



**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**

**30<sup>th</sup> September 2016**



**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: 30/09/2016**

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# 1. 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 48<sup>th</sup> 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 48<sup>TH</sup> 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 e-pharmacy service providers through internet was deliberated by the Drugs Technical Advisory Board (DTAB) in its 69<sup>th</sup> 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 e-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.
5. A copy of the order constituting the sub-committee is at Annexure 1.

## 2. 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

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.



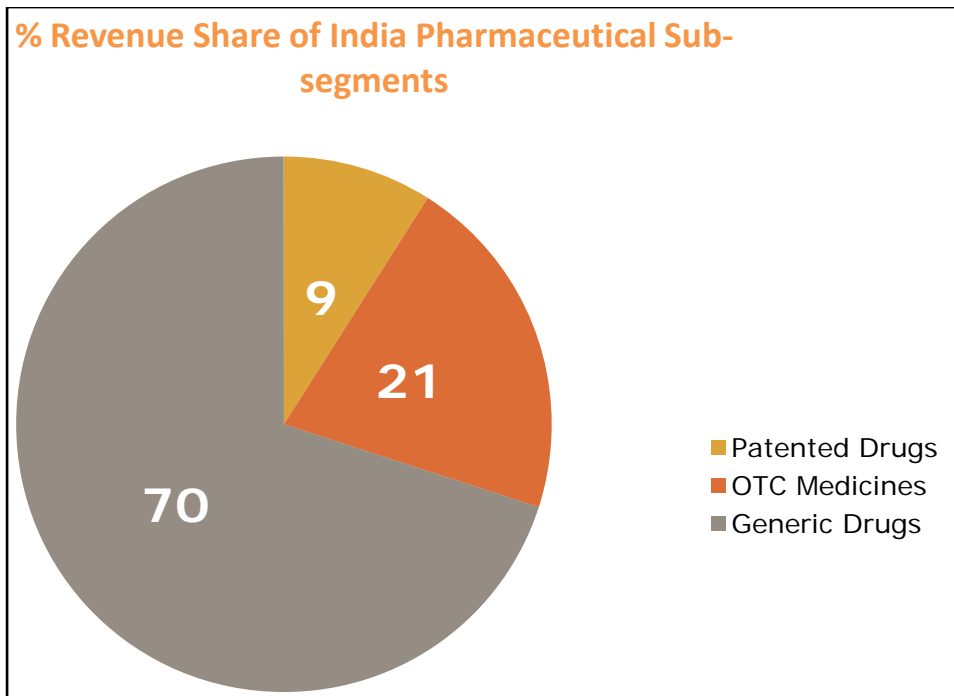
The existing rules are binding on whoever by himself or by any other person on behalf indulge in sell, distribute, stock, exhibit or offer for sale of any drugs. Therefore any drug which is to be sold by brick and mortar outlets or by e-pharmacy thorough web portals have to abide by the existing provisions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

## **2.2 INDIAN PHARMACEUTICAL INDUSTRY**

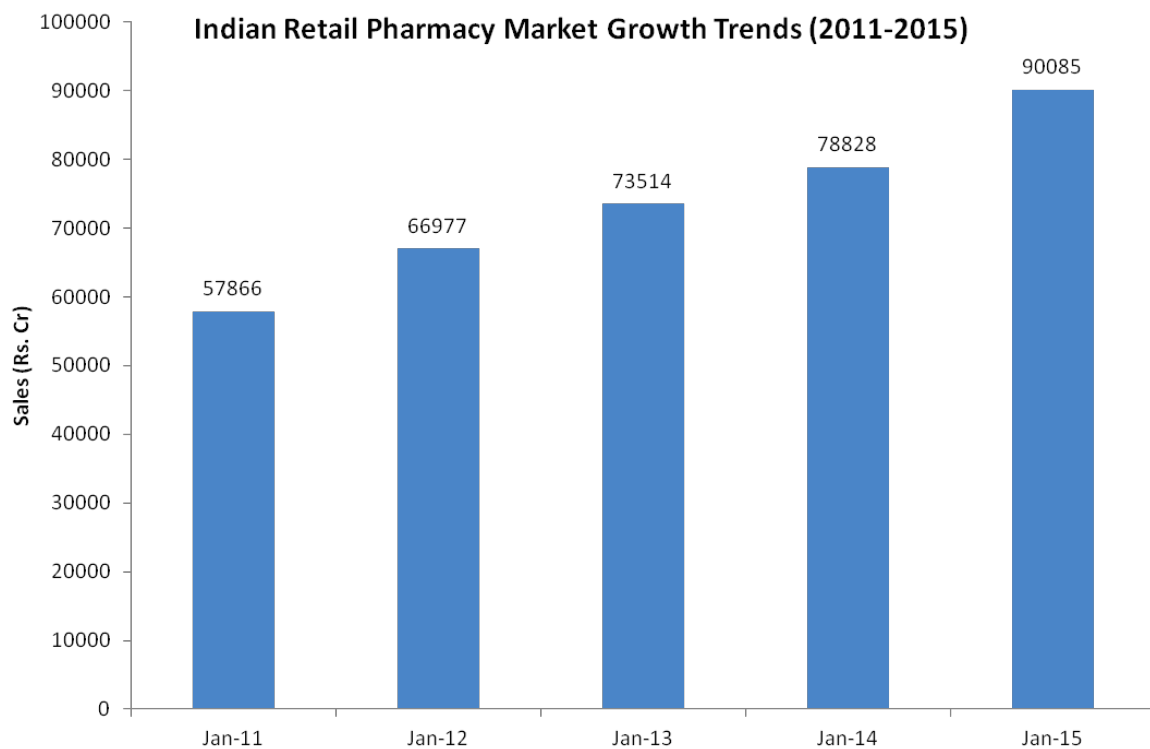
Indian Pharmaceutical Industry is one of the most vibrant sectors of Indian economy. It has been growing at the rate of 11-12%. It is the 3<sup>rd</sup> largest in the world by volume and 10<sup>th</sup> in value. The total size of the Indian Pharmaceutical Industry is about Rs 2 lakh crore out of which exports account for nearly 55%, out 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**

- Lack of patient counseling mechanism.
- Dissemination of drug information to the patients.
- Sale of drugs without prescription, thereby leading to drug abuse.
- Efficient mechanism of withdrawal of not of standard or prohibited drugs declared.
- Sale of drugs to the patient without bill may lead to traceability and recall problems.
- Requirement of huge inventory to be maintained leading to many products expiring on the shelf.

### **3. TECHNOLOGY ADOPTION AND TREND OF E-COMMERCE**

As per the mandate of the sub-committee the issue of IT enabled technologies and trend of e-commerce related issues were discussed and deliberated. A brief of which is given below;

Internet users in India in 2014 were 226.3 million and expected to be 411.1 millions in 2018. Global e-commerce 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, retailers 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 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;

### **3.2 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 to the regulatory compliances and access to the medicines for a lot of under-served population.

### 3.3 POSSIBLE BENEFITS OUT OF E-PHARMACY MODELS COULD BE

- Improves consumer convenience and access.
- It's 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.
- 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 will help in bringing price transparency, create awareness, find an appropriate healthcare service provider, medicine reminders, and pregnancy alerts to the consumers.
- Technology can be 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.
- Will increase entrepreneurship.

