations of the 48th meeting of Drugs Consultative Committee (DCC) held on 24.07.2015 and an office memorandum in this regard was issued on 11.08.2015 with the following composition:

1. The Commissioner, FDA, Maharashtra,
2. Shri Raghuraza Bhandary, Drugs Controller, Karnataka,
3. Shri H. Mahapatra, Drugs Controller, Odisha,
4. Shri Atul Kumar Nasa, Assistant Drugs Controller, Delhi
5. Shri Saiim A. Veljee, Director, Food & Drugs Admin -Goa,
6. Shri Pankaj Agarwal, State Licensing Authority, Madhya Pradesh
7. Dr. Eswara Reddy, Joint Drugs Controller, CDSCO, HQ

In this regard it is further stated that Dr. Harshdeep Kamble, I.A.S., Commissioner, Food and Drug Administration, Maharashtra will be the Chairman of the committee and Dr. Eswara Reddy, Joint Drugs Controller, CDSCO, HQ will be the convenor.


(Dr. G. N. Singh)
Drugs Controller General (India)

To,

All members of the committee

Annexure: 2 Representations and suggestions received

Sr. No	Date	Received from	Mode of receipt
1	22/04/20 15	The Maharashtra State Chemists & Druggists Association	Letter
2	7/5/2015	The Bangalore Dist Chemists and Druggists Association	Email (attachment)
3	14/05/20 15	The Hindu Business Line	Email
4	21/05/20 15	Senior Correspondant - DNA Money	Email
5	21/05/20 15	FDA Nashik	Email (attachment)
6	29/05/20 15	Article by vhshah2014@gmail.com	Email

7	29/05/20 15	Naishadh	Email
8	30/05/20 15	The Times Of India	Email
9	30/05/20 15	Amir Gandhi (Pune)	Email
10	30/06/20 15	The Retail & Dispensing Chemists Association (Mumbai)	Letter
11	2/7/2015	Mohan Kale (nnagencies@yahoo.com)	Email
12	29/07/20 15	Atul Bhosekar	Email
13	1/8/2015	Indian Pharmaceutical Association - Maharashtra State Branch	Letter
14	11/8/201 5	Raj Vaidya (community pharmacist, Goa)	Letter
15	20/08/20 15	Amar Dani (Thane District)	Email

16	21/08/20 15	All India Organisation of Chemists and Druggists	Letter
17	27/08/20 15	Dawa Bazar Hindu Monthly Magazine	Email (attachment)
18	29/08/20 15	Raj Vaidya (community pharmacist, Goa)	Email
19	31/08/20 15	Mahadev Patel (community pharmacist, Mumbai)	Email
20	4/9/2015	FICCI	Email (attachment)
21	7/9/2015	Joint Co-ordination Committee of the Retail & Dispensing Chemists Association & The Pharmaceutical Wholesalers Association	Letter
22	8/9/2015	All India Organisation of Chemists and Druggists	Letter (2)
23	8/9/2015	Maharashtra Registered Pharmacists Association	Email

24	21/09/20 15	Chemist & Druggist association Goa	Letter
25	22/09/20 15	Chandu Mhatre (chandumhatre12@gmail.com)	Email
26	22/09/20 15	Maharashtra Registered Pharmacist Association (Aurangabad)	Email
27	22/09/20 15	Qamrul Hasan Khan (Prince Medical StoreS)	Email
28	22/09/20 15	Liladhar Gosar (Shree Paras Medical & General Stores)	Email
29	22/09/20 15	rsjumani@yahoo.com	Email
30	23/09/20 15	Tomar Medical stores (New Delhi)	Email
31	23/09/20 15	Narang Chemist	Letter
32	23/09/20 15	Trinath Singh & Bros. Dispensing Chemists (Chandigarh)	Email

33	23/09/20 15	gurbakshluthra99@gmail.com	Email
34	23/09/20 15	Anand Medical Stores (Chandigarh)	Email
35	23/09/20 15	Consumer Rights Education & Awareness Trust	Email (attachment)
36	23/09/20 15	The Bangalore Dist Chemists and Druggists Association	Email (attachment)
37	23/09/20 15	Arvind Verma (vermabrothers14@gmail.com)	Email
38	23/09/20 15	New Plaza Medical Store	Email
39	23/09/20 15	Ravi Shankar V. V. (Tamil Nadu)	Email
40	23/09/20 15	Indian Pharmacist Association	Email (attachment)
41	23/09/20 15	Nemi Medical Stores (Gujarat)	Email

