

FICCI Stakeholder's Consultation on Online Sale of Drugs and Medicines

17th June, 2015
Committee Room, 2nd floor, Federation House, FICCI, New Delhi

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Stakeholders' Consultation on Guidelines for Online Sale of Pharmaceuticals and for Reinforcing Due Diligence for Intermediaries (E-commerce Marketplace)

June 17, 2015 – FICCI, New Delhi

1430 – 1500 Hrs	**Registration**
1500 – 1530 Hrs	**Welcome Address: Dr. Arbind Prasad, Director General, FICCI** **Special Address: Dr. G.N. Singh, Drugs Controller General (India)** **Industry Perspective: Mr. Aditya Berlia, Co-Chair, Pharma Committee, FICCI**
1530 – 1545 Hrs	**Networking Tea Break**
1545 – 1630 Hrs	**Panel Discussion: Need for Pharma Guidelines for Online Sales of Drugs** **Moderator: Mr. Aditya Berlia,** • Dr. K. K. Aggarwal, Honorary Secretary General, Indian Medical Association, Padma Shri Awardee – "Impact of e-Pharmacy" • Mr. Tabrez Ahmad, Secretary General, OPPI- "Ensuring Health and safety of the consumer while making drugs and pharmaceuticals accessible to all" • Mr. Ashish Chandra, General Counsel, Snapdeal- "Why online marketplaces are different from retail pharmacies and how government can treat them separately" • Mr. Prashant Tandon, CEO 1MG – "Experience of pure play online pharmacy w.r.t. to sales of OTCs" • Mr. B.R. Sikri, Vice-President - Northern Zone Bulk Drug Manufacturers Association & Director(Abs Mercantile Pvt. Ltd. -"Due diligence and awareness amongst the distribution cycle of medicines /drugs- what is presently perused and what more can be done" • Mr. Mohit Bansal, Senior Manager - Public Policy, Amazon- "Processes and best practices by market places for online sales of permitted drugs- OTC" • Mr. Vaijanath Jagushte, Managing Director, Maharashtra State Chemists & Druggists Association (AIOCD) – "Process of Licensing & Due Diligence that Retail Pharmacy follows in selling prescribed drugs / medicines • Prof. B. Suresh, President, Pharmacy Council of India – "Regulation is the key for Consumer safety – Global Practices so far" *
1630 – 1730 Hrs	**Interface: DCGI & Industry – Dr. G.N. Singh, Drugs Controller General (India)**
1730 Hrs	**Conclusion & Recommendations: Ms. Shilpa Gupta, Head – Retail / FMCG / Gems & Jewelry, FICCI** ***followed by High Tea***

**** To be confirmed***

FICCI REPRESENTATION TO DRUGS CONTROLLER GENERAL (INDIA) ON SUGGESTIVE GUIDELINES FOR REINFORCING DUE DILIGENCE FOR INTERMEDIARIES

Background

Over the last two decades, rising internet and mobile phone penetration has changed the way we communicate and do business. Various store and non-store retail formats have evolved to cater to this growing market and E-commerce is one such non-store retail format. The advent of e-commerce marketplaces has brought a paradigm shift in doing business transactions and in tandem with the digital world. People today can shop literally everywhere within minutes, be it their workstations or homes, and most importantly, at any time of the day when convenient. The online market space in the country is budding in terms of offerings ranging from travel, movies, hotel reservations and books to the likes of matrimonial services, electronic gadgets, fashion accessories and even groceries. Now with implementation of National e-Governance, lot of government to consumer services (pan card, passport etc.) can be availed online.

Nowadays, more and more small businesses are incorporating e-commerce platforms as part of their business systems. With the advent of the internet and smart phones, it is now easier than ever to integrate a workable solution that will work for many people.

Even though the sector is at a nascent stage, it has seen unprecedented growth in 2014. It is expected that India's e-commerce market will grow from US$ 2.9 billion in 2013 to over US$ 100 billion by 2020. E-Commerce is increasingly attracting customers from Tier 2 and 3 cities, where people have limited access to brands but have high aspirations, these cities have seen a 30% to 50% rise in transactions.

E-Commerce and E-Pharmacy

In the context of E-Pharmacy, the e-Commerce model can be divided into following two buckets:

a. e-Commerce portals / mobile applications which are designed for selling prescribed drugs. These could be on marketplaces model or on inventory model. More details are provided in subsequent section.
b. Generic e-Commerce portals / mobile applications which are designed for selling a wide variety of products like electronics, furniture, fashion, cosmetics etc. These e-Commerce portals / applications are primarily in the nature of online marketplaces or online auction websites.

The regulatory framework adopted by drugs regulators should be different for different type of e-Commerce portals.

What is E-Pharmacy?

The growth of the Internet has made it possible to compare prices and buy products without having to leave home. It started with books, gradually moving to gadgets, cars and clothes. One of the progressive technology models that have evolved in the last few years is tele-medicine that has enabled accessibility to the finest doctors at the tap of a button. Another recent innovation that has positioned itself as an attractive model in the healthcare space is E-pharmacy.