**However the sub-committee was also aware that the technology based e-commerce has its own issues and problems related with security, data integrity, illegal data exchange, infrastructure of IT in the country, possible misuse by the unscrupulous elements, etc. This was also discussed with the various stakeholders which is enumerated at page 35 & 36 of the Report.**

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

#### 3.4.1 TECHNOLOGY

- Web-based and/or mobile-based application for consumers transmits 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 by a licensed pharmacy.
- The web or mobile-based platform to be governed under the IT Act 2000 and rules there under.

### **3.4.2 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.

Details of the possible models of e-pharmacies are discussed in the later part of the report.

## 4. OVERVIEW OF THE STAKEHOLDERS

In all 6 meetings were convened 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 E-pharmacy, E-prescriptions, Electronic business platform, e-pharmacy service providers, 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 Policy for Due Diligence of E Pharmacy Model**

It suggested to provide for a separate chapter (Part VI-B) dealing with ‘Standards for facilitation of Sale of Drugs by Means of Internet, through Online Pharmacies’. This new chapter could specifically provide for the following:

##### **4.1.1.2 Separate License and Registry of Online Pharmacies**

- Separate form of license may be required for online pharmacies which will stock/sell medicines but not for online market places.
- For licensed physical pharmacies which desire to use the means of Internet and/or mobile applications to facilitate the sales of drugs would be required to procure this additional license.
- For entities which operate a purely market place model there would only be a requirement for obtaining this separate license from the appropriate authority.
- Provide for the creation of a registry of Online Pharmacies. Prescribe a specific logo for the purposes of identifying a licensed Online Pharmacy (‘Logo’).

##### **4.1.1.3 Information on the website**

- Detailed information regarding the Logo, License no and its authenticity, name and contact information of every pharmacy.
- The name and registration number of the responsible pharmacist.
- The procedure to lodge a complaint. An appropriate grievance redressal officer be duly appointed in this regard;

- The Online Pharmacy and marketplace may also be required to provide certain basic information regarding the drugs that are offered for sale on the Online Pharmacy.

#### 4.1.1.4 Exclusion of Schedule X and other habit forming drugs

- Schedule X and other habit forming drugs should be prohibited to be sold through internet.
- The Online Pharmacy may also be specifically obligated to ensure that adequate safeguards are in place to ensure that the Online Pharmacy does not process an order for Schedule X drugs or other habit forming drugs.
- The Drugs Rules may also provide for a Standard Operating Procedure (“SOP”) for the validation of the scanned copy of the prescription by the Online Pharmacy.

#### 4.1.1.5. Choice of Sellers

- The Online Pharmacy may also be obligated to conduct its due diligence before listing any pharmacy as a seller on its online portal.
- In the event some non-compliance is noted, the Online Pharmacy may be required to report the same to the appropriate authority under the Drugs Act read with the Drugs Rules, and immediately remove such physical pharmacy as a prospective seller of drugs ordered by the end-customer on the Online Pharmacy.

#### 4.1.1.6. Confidentiality of Patient Information

- Online Pharmacy would come into possession of certain sensitive personal information/ personal information [as defined under the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (“RSP Rules”), framed under Section 43A of the IT Act]. The Online Pharmacy would be required to fully comply with the provisions of the IT Act read with the RSP Rules regarding the handling and transfer of such information.

#### 4.1.1.7. Delivery of Drugs

- Suitable arrangements must be made to ensure that the medicines are packed, transported and delivered so that integrity, quality and effectiveness are preserved.
- The delivery mechanism must provide a verifiable audit trail
- The delivery mechanism must preserve the confidentiality and privacy of the end-customer

- Online Pharmacy to maintain a copy of the records required to be maintained and the same may be available for inspection by the appropriate authorities.
- 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, and 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 e-pharmacy in India as follows:

- The demand for e-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 e-pharmacy 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.
- E-pharmacy will create monopoly which will lead to non-viability of present physical pharmacies.
- Control and monitoring of the aggregators, courier operators, interstate transportation of medicines, loss of potency in transit, will be a major issue.
- The physical pharmacies especially in rural areas will not be viable hence will be shut to create unavailability of drugs in the rural areas.
- The monopoly will also create unemployment.
- Will lead to increase in self medication and use of drugs without intervention of professionals like Doctors and Pharmacists.

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 e-pharmacy service providers 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 e-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 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 e-pharmacy. 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 368 respondents in the form of benefits and risks of sale of drugs through internet are summarized below.

As suggested by the stakeholders there are 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.

In spite of above risks, some stakeholders have said in support of e-pharmacy, major benefits of online sale of drugs are:

1. Pharmacovigilance: As the supply of medicines to all patients 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.

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
General Public	173
Chemist & Druggists	45
Chemist Associations	111
NGOs	12
Press	6
Online Traders	4
Online Trade Associations	4
Mfg Companies	4
Mfg Co. Associations	4
Regulatory	4
Regulatory Association	1
	368

## 5. 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 elements 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.

#### **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 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.

MHRA is of the view that the continuous training for the effective monitoring of the mechanism of the online sale of medicines is necessary as it involves few risks as mentioned earlier.

## **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:

- E-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. SUMMARY OF SUGGESTIONS RECEIVED FROM VARIOUS STAKEHOLDERS

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.

### 6.1. Risks Involved

There are some alarming risks involved with sale of drugs through internet. They are:

- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- 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.
- 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.
- 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.
- Interstate transport: There are no specific rules for shipment of medicines from one state to another.
- 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.
- 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.
- 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.

## **6.2 Benefits of e-pharmacies**

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

- 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.
- 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.
- Consumer access: Online pharmacies can aggregate supplies, making otherwise hard to find medicines available to consumers across the country.
- Consumer education: Online pharmacies have the technology infrastructure to provide value added information to consumers, such as drug interactions, side effects, medicine reminders etc.
- 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.
- 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.
- 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.
- 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.
- Transaction records: Organized online players have systematic records for all transactions.
- 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.
- 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.

- Prediction of misuse of drugs: The customer order frequency is recorded along with the name of prescriber. This helps predict potential misuse of drugs.
- 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.

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

### **6.3 OBSERVATIONS OF THE SUB-COMMITTEE**

Based on the presentations made by the different stakeholders, invitees, information received and on the pros and cons of the issue the observations were looked into and the different models existing in the different countries, the ratio of benefits & risks of the IT based e-pharmacies, the sub-committee discussed various models of e-pharmacies. The brief of which is produced as follows;

#### **6.3.1 VARIOUS BUSINESS MODELS ABOUT E-PHARMACY**

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

6.3.1.1 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;

- Display of product on website
- Choose the product
- Order
- Order sent to the medical stores
- Medical stores packs the parcel
- Sends it by courier
- Courier company through delivery boy delivers to the customer
- 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 as it is done without a license as required under the said Act.

6.3.1.2 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:

- Display of product name on website
- Choose the product
- Order
- Upload the scanned copy of the prescription
- Order sent to the medical stores
- Medical stores packs the parcel
- Sends it by delivery boy
- Verifies the prescription, stamps it
- 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 not in compliance with the provision of Information Technology Act 2000 and other relevant rules notified under the said IT Act 2000.