42	23/09/20 15	Udupi Chamber of Commerce & Industry (Incorporated)	Letter
43	23/09/20 15	Mycon	Email
44	24/09/20 15	Jatin Jain (jatinnareshjain@gmail.com) ¹	Email
45	24/09/20 15	Nagpur District Chemist's & Druggists Association	Email
46	24/09/20 15	Super Medicos (New Delhi)	Email
47	24/09/20 15	Vardhaman Chemist	Email
48	24/09/20 15	Kuldeep Singh	Email
49	24/09/20 15	Hamza Lakdawala (Rehamt Medical)	Email
50	24/09/20 15	Rajeev Malik	Email

51	24/09/20 15	SKS Techno Tools (Nand Kishore)	Email
52	24/09/20 15	Arun (4th year, Law university)	Email
53	24/09/20 15	Shashi Bisht	Email
54	24/09/20 15	Lalit Aggarwal	Email
55	24/09/20 15	Arvind Verma (vermabrothers14@gmail.com)	2nd Email
56	24/09/20 15	Jai Aggarwal	Email
57	24/09/20 15	G. S. Medicine Company	Email
58	24/09/20 15	KK Selvan	Email
59	24/09/20 15	Sakthi Medical	Email

60	24/09/20 15	Vikas Singh	Email
61	24/09/20 15	Rachna Goel	Email
62	24/09/20 15	Dr. Vishnu Dua	Email
63	24/09/20 15	Sneha Narang	Email
64	24/09/20 15	Avinash Pandey	Email
65	24/09/20 15	Priyanka Srivastava	Email
66	24/09/20 15	Ajay Aggarwal (Shiv Meidcal Store, Delhi)	Email
67	24/09/20 15	Santosh Kumar	Email
68	24/09/20 15	Unique Medical (Mumbai)	Email

69	24/09/20 15	K. Jayawant (Drugs Controller, RMSC, Rajasthan, Jaipur)	Email
70	24/09/20 15	Team Doar India (NGO Founder)	Email
71	24/09/20 15	Hakimi Pharmacy (Mumbai)	Email
72	24/09/20 15	Jitndra Kumat	Email
73	24/09/20 15	Rekha tomar	Email
74	24/09/20 15	Sunit Tanwar (Delhi)	Email
75	24/09/20 15	The maharashtra state chemist & druggists associatopn	Letter
76	25/09/20 15	Pashim Nimad Jila Chemist Association	Letter
77	25/09/20 15	Ujjain District Chemist & Druggist Association	Letter

78	25/09/20 15	Jila Aushadhi Vikreta Sangh, Sagar	Letter
79	25/09/20 15	Jila Rajgad Aushad Vikrata Sangh	Letter
80	25/09/20 15	Orissa Homeopathic Druggist Association	Letter
81	25/09/20 15	Netmeds Marketplace Ltd.	Letter
82	25/09/20 15	The Tamilnadu Chemists & Druggists Association	Letter
83	25/09/20 15	Bruhath Bengaluru Chemists and Druggists Association	Letter
84	25/09/20 15	Ballia Chemist & Druggist Association	Letter
85	26/09/20 15	Ankur Gambhi (Pharmacist, Delhi)	Email
86	26/09/20 15	Ankit Tyagi (Noida)	Email

87	26/09/20 15	Consumers' Forum (Karnataka)	Letter
88	26/09/20 15	All Kerala Chemists & Druggists Association	Letter
89	26/09/20 15	Vinay Kumar Bharti (Journalist, Delhi)	Email
90	26/09/20 15	Avinash Chaturvedi (Delhi)	Email
91	27/09/20 15	Health Saverz	Email
92	27/09/20 15	Consumer Online Foundation	Letter
93	27/09/20 15	Monika karla	Email
94	27/09/20 15	Laxmikant Sharma	Email
95	27/09/20 15	Seoni District Chemist Asosication	Letter