6.3.1.3 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;

- Medical Practitioner writes a prescription / eprescription
- Directly transmits it to medical stores with a copy to the customer
- Medical stores packs the parcel
- Sends it by delivery boy
- Verifies the prescription, stamps it
- 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 license 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 not in compliance with the provision of Information Technology Act 2000 and other relevant rules notified under the said IT Act 2000.

#### **6.4 E-PRESCRIPTION**

Integrity, authenticity of prescription is crucial in this process. Major non compliance observed in the above said online pharmacy cases is regarding prescriptions, its multiple use, issued from fake doctors, etc. To address this issue subcommittee looked into the possibility of electronic prescriptions.

Electronic prescriptions are medical prescriptions generated by electronic mode, gadgets, devices which are verifiable, can be printed, transmitted.

##### **6.4.1. BENEFITS OF E-PRESCRIPTIONS ARE:**

- Easy and efficient 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 be 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.

## **6.5 NATIONAL PORTAL**

After lot of discussions and deliberations, based on the above information, in view of sub-committee, the concept of National portal could be appropriate to minimise the risks involved and its impact on public health, to handle the issue of e-pharmacy. So the sub-committee was of the view that;

National Portal may be setup at central level so as to route all the online transactions, eprescriptions through this portal, to which all the existing Wholesalers, Retailers can be registered. Online sale of medicine shall be only allowed through this national portal.

Registration should be provided in the Drugs and Cosmetics Rules, 1945 and could have geographical restriction to operate.

To avoid misuse, malpractices and self medication, online sale of drugs shall be made only on eprescriptions or electronically generated and signed in compliance with provisions of IT Act 2000 and other rules under the said act.

The different models can be designed about the working of National Portal depending on the technology and structure used. A suggestion on possible model is annexed.

## 7. RECOMMENDATIONS

Subcommittee was of the view that adopting technology for benefit of human being should not pose risk, since medicines deals with human life and it affects the interest of public health. Any ill effect of online sale of medicine would be irreversible and hence the approach has to be very cautious. Hence the sub-committee is of the view that until the systems and specific provisions is in place, e-pharmacy may not be allowed.

Considering the above Subcommittee is of the view of that in order to minimize risk and adverse effect use of technology for benefit in case of online sale of medicine, it can be allowed in a limited way and that too with strict monitoring and supervisory approach.

So also to have effective monitoring and proper enforcement of the act in achieving aims and objects of the Act, some geographical restrictions are required for administrative convenience. Geographical restrictions will assure proper regulatory control through periodical inspections through local enforcement agency and sampling of medicines sold through these 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.

It is observed that due to technology development and evolving different model for business it is inevitable to accept these business processes in the interest of patients and consumer. It is well known that online sell of commodities is in the interest of consumer convenience. It will also have increase consumer access to the medicine. Fair competition will also compel the market players to offer medicine at rescannable prices and sometimes at discounts. In light of Government of India policy about ease of doing business, new business models cannot be ignored.

The committee had detailed discussions based on suggestions and comments offered by various stakeholders involved in the manufacture, sale and distribution of drugs, consumer, medical and pharma associations, regulatory agencies including customs, NCB, ED, and IT organizations viz., NIC, CDAC on the issues relating to online sale of drugs. It also received around 368 representations from individuals and other organizations. The Committee had examined the suggestions made by various stakeholders and also the international practices followed in some of the major countries. The Committee agrees that the sale of medicine, being an integral part of the healthcare system, shall ensure safety of the patients, availability of quality medicines at affordable price to all the consumers whether in urban or rural areas and also provide proper level playing mechanism for all. Further, it was felt that there is a immediate need to have

effective regulatory mechanism before adopting new technologies in the sale of medicines to protect public health.

After going through the suggestions made by various stakeholders and also keeping the existing provisions of the Drugs and Cosmetics Act, 1940 and rules made there under, NDPS Act, 1985, DMR(OA) Act, 1954, DPCO, 2013, IT Act, 2000 etc., the members of the Committee deliberated the issue in detail, Committee makes the following recommendations:

- 7.1 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 or abuse 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.
- 7.2 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.
- 7.3 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 due to lack of clarity on the applicability of the provisions under the Drugs and Cosmetics Rules, 1945. 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.
- 7.4 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.

- 7.5 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.
- 7.6 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 e-pharmacy service providers which do not directly indulge in stocking, exhibiting and sale of drugs. Since e-pharmacy 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.
- 7.7 E-pharmacy Service providers for sale of drugs may be considered as intermediaries for the purpose of service with respect to the e-pharmacy. It is, therefore, recommended that suitable amendments need to be made in the Drugs and Cosmetics Rules, 1945 in order to define functions, responsibilities, procedures for registration, fee, suspension and cancellation of registration and conditions of registration of such e-pharmacy service providers.
- 7.8 E-pharmacy service providers shall effect sale only from the respective State from where it has received the order and expected it to be delivered through licensed retail chemist of that State
- 7.9 All the existing licensees carrying out sale of drugs by way of retail would also be able to register on the National portal for carrying out online sale of drugs. All 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.
- 7.10 Online sale of drugs may be permitted either on e-prescriptions (electronically generated and digitally signed) or scanned copy of the prescription, verified by the prescriber through the National portal, in compliance with provisions of IT Act, 2000 and rules made there under.
- 7.11 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 fake or forged prescription. To address these issues, it is recommended to accept only e-prescriptions or electronically generated and digitally signed prescriptions.

- 7.12 The dispensing of drugs be done from a premises holding license by way of retail under part VI of Drugs and Cosmetics Rules, 1945 against valid e-prescription including scanned copy of the prescription issued by a Registered Medical Practitioner.
- 7.13 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.
- 7.14 Provision shall be made in the rules for patients to easily contact internet pharmacies, through telephone helpline, message and email, to clarify any questions regarding dosage, method of administration, contraindications, drug type, adverse effects etc.
- 7.15 Critical areas such as validity and verifiability of prescriptions, delivery of medicines, monopolistic practices, technology platform, policy for honoring prescriptions, database of medical practitioners and 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 internet pharmacies.
- 7.16 Detailed system architecture for the National portal/cloud need to be developed. Some ideas on this are at Annexure 2.
- 7.17 Drugs not permitted through e-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 e-pharmacies.
- 7.18 Confidentiality of patient information
  - Safety of patient is of utmost importance and it is his right to keep his personal 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.

7.19 A registry of internet pharmacies should be made available on the National portal. Information to be available on the website of e-pharmacy is as under:

- All internet 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 e-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 internet pharmacy.

7.20 Delivery of medicines

- The licensee shall ensure that the medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved.
- All the internet pharmacies shall be in conformance to Good Distribution Practices (GDP).

7.21 Amendments required in the Drugs and Cosmetics Rules, 1945

- Proposed rules for amendment of Drugs and Cosmetic Rules, 1945 is annexed at Annexure 3.
- 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 internet Pharmacies.
- Product advertisements of the Scheduled drugs shall be prohibited on the electronic Medias.

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

It is suggested that while developing the model, help from other countries like USA, UK may be sought, so that their experience will facilitate in creating the effective and robust system.

## 8. ACKNOWLEDGEMENT

Sub-committee hereby acknowledges

1. The Drugs Consultative Committee for entrusting the subject to the members of the sub-committee.
2. Drugs Controller General for extending all the support to the sub-committee
3. All the stakeholders such as industry, Associations, NGOs, representatives from the various departments of the State and Central Government, individuals, etc. for participating and making valuable suggestions to the committee.

## 9. ANNEXURES

### 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 46<sup>th</sup> 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 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

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: E-PHARMACY (PROPOSED MODEL):**

### **PROPOSED MODEL FOR E-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. RMPs will be required to generate electronic prescriptions or paper prescriptions which can be scanned and uploaded in the cloud by the RMPs or patient through intermediary link. Prescriptions that are uploaded by the patient in a cloud are required to be authenticated by the concerned prescriber to avoid multiple upload of the prescription and to verify its authenticity. These prescriptions may be linked with patient's Aadhar card. These prescriptions will be uploaded on National portal using text messaging (SMS) or through mobile applications.
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 of the medicine in capital letters
  - e. Dosage of the medicine
  - f. Compounding / Drug formularies
  - g. How many refills are allowed?
3. Patient can then walk into an offline licensed retail chemist and show the code to the pharmacist or go to any one of the internet pharmacy, registered with Central Govt.
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 registered pharmacist 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. It also helps to recall the medicine as and when required from the patient/consumer.
- e. Data Mining
  - All prescription data and dispensing transactions will be maintained and tracked in a cloud
- f. Flexible Architecture
  - Interfaces can also be provided to pharmacy inventory management software vendors to automate inventory control.

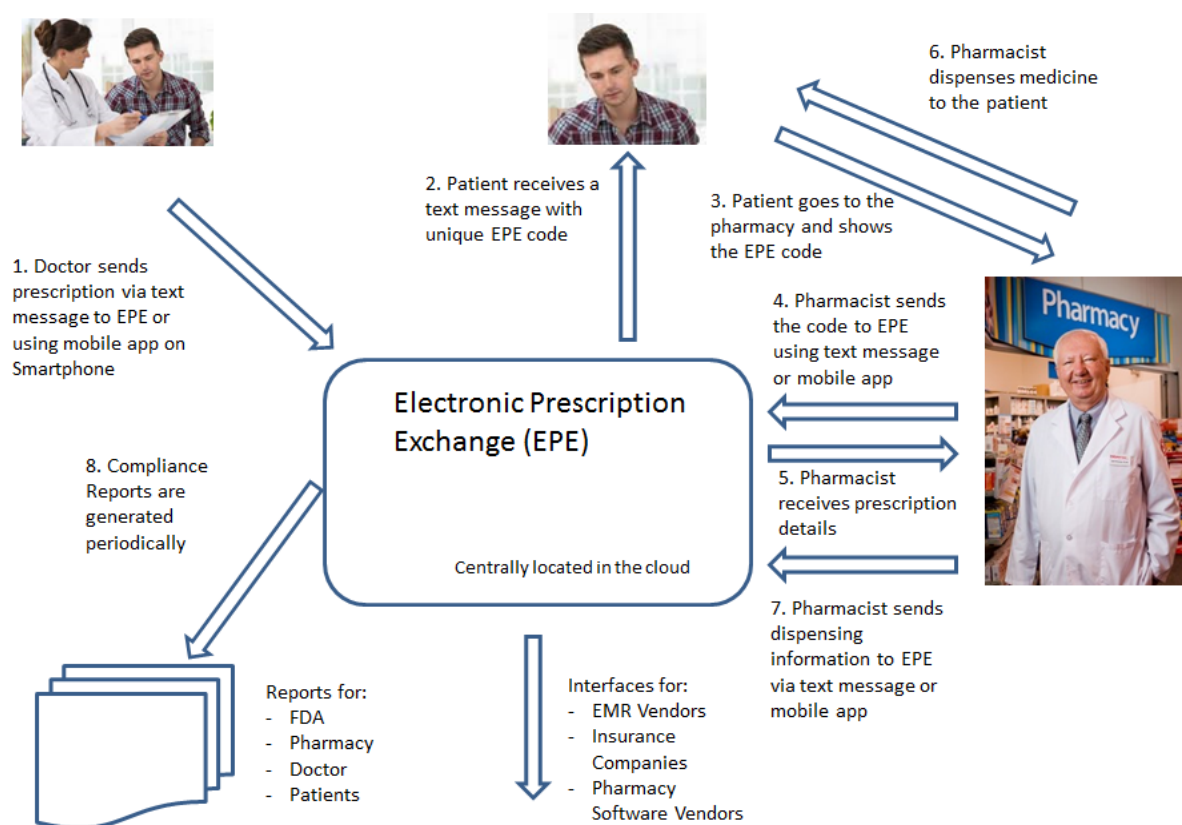
## **CREATION OF NATIONAL PORTAL**

- 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 e-pharmacy transactions, e-prescriptions through this portal.
- All the existing retailers can be registered at this National portal.

- System may be designed such that E-prescription issued by Doctor to online portal will be used only once.
- Creation of suitable trust/board consisting of officials from relevant Ministries, drugs regulatory officials, representatives from e-pharmacy service providers, on PPP model for developing/maintaining National portal.
- Trust/board may collect fee towards maintaining National portal from e-pharmacy service providers involved in online sale of medicine
- Registered Medical Practitioners (RMPs), licensed pharmacies and patients involved in online pharmacy may be registered with the National portal for verification of credentials.

### POSSIBLE TECHNOLOGICAL MODEL

Proposed model involves replacing paper based prescriptions with electronic prescriptions as



shown below.

*Figure 1: Workflow*

“Electronic Prescription Exchange” in the Cloud will be used to manage and track new Drug Dispensing process. Doctors will be required create electronic prescriptions rather than paper prescriptions. These prescriptions can be sent using text messaging (SMS) or EPE application on Smart phones (iPhones or Android phones). At a minimum, each prescription will contain the following information:

- Unique Identifier
- Name of the patient
- Phone number of the patient
- Name/Dosage of the medicine
  - Compounding / Drug formularies
- How many refills are allowed? (Optional)

Doctor’s name and registration number is automatically identified by matching phone number of the incoming message with the registered phone number of the doctor in the “EPE registry”. All the prescription information is maintained by EPE. A unique code is generated for each prescription and sent to the patient’s phone as a text message (SMS). Patient can then walk into a pharmacy and show the code on his/her phone to the pharmacist or go to an online pharmacy and enter the code on the online pharmacy’s website. Retail pharmacist sends the prescription code and patient’s phone number to EPE by entering it on EPE’s website or by sending it to EPE via text messaging or Smart phone application. EPE matches the code and patient’s phone number to retrieve the prescription and sends it to the pharmacist via text message or Smart phone application message. For security, prescription information is sent only to a pharmacist registered with EPE. Once pharmacist receives the prescription information, he/she dispenses the medicine and sends amount dispensed to EPE by entering it on EPE’s website or via text messaging or Smart phone application. EPE keeps track of amount dispensed for compliance reporting and for tracking refill requests. EPE periodically generated (once a month) and sends compliance reports to FDA and sends financial/medical history reports to doctors, pharmacists and patients.