96	27/09/20 15	A. P Rationallist Association (Andhra Pradesh)	Email
97	27/09/20 15	Girish Vaghela	Email
98	27/09/20 15	Jilha aushadhi vikreta sangh Chindvada(M.P.)	Letter
99	28/09/20 15	Tausif Ahmed	Email(attachme nt)
100	28/09/20 15	Panneer Selvam	Email
101	28/09/20 15	Indian Pharmaceutical Association	Email (attachment)
102	28/09/20 15	Practo.com	Email (attachment)
103	28/09/20 15	The Maharashtra State Chemists & Druggists Association	Email (attachment)
104	28/09/20 15	Lalita Devi (Patient)	Email

105	28/09/20 15	Indian Internet Pharmacy Association	Email (attachment)
106	28/09/20 15	Jomy (Student - Manipal College of Pharmaceutical Sciences)	Email (attachment)
107	25/09/20 15	M/S Upasham (Hooghly/0	Email
108	28/09/20 15	All India Organisation of Chemists and Druggists	Letter (3)
109	28/09/20 15	Tiruvarur District Chemists & Druggists Association	Letter
110	28/09/20 15	HIMSS Asia-Pacific India Chapter	Letter
111	28/09/20 15	SUN Pharma	Letter
112	28/09/20 15	Betul Jila Aushadhi Vikreta Sangh (Betul)	Letter
113	28/09/20 15	All India Chemist and Distributors Federation	Email

114	28/09/20 15	Jila Chemist and Druggist Association (Barhanpur)	Email (attachment)
115	28/09/20 15	The Federation of Gujarat State Chemists & Druggists Associations	Letter
116	28/09/20 15	IIPA	Email(attachme nt)
117	28/09/20 15	Tirath Singh & Bros.	Email
118	28/09/20 15	Krishanan Krishanan	Email
119	28/09/20 15	Pradeep Tomar	Email
120	28/09/20 15	Vinod Gupta	Email
121	28/09/20 15	Dev Mediplus	Email
122	28/09/20 15	Anjaneyulu Chidella	Email

123	28/09/20 15	Paras Medicals	Email
124	28/09/20 15	RS Jumani	Email
125	28/09/20 15	Ravi Medical & General Store	Email
126	28/09/20 15	Pankaj	Email
127	28/09/20 15	Gaurav Sethi	Email
128	28/09/20 15	Sujeet Gupta	Email
129	28/09/20 15	Apna Medical Store	Email
130	28/09/20 15	Praveen Medical Store	Email
131	28/09/20 15	Jitendra Kumar	Email

132	28/09/20 15	Al Madina Medical & General Store	Email
133	28/09/20 15	Vaibhav Rastogi	Email
134	28/09/20 15	Paras Jain	Email
135	28/09/20 15	Gajendra Singh	Email
136	28/09/20 15	Murtuza	Email
137	28/09/20 15	Shyam Aggarwal	Email
138	28/09/20 15	Rakesh Kakrian	Email
139	28/09/20 15	Divvay Tomar	Email
140	28/09/20 15	Deepanshu Jain	Email

141	28/09/20 15	Satna Distt. Chemist Association	Letter
142	28/09/20 15	Hoshangabad District Chemist and Druggist Association	Email (attachment)
143	28/09/20 15	Dr. B. R. Jagashetty	Letter
144	28/09/20 15	Medlife International Ovt. Ltd.	Letter
145	28/09/20 15	Mandi Chemist and Pharmacists Association	Email
146	29/09/20 15	Kuldeep Jain	Email
147	29/09/20 15	shivam surgical and medicos	Email
148	29/09/20 15	Alakh Bhatia	Email
149	29/09/20 15	District Gurgaon Chemist & druggist association	Email(attachme nt)

150	29/09/20 15	Archana and team community	Email
151	29/09/20 15	Anil Aggarwal	Email
152	29/09/20 15	Aji Eapen	Email
153	29/09/20 15	Rohit Bhatia	Email
154	29/09/20 15	Rajeev Ranjan	Email
155	29/09/20 15	Kavin Sachin	Email
156	29/09/20 15	Sachin Gupta	Email
157	29/09/20 15	Ravi Narayan	Email
158	29/09/20 15	Mandsar Dist Chemist and Druggist Association	Email (attachment)

159	29/09/20 15	Ankur Gambhir	Email
160	29/09/20 15	Lialitha	Email (attachment)
161	29/09/20 15	Chemist Association	Email (attachment)
162	29/09/20 15	Rajendra Kumar Chawla	Email
163	29/09/20 15	GS Medicine Company	Email
164	29/09/20 15	Vishnu Dua	Email
165	29/09/20 15	Tarun Sarna	Email
166	29/09/20 15	Shiv Medical Store	Email
167	29/09/20 15	Junaid Thunder	Email