#### **BENEFITS OF THE PROPOSED SOLUTION**

- Patient Satisfaction and Convenience → Easy and Convenient, Speedy process as it will use existing mobile phones/smart phones and messaging technology
  - Physician and Pharmacist can always use computer is at all required

- **Efficient Drug Surveillance**→All the prescriptions are electronic; they can be easily tracked. Nobody can produce counterfeit, forged prescriptions or reuse old prescriptions
- **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
- **Monitoring** →Patient cannot get prescription details, and he/she cannot get the medicine from anybody other than registered pharmacist. The System can also track the specific pharmacist who dispensed medications to each particular patient.
- **Data Mining** →Drug Interactions→All prescription data and dispensing transactions are 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.
- **Flexible Architecture** →Interfaces can also be provided to pharmacy inventory management software vendors to automate inventory control and prevent unauthorized drug dispensing.
- **Potential Cost Saving**→EPE 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

## **TECHNICAL CONCEPTS AND HIGHLIGHTS**

- **Infrastructure**
  - Cloud based Electronic Prescription Exchange→ Load balancing → Failover
  - Push and Pull Technologyto facilitate multiple use case scenarios – both for retail pharmacies and online pharmacies
    - ~ Push: Physician →EPE Platform
    - ~ Push: Patients →sms/text messages → EPE Platform
    - ~ Pull: Pharmacist ←EPE Platform
    - ~ Push: Completed transactions: Pharmacist ←EPE Platform
- **Frees solutions from Platforms Portal (Physician, Pharmacist)**
- **Software development Kits for third party**

- For application vendors to develop Smart phone and Laptop applications for Doctors, Pharmacists
- Regional languages User Interface can be build (Backend transactions will always be standardized)
- For EMS vendors to do integration with EPE
- For Insurance companies to do integration with EPE
- For Pharmacy Inventory Software vendors to do integration with EPE
- **Centralized Business Rules**
  - ~ Onboarding for Doctors
    - Consent forms
    - Compliance forms
  - ~ Onboarding of Pharmacies
    - Consent forms
    - Compliance forms
    - E.g. Pharmacies send information back to EPE after transaction is complete.
    - If data not received for last 3 transactions → send warning → Disable further transactions
  - ~ Onboarding for online Pharmacies
    - Consent forms
    - Compliance forms

## HIGH LEVEL TECHNICAL ARCHITECTURE

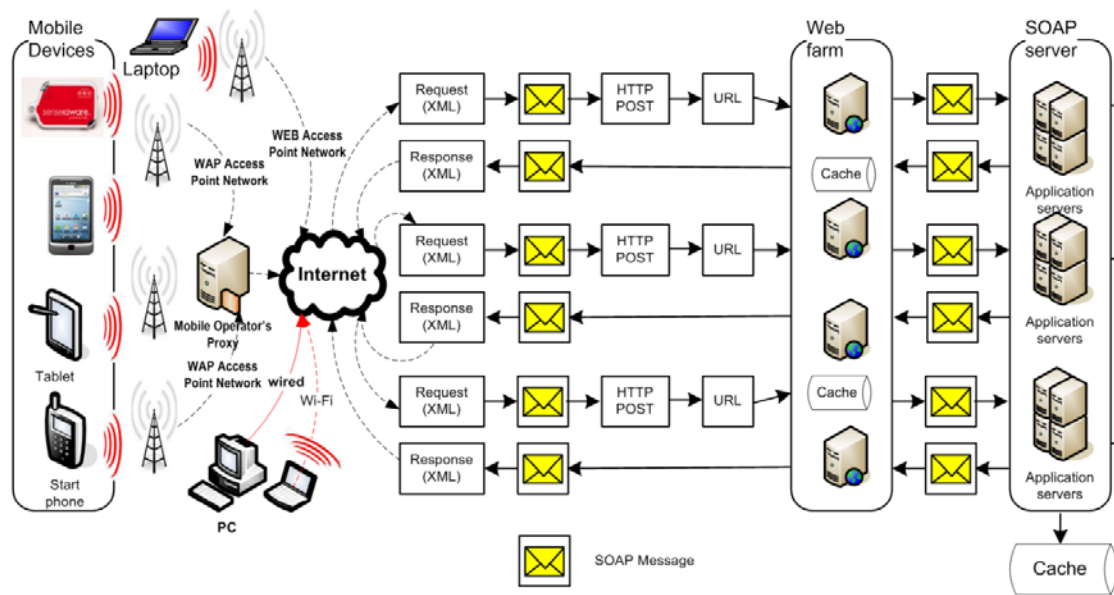


Figure 2: Infrastructure

### RESOURCES/ EXPERTISE REQUIRED

Based on the current high level requirements the following team will be required to deliver the solution

- Consultants with experience and IP in US markets
- Solution Architects with experience
- Development Team
- Operations team

## **ANNEXURE 3: DRAFT RULES FOR AMENDMENT OF DRUGS AND COSMETICS RULES, 1945.**

### **PART VI B**

#### **REGISTRATION OF E-PHARMACY SERVICE PROVIDERS TO CARRYOUT E-PHARMACY**

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

- a. “E-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 information technology and is registered under these rules.
- 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. “E-pharmacy service provider” means any person or another person on his behalf or entity, receives, stores or transmits information or provides any service through E-pharmacy or chemist and druggist and is registered under these rules.

Explanation: For the purposes of this rule “information” means as defined under section 2(v) of the Information Technology Act, 2000.

67 J.(1) (A) Application for grant of registration of E-pharmacy service providers: Application for grant of Registration for carrying out e-pharmacy shall be made in Form...XX(A) ..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 /Passport/ Driving license )
- iv. Information about role and responsibilities of E-pharmacy service provider.
- v. Name, qualification, registration number of the registered pharmacist whose services are employed.
- vi. List of retail sale licensees, with whom contract has been made to supply drugs.
- vii. Lists of the States /UTs where the applicant intend to offer the service.
- viii. Details of the licenses issued by the SLA to the applicant in the respective State where they intent to offer the services.



(B) Application for grant of registration of chemist and druggist to carryout E-pharmacy: Application for grant of Registration for carrying out e-pharmacy shall be made in Form...XX(B) ..to the Licensing Authority, as defined under Rule 21, and shall be accompanied by

- i. an fee of rupees ten thousand
- ii. Details of the licenses issued by the State Licensing Authority.

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 of the E-pharmacy service provider shall remain valid, unless, it is suspended or cancelled, provided the E-pharmacy service provider deposits a registration certificate retention fee of rupees fifty thousand in every two years from the date of its issue.

Provided if the E-pharmacy service provider 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 one thousand 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 through which they are offering services and mining the data thereof.
- ii. Registration holder shall carryout the e-pharmacy, with respect to drugs categorized under schedule H, H1 or G, only on the e-prescriptions and not otherwise.
- iii. Registration holder shall engage the services of at least one registered pharmacist.
- iv. Registration holder shall comply with relevant provisions of Information Technology Act 2000 and Rules thereunder.
- v. All transactions of e-pharmacy shall comply with the provisions of Drugs and Cosmetics Rules 1945.

- vi. Information about due diligence observed by the e-pharmacy service providers as specified in IT Act and Rules made thereunder and shall be provided to concern Licensing Authority appointed by the State Government, as and when required.
- vii. Registration holder shall not advertise any drug for promotion.
- viii. Prescription details shall be kept confidential and shall not be disclosed or used unless otherwise permitted by the Licensing Authority.
- ix. 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 and will display the unique identification generated through national portal.
- x. E-pharmacy service provider shall provide facility for grievance redressal and online help by way of toll free helpline and by email to the patients.
- xi. Registration holder shall ensure that the storage conditions of the drugs are observed throughout and upto the delivery to the patient.
- xii. Registration holder shall effect sale only from the respective State / UT from where it has received the order and expected it to be delivered through licensed retail chemist of that State.
- xiii. E-pharmacy service providers shall effect sale only from the respective State from where it has received the order and expected it to be delivered through licensed retail chemist of that State.
- xiv. Registration holder shall not carry out e-pharmacy with respect to the drugs covered under the categories of the Narcotic, psychotropic, tranquilizers, and Schedule X drugs.
- xv. Registration holder shall carry out e-pharmacy only to the place located in India.

(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

## ANNEXURE: 4 REPRESENTATIONS AND SUGGESTIONS RECEIVED

Sr. No	Date	Received from	Mode of receipt
1	22/04/2015	The Maharashtra State Chemists & Druggists Association	Letter
2	7/5/2015	The Bangalore Dist Chemists and Druggists Association	Email (attachment)
3	14/05/2015	The Hindu Business Line	Email
4	21/05/2015	Senior Correspondent - DNA Money	Email
5	21/05/2015	FDA Nashik	Email (attachment)
6	29/05/2015	Article by vhshah2014@gmail.com	Email
7	29/05/2015	Naishadh	Email
8	30/05/2015	The Times Of India	Email
9	30/05/2015	Amir Gandhi (Pune)	Email
10	30/06/2015	The Retail & Dispensing Chemists Association (Mumbai)	Letter
11	2/7/2015	Mohan Kale (nnagencies@yahoo.com)	Email
12	29/07/2015	Atul Bhosekar	Email
13	1/8/2015	Indian Pharmaceutical Association - Maharashtra State Branch	Letter
14	11/8/2015	Raj Vaidya (community pharmacist, Goa)	Letter
15	20/08/2015	Amar Dani (Thane District)	Email
16	21/08/2015	All India Organisation of Chemists and Druggists	Letter

17	27/08/2015	Dawa Bazar Hindu Monthly Magazine	Email (attachment)
18	29/08/2015	Raj Vaidya (community pharmacist, Goa)	Email
19	31/08/2015	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	21/09/2015	Chemist & Druggist association Goa	Letter
25	22/09/2015	Chandu Mhatre (chandumhatre12@gmail.com)	Email
26	22/09/2015	Maharashtra Registered Pharmacist Association (Aurangabad)	Email
27	22/09/2015	Qamrul Hasan Khan (Prince Medical StoreS)	Email
28	22/09/2015	Liladhar Gosar (Shree Paras Medical & General Stores)	Email
29	22/09/2015	rsjumani@yahoo.com	Email
30	23/09/2015	Tomar Medical stores (New Delhi)	Email
31	23/09/2015	Narang Chemist	Letter
32	23/09/2015	Trinath Singh & Bros. Dispensing Chemists (Chandigarh)	Email
33	23/09/2015	gurbakshluthra99@gmail.com	Email

34	23/09/2015	Anand Medical Stores (Chandigarh)	Email
35	23/09/2015	Consumer Rights Education & Awareness Trust	Email (attachment)
36	23/09/2015	The Bangalore Dist Chemists and Druggists Association	Email (attachment)
37	23/09/2015	Arvind Verma (vermabrothers14@gmail.com)	Email
38	23/09/2015	New Plaza Medical Store	Email
39	23/09/2015	Ravi Shankar V. V. (Tamil Nadu)	Email
40	23/09/2015	Indian Pharmacist Association	Email (attachment)
41	23/09/2015	Nemi Medical Stores (Gujarat)	Email
42	23/09/2015	Udupi Chamber of Commerce & Industry (Incorporated)	Letter
43	23/09/2015	Mycon	Email
44	24/09/2015	Jatin Jain (jatinnareshjain@gmail.com) <sup>1</sup>	Email
45	24/09/2015	Nagpur District Chemist's & Druggists Association	Email
46	24/09/2015	Super Medicos (New Delhi)	Email
47	24/09/2015	Vardhaman Chemist	Email
48	24/09/2015	Kuldeep Singh	Email
49	24/09/2015	Hamza Lakdawala (Rehamt Medical)	Email
50	24/09/2015	Rajeev Malik	Email
51	24/09/2015	SKS Techno Tools (Nand Kishore)	Email
52	24/09/2015	Arun (4th year, Law university)	Email

53	24/09/2015	Shashi Bisht	Email
54	24/09/2015	Lalit Aggarwal	Email
55	24/09/2015	Arvind Verma (vermabrothers14@gmail.com)	2nd Email
56	24/09/2015	Jai Aggarwal	Email
57	24/09/2015	G. S. Medicine Company	Email
58	24/09/2015	KK Selvan	Email
59	24/09/2015	Sakthi Medical	Email
60	24/09/2015	Vikas Singh	Email
61	24/09/2015	Rachna Goel	Email
62	24/09/2015	Dr. Vishnu Dua	Email
63	24/09/2015	Sneha Narang	Email
64	24/09/2015	Avinash Pandey	Email
65	24/09/2015	Priyanka Srivastava	Email
66	24/09/2015	Ajay Aggarwal (Shiv Meidcal Store, Delhi)	Email
67	24/09/2015	Santosh Kumar	Email
68	24/09/2015	Unique Medical (Mumbai)	Email
69	24/09/2015	K. Jayawant (Drugs Controller, RMSC, Rajasthan, Jaipur)	Email
70	24/09/2015	Team Doar India (NGO Founder)	Email
71	24/09/2015	Hakimi Pharmacy (Mumbai)	Email
72	24/09/2015	Jitendra Kumat	Email

73	24/09/2015	Rekha tomar	Email
74	24/09/2015	Sunit Tanwar (Delhi)	Email
75	24/09/2015	The maharashtra state chemist & druggists associatopn	Letter
76	25/09/2015	Pashim Nimad Jila Chemist Association	Letter
77	25/09/2015	Ujjain District Chemist & Druggist Association	Letter
78	25/09/2015	Jila Aushadhi Vikreta Sangh, Sagar	Letter
79	25/09/2015	Jila Rajgad Aushad Vikrata Sangh	Letter
80	25/09/2015	Orissa Homeopathic Druggist Association	Letter
81	25/09/2015	Netmeds Marketplace Ltd.	Letter
82	25/09/2015	The Tamilnadu Chemists & Druggists Association	Letter
83	25/09/2015	Bruhath Bengaluru Chemists and Druggists Association	Letter
84	25/09/2015	Ballia Chemist & Druggist Association	Letter
85	26/09/2015	Ankur Gambhi (Pharmacist, Delhi)	Email
86	26/09/2015	Ankit Tyagi (Noida)	Email
87	26/09/2015	Consumers' Forum (Karnataka)	Letter
88	26/09/2015	All Kerala Chemists & Druggists Association	Letter
89	26/09/2015	Vinay Kumar Bharti (Journalist, Delhi)	Email
90	26/09/2015	Avinash Chaturvedi (Delhi)	Email
91	27/09/2015	Health Saverz	Email