168	29/09/20 15	Uma	Email
169	29/09/20 15	Inder Sachdev	Email
170	29/09/20 15	Trupti Powar	Email
171	29/09/20 15	Saroj medicals	Email
172	29/09/20 15	S P Suresh	Email
173	29/09/20 15	Shaikh Rais Ahmed	Email (attachment)
174	29/09/20 15	G venkateshan	Email
175	29/09/20 15	Harish Kumar	Email
176	29/09/20 15	MRTOP Retailers	Email

177	29/09/20 15	Dawar Medicos	Email
178	29/09/20 15	Ramchandran Srini	Email(attachme nt)
179	29/09/20 15	Panchal Sandesh	Email (attachment)
180	29/09/20 15	Rajesh Kumar	Email (attachment)
181	29/09/20 15	Yashpal Soni	Email
182	29/09/20 15	Manish Karel	Email
183	29/09/20 15	Rohit	Email
184	29/09/20 15	Vijay Jadhawani	Email
185	29/09/20 15	Dinesh Singh	Email

186	29/09/20 15	Raghvendra Singh	Email
187	29/09/20 15	Srinivas.chidurala	Email
188	29/09/20 15	Arun	Email
189	29/09/20 15	Ashish Medical Agency	Email
190	29/09/20 15	A.P Rationalist association	Email
191	29/09/20 15	Yasho Pharma	Email
192	29/09/20 15	Atul Shah	Email (attachment)
193	29/09/20 15	Sunil Tanwar	Email
194	29/09/20 15	Ashok Medical Store	Email

195	29/09/20 15	Radical humanist association	Email
196	29/09/20 15	Dhiraj Bhatia	Email
197	29/09/20 15	Pharma gladiators	Email (attachment)
198	29/09/20 15	Udupi District chemist & druggist	Email
199	29/09/20 15	Mohammad Zahiruddin Ansari	Email
200	29/09/20 15	Devakottai Taluk Chemists & Druggists Association	Email
201	29/09/20 15	Nikhil Gupta	Email
202	29/09/20 15	Neeraj Kumar Jain	Email
203	29/09/20 15	Kuldeep Rathi	Email

204	29/09/20 15	Virudhnagar District Chemist and Druggist Association	Email
205	29/09/20 15	Pritpal Singh	Email
206	29/09/20 15	Nitin Dahiya	Email
207	29/09/20 15	Sunil Narang	Email
208	29/09/20 15	Monica Sadh	Email
209	29/09/20 15	Anshum Aneja	Email
210	29/09/20 15	Nishant Jain	Email
211	29/09/20 15	Ravinder Sukheja	Email
212	29/09/20 15	Hardeep Singh	Email

213	29/09/20 15	Deepak Rai	Email
214	29/09/20 15	Rajinder Aroroa	Email
215	29/09/20 15	Ravi Rajput	Email
216	29/09/20 15	Swati Arora	Email
217	29/09/20 15	Mohan Choudhary	Email
218	29/09/20 15	Omprakash	Email
219	29/09/20 15	Shalini Rajendran	Email
220	29/09/20 15	Deepak Khandelwal	Email
221	29/09/20 15	Mayank Garg	Email

222	30/09/20 15	k.shanmugam, Scientific Officer	Email (attachment)
223	30/09/20 15	Khandwa District chemist Association	Email (attachment)
224	30/09/20 15	Muthu Laxmi	Email
225	1/10/201 5	David Ravi	Email
226	1/10/201 5	Vinod Nagar	Email
227	1/10/201 5	Raghunandan	Email
228	1/10/201 5	Kamal kumar Mukim	Email(attachme nt)
229	1/10/201 5	S Arul	Email
230	1/10/201 5	Sandeep Malhotra Malhotra Medico	Email

231	1/10/2015	Mohit Bansal	Email
232	1/10/2015	Girish	Email
233	1/10/2015	Ruchika Karla	Email
234	1/10/2015	Parappa Kumaran	Email
235	1/10/2015	Praful Paruthi	Email
236	1/10/2015	Sachin Bhatija	Email
237	1/10/2015	Aman Bansal	Email
238	1/10/2015	Sajeev Kumar	Email
239	1/10/2015	Rakesh kumar Garg	Email

240	1/10/2015	Nisha Agarwal	Email
241	1/10/2015	Distt chemist association	Email
242	1/10/2015	Vidisha District Chemist & Druggist Association	Letter
243	2/10/2015	Neemach District chemist association	Email(attachme nt)
244	3/10/2015	Kushum Gulati	Email
245	5/10/2015	Ahmadnagar district chemist & druggist association	Letter
246	5/10/2015	Bharatiya Janata Party Chemist mahasangh Maharashtra Pradesh	Letter
247	6/10/2015	Bhind Chemist Association	Email (attachment)
248	6/10/2015	Sunil Kukreja	Email

249	6/10/201 5	Nirdosh Kumar	Email
250	6/10/201 5	Delhi Computer Academy	Email
251	6/10/201 5	Magnet Computer Academy	Email
252	6/10/201 5	Rannim Associates	Email (attachment)
253	6/10/201 5	Dhule jilha chemist & Druggist association	Letter
254	6/10/201 5	Balakedaarara Hitarakshak Sangh	Letter
255	7/10/201 5	Solapur District chemists & Druggist association	Letter
256	7/10/201 5	Internet and Mobile Association of India	Letter
257	7/10/201 5	Amitayu Sengupta	Email

258	7/10/201 5	Manisha Mavi	Email
259	7/10/201 5	Saurabh Mittal	Email
260	7/10/201 5	Pooja Chavan	Email
261	7/10/201 5	Shaji tk	Email
262	7/10/201 5	Chemist & druggisat association shivpuri	Email
263	7/10/201 5	Sai kitchen equipments	Email
264	7/10/201 5	Jabalpur Chemist & druggisat association	Email (attachment)
265	7/10/201 5	Deepa medical	Email
266	7/10/201 5	Chemist & Druggist association-Bhadohi	Letter

267	7/10/201 5	Amit Goel	Email
268	7/10/201 5	Giri Den	Email
269	7/10/201 5	Krishna Kumar Saini	Email
270	7/10/201 5	Ashok Sakhuja	Email
271	7/10/201 5	Sahil Sanjay	Email
272	7/10/201 5	Jayesh Nalawade	Email
273	7/10/201 5	Sanjeev Jaggi	Email
274	7/10/201 5	Naveen Jain	Email
275	7/10/201 5	R N Distributors	Email

276	7/10/201 5	Kharbanda Murayan	Email
277	7/10/201 5	Rahul Mhetre	Email
278	7/10/201 5	Dr Shanti Swarup	Email
279	7/10/201 5	Sushma Tumma	Email
280	8/10/201 5	Shirpur taluka chemist & Druggist association	Letter
281	8/10/201 5	Ambernath chemist association	Letter
282	9/10/201 5	Nagpur District Chemist's & Druggists Association	Letter
283	10/10/20 15	chemist's association of Thane district	Letter
284	10/10/20 15	Jalgaon District Medicine Dealers Association	Letter

285	10/10/20 15	The Karnataka Chemists & Druggist Association	Letter
286	12/10/20 15	Shrirampur taluka chemist & druggist association	Letter
287	12/10/20 15	chemist & druggist association district Saharanpur	Letter
288	12/10/20 15	Yevala taluka chemist & druggist association	Letter
289	12/10/20 15	Dava Vyapar Mandal	Letter
290	13/10/20 15	Akhilesh Shukla	Email
291	13/10/20 15	Global pharma sekar	Email
292	13/10/20 15	Latur District Chemist & Druggist association	Letter
293	13/10/20 15	Solapur District chemists & Druggist association	Letter

294	13/10/20 15	Dindori Taluka chemsit & druggist association	Letter
295	14/10/20 15	District Bareilly Chemists Association, Bareilly(U.P)	Letter
296	14/10/20 15	Ballia Chemist & Druggist Association	Letter
297	14/10/20 15	Chemest & Drugist Klyan Association	Letter
298	14/10/20 15	Chemists Druggists Welfare Association	Letter
299	14/10/20 15	Chemist & Druggist association-Balarampur	Letter
300	14/10/20 15	Gautam Budh Nagar zila chemist association	Letter
301	14/10/20 15	Lakhimpur Chemist & Druggist association	Letter
302	14/10/20 15	Chemist & Druggist Kalyan association Gonda	Letter