92	27/09/2015	Consumer Online Foundation	Letter
93	27/09/2015	Monika karla	Email
94	27/09/2015	Laxmikant Sharma	Email
95	27/09/2015	Seoni District Chemist Asosication	Letter
96	27/09/2015	A. P Rationallist Association (Andhra Pradesh)	Email
97	27/09/2015	Girish Vaghela	Email
98	27/09/2015	Jilha aushadhi vikreta sangh Chindvada(M.P.)	Letter
99	28/09/2015	Tausif Ahmed	Email(attachment)
100	28/09/2015	Panneer Selvam	Email
101	28/09/2015	Indian Pharmaceutical Association	Email (attachment)
102	28/09/2015	Practo.com	Email (attachment)
103	28/09/2015	The Maharashtra State Chemists & Druggists Association	Email (attachment)
104	28/09/2015	Lalita Devi (Patient)	Email
105	28/09/2015	Indian Internet Pharmacy Association	Email (attachment)
106	28/09/2015	Jomy (Student - Manipal College of Pharmaceutical Sciences)	Email (attachment)
107	25/09/2015	M/S Upasham (Hooghly/0	Email
108	28/09/2015	All India Organisation of Chemists and Druggists	Letter (3)
109	28/09/2015	Tiruvarur District Chemists & Druggists Association	Letter

110	28/09/2015	HIMSS Asia-Pacific India Chapter	Letter
111	28/09/2015	SUN Pharma	Letter
112	28/09/2015	Betul Jila Aushadhi Vikreta Sangh (Betul)	Letter
113	28/09/2015	All India Chemist and Distributors Federation	Email
114	28/09/2015	Jila Chemist and Druggist Association (Barhanpur)	Email (attachment)
115	28/09/2015	The Federation of Gujarat State Chemists & Druggists Associations	Letter
116	28/09/2015	IIPA	Email (attachment)
117	28/09/2015	Tirath Singh & Bros.	Email
118	28/09/2015	Krishanan Krishanan	Email
119	28/09/2015	Pradeep Tomar	Email
120	28/09/2015	Vinod Gupta	Email
121	28/09/2015	Dev Mediplus	Email
122	28/09/2015	Anjaneyulu Chidella	Email
123	28/09/2015	Paras Medicals	Email
124	28/09/2015	RS Jumani	Email
125	28/09/2015	Ravi Medical & General Store	Email
126	28/09/2015	Pankaj	Email
127	28/09/2015	Gaurav Sethi	Email
128	28/09/2015	Sujeet Gupta	Email

129	28/09/2015	Apna Medical Store	Email
130	28/09/2015	Praveen Medical Store	Email
131	28/09/2015	Jitendra Kumar	Email
132	28/09/2015	Al Madina Medical & General Store	Email
133	28/09/2015	Vaibhav Rastogi	Email
134	28/09/2015	Paras Jain	Email
135	28/09/2015	Gajendra Singh	Email
136	28/09/2015	Murtuza	Email
137	28/09/2015	Shyam Aggarwal	Email
138	28/09/2015	Rakesh Kakrian	Email
139	28/09/2015	Divvay Tomar	Email
140	28/09/2015	Deepanshu Jain	Email
141	28/09/2015	Satna Distt. Chemist Association	Letter
142	28/09/2015	Hoshangabad District Chemist and Druggist Association	Email (attachment)
143	28/09/2015	Dr. B. R. Jagashetty	Letter
144	28/09/2015	Medlife International Ovt. Ltd.	Letter
145	28/09/2015	Mandi Chemist and Pharmacists Association	Email
146	29/09/2015	Kuldeep Jain	Email
147	29/09/2015	shivam surgical and medicos	Email
148	29/09/2015	Alakh Bhatia	Email
149	29/09/2015	District Gurgaon Chemist & druggist	Email(attachment)

		association	
150	29/09/2015	Archana and team community	Email
151	29/09/2015	Anil Aggarwal	Email
152	29/09/2015	Aji Eapen	Email
153	29/09/2015	Rohit Bhatia	Email
154	29/09/2015	Rajeev Ranjan	Email
155	29/09/2015	Kavin Sachin	Email
156	29/09/2015	Sachin Gupta	Email
157	29/09/2015	Ravi Narayan	Email
158	29/09/2015	Mandsar Dist Chemist and Druggist Association	Email (attachment)
159	29/09/2015	Ankur Gambhir	Email
160	29/09/2015	Lialitha	Email (attachment)
161	29/09/2015	Chemist Association	Email (attachment)
162	29/09/2015	Rajendra Kumar Chawla	Email
163	29/09/2015	GS Medicine Company	Email
164	29/09/2015	Vishnu Dua	Email
165	29/09/2015	Tarun Sarna	Email
166	29/09/2015	Shiv Medical Store	Email
167	29/09/2015	Junaid Thunder	Email
168	29/09/2015	Uma	Email
169	29/09/2015	Inder Sachdev	Email

170	29/09/2015	Trupti Powar	Email
171	29/09/2015	Saroj medicals	Email
172	29/09/2015	S P Suresh	Email
173	29/09/2015	Shaikh Rais Ahmed	Email (attachment)
174	29/09/2015	G venkateshan	Email
175	29/09/2015	Harish Kumar	Email
176	29/09/2015	MRTOP Retailers	Email
177	29/09/2015	Dawar Medicos	Email
178	29/09/2015	Ramchandran Srin	Email(attachment)
179	29/09/2015	Panchal Sandesh	Email (attachment)
180	29/09/2015	Rajesh Kumar	Email (attachment)
181	29/09/2015	Yashpal Soni	Email
182	29/09/2015	Manish Karel	Email
183	29/09/2015	Rohit	Email
184	29/09/2015	Vijay Jadhawani	Email
185	29/09/2015	Dinesh Singh	Email
186	29/09/2015	Raghvendra Singh	Email
187	29/09/2015	Srinivas.chidurala	Email
188	29/09/2015	Arun	Email
189	29/09/2015	Ashish Medical Agency	Email
190	29/09/2015	A.P Rationalist association	Email