303	14/10/20 15	Chemist association Raybareli	Letter
304	14/10/20 15	Chemist association Dehradun	Letter
305	14/10/20 15	Chemist& Druggist association District Unnao	Letter
306	14/10/20 15	Dava Vyapar Welfare Society (Mau)	Letter
307	14/10/20 15	Kolhapur District Chemist Association	Letter
308	14/10/20 15	Agra Pharma association	Letter
309	14/10/20 15	The Akola District chemist & Druggist association	Letter
310	14/10/20 15	Kolhapur District Chemist Association	Email (attachment)
311	14/10/20 15	Satar District chemist & Druggist association	Letter

312	14/10/20 15	Ahmadnagar District chemist & druggist association	Letter
313	14/10/20 15	Jilha grahak sarkshan parishad Solapur	Letter
314	14/10/20 15	The Aurangabad jilha chemist & druggist association	Letter
315	15/10/20 15	S S Patil	Email
316	15/10/20 15	Priyadarshan Pradhan	Email
317	15/10/20 15	Mr Jain	Email
318	15/10/20 15	Sadashiv Pandit	Email
319	16/10/20 15	Bengal Chemists and Druggists Association	Letter
320	20/10/20 15	Progress Harmony Development	Letter

321	21/10/20 15	The Maharashtra state chemists & druggist association	Letter
322	22/10/20 15	Sriram Subramanian	Email
323	23/10/20 15	Pragnesh Panchavadi	Email
324	23/10/20 15	(CIPI) Confederation of Indian Pharmaceutical Industry (SSI)	Letter
325	26/10/20 15	G. Hubert	Email
326	26/10/20 15	C.Arumugam. Saroj medicals	Email
327	26/10/20 15	T.Rajasekaran, chennai	Email (attachment)
328	26/10/20 15	Pragnesh Panchmvedi	Email
329	31/10/20 15	Jeetu Belani	Email

330	2/11/2015	The Maharashtra state chemists & druggist association	Letter
331	16/11/2015	N. Ruthyra Moorthy	Letter
332	24/11/2015	Sami labs limited	Letter
333	28/11/2015	Punjab chemists association	Letter
334	2/12/2015	The Maharashtra state chemists & druggist association	Letter
335	2/12/2015	The Maharashtra state chemists & druggist association	Letter
336	17/12/2015	1mg Pvt. Ltd.	Email (attachment)
337	21/12/2015	The Maharashtra state chemists & druggist association	Letter
338	1/2/2016	Kota Wholesale Chemist Welfare Society	Letter

339	1/2/2016	Chemist & Druggist Association Rampur Maniharan Distt - Saharanpur	Letter
340	1/2/2016	Churu District Chemists Association	Letter
341	1/2/2016	The Chemists & Druggists Association, Jaipur	Letter
342	1/2/2016	Jila Chemist and Druggist Association (Sambhal)	Letter
343	1/2/2016	Kheda District Chemists & Druggists Association	Letter
344	13/01/20 16	Indian Pharmaceutical alliance	Letter
345	21/01/20 16	Karnataka chemist & druggist association	Letter
346	2/2/2016	Chemist & Druggist Association District Unnao	Letter
347	2/2/2016	Chemist & Druggist Association - Balrampur	Letter

348	2/2/2016	Katni Chemists & Druggists Association	Letter
349	2/2/2016	Chemists Druggists Welfare Association	Letter
350	2/2/2016	Ballia Chemist & Druggist Association	Letter
351	2/2/2016	Chemists & Druggists Kalyan Association, Gonda	Letter
352	2/2/2016	Lakhimpur Chemist & Druggist association	Letter (2)
353	2/2/2016	Chemest & Drugist Klyan Association	Letter
354	Undated	Kailash Wani	Letter
355	Undated	A One Pharmacy	Letter
356	Undated	D S Rawat	Letter
357	Undated	SACHDEVA CHEMISTS	Letter
358	Undated	Giftland Chemo Agencies	Letter
359	Undated	Sondhi Chemist & Cosmetics	Letter
360	Undated	Yashpal	Letter

Annexure 3: E-prescription & E Pharmacy (Proposed model):

Benefits of E-prescriptions are:

- Easy and efficiently management of patient's medications.
- Achieving accuracy in prescriptions and dispensing averting medication errors
- Active monitoring
- Speedy process of renewing medications.
- Specifically, the benefits of e-prescribing to both patients and clinicians by eliminating problems of illegibility from handwritten
- Enhance an overall medication management process and can perform checks against the patient's current medications for drug-drug interactions, drug-allergy interactions and correctness of doses.
- System can set to give alerts about contradictions, adverse reactions, and duplications.
- Increased patient convenience and medication compliance.
- Improved drug surveillance, recall and management of Pharmacovigilance.
- Ruling out unauthorized dispensing, prescribing mistakes, illegible prescriptions, and patient misuse can cause personal health hazards.
- E-prescriptions generated can be printed and handed over to the

patient or can be transmitted electronically to the patient through Central portal. Patient carries this e-prescription to chemist or pharmacy (offline or online) of his choice. Such chemist will honor such prescription and register such transaction on NPE. Immediately after such registration of transaction e-prescription shall be defaced. No defaced prescription shall be honored.

- All the provisions proposed for online sale of drugs will be applicable to non-prescription drugs also except for the compliance of requirements of prescription.

Proposed model for online pharmacy

1. National portal shall be designed by utilizing all the latest technological advancements. It may be hosted in the cloud to manage and track Drug Dispensing process. Doctors will be required to create electronic prescriptions or paper prescriptions which can be scanned and uploaded in the cloud by the doctor or patient through intermediary link. These prescriptions may be linked with Aadhar card. These prescriptions will be uploaded on National portal using text messaging (SMS) or National portal application on Smart phones (iPhones or Android phones).
2. At a minimum, each prescription will contain the following information:
 - a. Unique Identification number

- b. Name of the patient
 - c. Phone number of the patient
 - d. Name/Dosage of the medicine
 - e. Compounding / Drug formularies
 - f. How many refills are allowed?
3. Patient can then walk into a pharmacy and show the code to the pharmacist or go to any one of the online pharmacy, registered with CDSCO.
 4. The scan copy of prescription uploaded by the patient on the intermediary link will be transmitted to the National portal wherein the authenticity of the patient will be verified through Aadhar card. National portal will generate One Time Password (OTP) and transmitted through the intermediary.
 5. Intermediary will validate the prescription by the competent technical staff and communicate to the patient their willingness to dispense the medicine along with the conditions.
 6. After receipt of confirmation from the patient, the intermediary will dispense the medicines as per the prescription. The details of the dispensation will also electronically transmitted to National portal.

Benefits of the Proposed model:

- a. Patient Satisfaction and Convenience

- Easy and Convenient
- Speedy process as it will use existing mobile phones/smart phones and messaging technology

b. Efficient Drug Surveillance

- All the prescriptions are electronic
- It can be easily tracked
- No possibility of counterfeit, forged prescriptions or reuse old prescriptions

c. Accuracy of Delivery

- The prescriptions are virtualized and once filled by the pharmacy cannot be used again to avoid patient misuse
- duplicate therapy or fraud or any medication errors

d. Monitoring

- The System can also track the specific pharmacist who dispensed medications to each particular patient.

e. Data Mining

- All prescription data and dispensing transactions will be maintained and tracked in a cloud
- Interfaces can be provided to insurance companies and

electronic medical record system vendors to detect drug interactions and formulary coverage checks.

f. Flexible Architecture

- Interfaces can also be provided to pharmacy inventory management software vendors to automate inventory control and prevent unauthorized drug dispensing.

g. Potential Cost Saving

- National portal prescription data will allow hospital emergency room physicians early detection of drug interaction or drug overdose problems which will result in huge savings for the government and private hospitals

Creation of National portal

- A National portal should be put in place through which prescription can be routed and it should be mandatorily by e-prescription. Therefore, all the transactions shall be routed through National portal owned by Government.
- The National Portal may be at Central level so as to route all the online transactions, e-prescriptions through this portal.
- All the existing retailers can be registered at this National portal.
- E-prescription issued by Doctor to online portal will be used only once and then it will be defaced by the system.

- Creation of suitable trust/board consisting of officials from relevant Ministries, drugs regulatory officials, representatives from intermediaries, on PPP model for developing/maintaining National portal
 - Trust/board may collect fees towards maintaining National portal from intermediaries involved in online sale of medicine
 - Registered Medical Practitioners (RMP), licensed pharmacies and patients involved in online pharmacy shall be registered with the National portal for verification of credentials.
-

Annexure 4: Draft Rules for amendment of Drugs and Cosmetics Rules,

1945.