191	29/09/2015	Yasho Pharma	Email
192	29/09/2015	Atul Shah	Email (attachment)
193	29/09/2015	Sunil Tanwar	Email
194	29/09/2015	Ashok Medical Store	Email
195	29/09/2015	Radical humanist association	Email
196	29/09/2015	Dhiraj Bhatia	Email
197	29/09/2015	Pharma gladiators	Email (attachment)
198	29/09/2015	Udupi District chemist & druggist	Email
199	29/09/2015	Mohammad Zahiruddin Ansari	Email
200	29/09/2015	Devakottai Taluk Chemists & Druggists Association	Email
201	29/09/2015	Nikhil Gupta	Email
202	29/09/2015	Neeraj Kumar Jain	Email
203	29/09/2015	Kuldeep Rathi	Email
204	29/09/2015	Virudhnagar District Chemist and Druggist Association	Email
205	29/09/2015	Pritpal Singh	Email
206	29/09/2015	Nitin Dahiya	Email
207	29/09/2015	Sunil Narang	Email
208	29/09/2015	Monica Sadh	Email
209	29/09/2015	Anshum Aneja	Email
210	29/09/2015	Nishant Jain	Email

211	29/09/2015	Ravinder Sukheja	Email
212	29/09/2015	Hardeep Singh	Email
213	29/09/2015	Deepak Rai	Email
214	29/09/2015	Rajinder Aroraa	Email
215	29/09/2015	Ravi Rajput	Email
216	29/09/2015	Swati Arora	Email
217	29/09/2015	Mohan Choudhary	Email
218	29/09/2015	Omprakash	Email
219	29/09/2015	Shalini Rajendran	Email
220	29/09/2015	Deepak Khandelwal	Email
221	29/09/2015	Mayank Garg	Email
222	30/09/2015	k.shanmugam, Scientific Officer	Email (attachment)
223	30/09/2015	Khandwa District chemist Association	Email (attachment)
224	30/09/2015	Muthu Laxmi	Email
225	1/10/2015	David Ravi	Email
226	1/10/2015	Vinod Nagar	Email
227	1/10/2015	Raghunandan	Email
228	1/10/2015	Kamal kumar Mukim	Email(attachment)
229	1/10/2015	S Arul	Email
230	1/10/2015	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(attachment)
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	6/10/2015	Nirdosh Kumar	Email
250	6/10/2015	Delhi Computer Academy	Email
251	6/10/2015	Magnet Computer Academy	Email



252	6/10/2015	Rannim Associates	Email (attachment)
253	6/10/2015	Dhule jilha chemist & Druggist association	Letter
254	6/10/2015	Balakedaarara Hitarakshak Sangh	Letter
255	7/10/2015	Solapur District chemists & Druggist association	Letter
256	7/10/2015	Internet and Mobile Association of India	Letter
257	7/10/2015	Amitayu Sengupta	Email
258	7/10/2015	Manisha Mavi	Email
259	7/10/2015	Saurabh Mittal	Email
260	7/10/2015	Pooja Chavan	Email
261	7/10/2015	Shaji tk	Email
262	7/10/2015	Chemist & druggisat association shivpuri	Email
263	7/10/2015	Sai kitchen equipments	Email
264	7/10/2015	Jabalpur Chemist & druggisat association	Email (attachment)
265	7/10/2015	Deepa medical	Email
266	7/10/2015	Chemist & Druggist association-Bhadohi	Letter
267	7/10/2015	Amit Goel	Email
268	7/10/2015	Giri Den	Email
269	7/10/2015	Krishna Kumar Saini	Email
270	7/10/2015	Ashok Sakhuja	Email
271	7/10/2015	Sahil Sanjay	Email
272	7/10/2015	Jayesh Nalawade	Email

273	7/10/2015	Sanjeev Jaggi	Email
274	7/10/2015	Naveen Jain	Email
275	7/10/2015	R N Distributors	Email
276	7/10/2015	Kharbanda Murayan	Email
277	7/10/2015	Rahul Mhetre	Email
278	7/10/2015	Dr Shanti Swarup	Email
279	7/10/2015	Sushma Tumma	Email
280	8/10/2015	Shirpur taluka chemist & Druggist association	Letter
281	8/10/2015	Ambernath chemist association	Letter
282	9/10/2015	Nagpur District Chemist's & Druggists Association	Letter
283	10/10/2015	chemist's association of Thane district	Letter
284	10/10/2015	Jalgaon District Medicine Dealers Association	Letter
285	10/10/2015	The Karnataka Chemists & Druggist Association	Letter
286	12/10/2015	Shrirampur taluka chemist & druggist association	Letter
287	12/10/2015	chemist & druggist association district Saharanpur	Letter
288	12/10/2015	Yevala taluka chemist & druggist association	Letter
289	12/10/2015	Dava Vyapar Mandal	Letter
290	13/10/2015	Akhilesh Shukla	Email

291	13/10/2015	Global pharma sekar	Email
292	13/10/2015	Latur District Chemist &Druggist association	Letter
293	13/10/2015	Solapur District chemists & Druggist association	Letter
294	13/10/2015	Dindori Taluka chemsit &druggist association	Letter
295	14/10/2015	District Bareilly Chemists Association, Bareilly(U.P)	Letter
296	14/10/2015	Ballia Chemist & Druggist Association	Letter
297	14/10/2015	Chemest & Drugist Klyan Association	Letter
298	14/10/2015	Chemists Druggists Welfare Association	Letter
299	14/10/2015	Chemist & Druggist association-Balarampur	Letter
300	14/10/2015	Gautam Budh Nagar zila chemist association	Letter
301	14/10/2015	Lakhimpur Chemist & Druggist association	Letter
302	14/10/2015	Chemist & Druggist Kalyan association Gonda	Letter
303	14/10/2015	Chemist association Raybareli	Letter
304	14/10/2015	Chemist association Dehradun	Letter
305	14/10/2015	Chemist& Druggist association District Unnao	Letter
306	14/10/2015	Dava Vyapar Welfare Society (Mau)	Letter
307	14/10/2015	Kolhapur District Chemist Association	Letter
308	14/10/2015	Agra Pharma association	Letter

309	14/10/2015	The Akola District chemist & Druggist association	Letter
310	14/10/2015	Kolhapur District Chemist Association	Email (attachment)
311	14/10/2015	Satar District chemist & Druggist association	Letter
312	14/10/2015	Ahmadnagar District chemist & druggist association	Letter
313	14/10/2015	Jilha grahak sarkshan parishad Solapur	Letter
314	14/10/2015	The Aurangabad jilha chemist & druggist association	Letter
315	15/10/2015	S S Patil	Email
316	15/10/2015	Priyadarshan Pradhan	Email
317	15/10/2015	Mr Jain	Email
318	15/10/2015	Sadashiv Pandit	Email
319	16/10/2015	Bengal Chemists and Druggists Association	Letter
320	20/10/2015	Progress Harmony Development	Letter
321	21/10/2015	The Maharashtra state chemists & druggist association	Letter
322	22/10/2015	Sriram Subramanian	Email
323	23/10/2015	Pragnesh Panchavadi	Email
324	23/10/2015	(CIPI) Confederation of Indian Pharmaceutical Industry (SSI)	Letter
325	26/10/2015	G. Hubert	Email
326	26/10/2015	C.Arumugam. Saroj medicals	Email

327	26/10/2015	T.Rajasekaran, chennai	Email (attachment)
328	26/10/2015	Pragnesh Panchmvedi	Email
329	31/10/2015	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	13/01/2016	Indian Pharmaceutical alliance	Letter

345	21/01/2016	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	Chemist & Druggist Kalyan 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