Part VI B

Registration of Intermediaries to carryout Internet Pharmacy

67 I. Definitions: In these Rules, unless there is anything repugnant in the subject or context-

(a) "Internet Pharmacy" means, any person or any other person on his behalf or entity, offer or exhibit for sale or sale, distribute or dispense drug by means of the Internet.

(b) "E-Prescription" means an electronically generated prescription from a Registered Medical Practitioner to a Pharmacist to compound or dispense a drug to a patient.

(c) "Intermediaries" means any person or another person on his behalf or entity, receives, stores or transmits message or provides any service with respect to the Internet Pharmacy.

67 J.(1) Application for grant of registration of Intermediaries to carryout Internet Pharmacy: Application for grant of Registration for carrying out internet pharmacy shall be made in Form...XX ..to the Licensing Authority, as defined under Rule 21, and shall be accompanied by

i. an fee of rupees one lakh

- ii. constitution details of the applicant
- iii. Address proof of the applicant (Aadhar and PAN card)
- iv. Information about role and responsibilities of Intermediary
- v. List of retail sale licensees, with whom contract has been made to supply drugs.

Provided that the applicant shall furnish to the Licensing Authority such additional information as may be required by him in connection with the application in Form....XX

(2) On receipt of an application under sub-rule (1) of rule 67 J, the Licensing Authority shall, on being satisfied about the information and the documents enclosed with the application, grant the Registration in Form....YY.

(3) If the Licensing Authority is not satisfied with the information submitted for the requirements as specified under sub-rule (1) is not complied with, he shall reject the application and shall inform the applicant of the reasons for such rejection.

(4) A Registration Certificate shall remain valid, unless, it is suspended or cancelled, provided the registration holder deposits a registration certificate retention fee of rupees fifty thousand in every two years from the date of its issue.

Provided if the registration holder fails to pay registration certificate retention fee on or before the due date, he shall be liable to pay registration certificate retention fee along with a late fee calculated at the rate of rupees five hundred per day up to three months and thereafter the registration certificate shall be deemed to have been cancelled.

(5) The registration holder shall comply with the following conditions, namely:-

- i. The web servers of the registration holders shall be located in India.
- ii. Registration holder shall comply with relevant provisions of Information Technology Act 2000 and Rules thereunder.
- iii. All transactions of internet pharmacy shall comply with the provisions of Drugs and Cosmetics Rules 1945.
- iv. Information about due diligence observed by the intermediaries as specified in IT Act and Rules made thereunder shall be provided to concern Licensing Authority appointed by the State Government, as and when required.
- v. Registration holder shall not advertise any drug for promotion.
- vi. Prescription details shall be kept confidential and shall not be disclosed or used unless otherwise permitted by the Licensing Authority.

- vii. Registration holder shall link his website to the portal of the Central Government so as to allow all e-prescriptions to be transmitted to the said portal.
- viii. Registration holder shall provide facility for grievance redressal and online help by way of toll free helpline and by email to the patients.
- ix. Registration holder shall ensure that the storage conditions of the drugs are observed throughout and upto the delivery to the patient.
- x. Registration holder shall effect sale only from the respective State, from where it has received the order and expected it to be delivered.

6. Where the registration holder contravenes any provision of these rules, the Licensing Authority after giving the registration holder an opportunity to show cause why such an order should not be passed, shall by an order in writing including the reasons thereof suspend it for such period as it thinks fit or cancel the registration.

7. A registration holder whose registration certificate has been suspended or cancelled by the Licensing Authority may within sixty days of the receipt of a copy of the order by him, prefer an appeal to the Central Government, may after giving the registration holder an opportunity of being heard, confirm, reverse or modify such order.

8. E-Prescription shall have following content:

(i) Prescribers office information – [Name, qualification, address & Regn. No.]

(ii) Patient information – [Name & address, Age, Sex, Ref.No.]

(iii) Date

(iv) Rx Symbol

(v) Medication prescribed

(vi) Dispensing directions to Pharmacist

(vii) Directions for patient [to be placed on lable]

(viii) Refill, special labeling and /or other instructions

(ix) Prescriber's signature