Three models of E-pharmacy have been misunderstood and used interchangeably. Clearly, model under organized e pharmacy has scope of adding value to the ecosystem. While the unorganized and international trade models need to be controlled, it is important to enable and support the organized model which has tremendous benefits and opportunity to create significant innovation

1. ***The Organized e-pharmacy:*** There are two models which operate in this category. One is a market place model where a technology company connects neighbourhood licensed pharmacies to the end user. Other is an inventory based model where E-pharmacy is an online service of an offline licensed pharmacy.

In an Organized Pharmacy, every order that is received is verified and checked by a team of registered pharmacists. Drugs requiring a prescription medicine are checked for a copy of the prescription. The validity of the prescription is checked as the set format. The medicines are dispensed by registered pharmacists in a licensed premise in a sealed tamper proof pack. Without a prescription the medicines are not dispensed. With the most advanced technology aligned with their processes, they keep track of each and every order.

Drugs that do not require prescription from a medical practitioner or are sold over-the-counter ("**OTC Drugs**") are even better administered in Organized Pharmacy. Given that OTC Drugs can be sold by any person holding a 'Restricted Drug License' and does not require involvement of a registered pharmacist, such persons should be allowed to sell OTC Drugs online as long as they hold a valid license.

2. ***Unorganized e-pharmacy:*** In this model prescription medicines are ordered without any validated prescription. There is no check on the genuineness of the order due to absence of qualified pharmacists. Also improper record keeping and no audits is a major area of concern.

3. ***Illegal International trade through E pharmacy:*** Drugs being shipped across the international borders without any prescription and approval from the concerned authorities.

Benefits of E- Pharmacy for the Patients

1. **Increased Convenience and access:** The E-pharmacy can be very convenient and significantly improve the access of medicines for the patients. This will be pertinent with increasing nuclear family concept, working couples, increasing number of elderly population and urban development in periphery of the metro cities. The access of medicines is difficult for a significant number of people in the country, especially when one is sick
2. **Improved Availability:** Offline pharmacies can only keep limited inventory, resulting in a patient visiting multiple stores to get his or her medicine. With the use of technology and access to Inventory of multiple stores at a time an E-Pharmacy concept can significantly improve the availability of the drugs.
3. **Enhanced Services of the Pharmacist and Pharmacologist:** The E- pharmacy can enhance the services of the pharmacist. Routine questions about medication can be answered by online pharmacists using e-mail or other real-time chat options. Knowledge of a patient's diagnosis, results of laboratory tests, and established drug monitoring parameters, largely unavailable to pharmacists at present, could be made accessible through the Internet. Digitally, very important information can be provided to help a patient learn more

4. **Data records and Analytics:** All medicine purchases can be tracked - effectively reducing the problem of drug abuse and self-medication. The records of patients name and address of delivery can be tracked. Online pharmacies can store and analyse large amounts of data on consumers across the nation which can be very useful for planning public health policies
5. **Patients Compliance and Education:** E-pharmacies have the technology infrastructure to provide value added information to consumers, such as precautions, side effects and information on cheaper substitutes. The more aware consumer will always benefit from the power of knowledge, which is easily distributed through the electronic medium. Using Medication reminders the compliance of the patients can be improved.
6. **Transparency in the system:** Patients can compare the prices of affordable equivalents and can discuss with their health care provider. All the transactions will be digitally stored so making it easy to track the supply chain therefore decreasing **the risk of counterfeit medicines**.
7. **Medicine Authenticity:** With full tracking systems and solid technology backend, counterfeit medicines can be traced back to the channel/ manufacturer/ supplier thereby making the market a lot more transparent and ensuring authenticity is strictly maintained
8. **Transaction records:** Organized online players would have systematic records for all transactions, with full taxes paid on each transaction. A great benefit to the state considering the size of the market

Regulation of e-Commerce platform designed to sell prescription drugs:

There may be Intermediaries who wants to allow sale of drugs for the benefit of public at large. Hence, there is a need to bring out comprehensive guidelines for those Intermediaries that balance liability with safe harbour provisions. This would provide a reasonable precaution against misuse of e-commerce platforms for any illegitimate transactions. Further Government should in fact consider using e-commerce to play an important role in reaching out to the rural and sub-urban consumers specially in case of OTC Drugs and basic necessities which otherwise are not accessible conveniently to the rural population. It is recommended that Government should encourage self-regulatory pharmaceutical guidelines which this industry could abide by so that this channel can be used optimally for its far reaching penetration. It is an opportune time to define the policy framework and to support the development of E-commerce platforms to operate. This industry can create tremendous value for all stakeholders if the high friction in the system is eliminated and the social cost caused by an industry under pressure is mitigated.

Online pharmacies have been specifically notified in many of the largest economies such as Germany, USA & Britain. China is also expected to provide guidelines for Internet sales of prescription drugs under the new regulations set to become effective from this year. It is suggested that India too defines the regulatory framework to help online pharmacies have a clear operating model, in line with the concerns of the regulator, while providing the benefits to consumers.

(A status of E-pharmacy in other countries is provided in the Annexure A)

What are generic e-Commerce marketplaces?

e-Commerce marketplaces are technology driven electronic platform which acts as an intermediary to provide technology and tools to enable buying and selling between independent third party sellers and independent third party buyers. In the case of e-Commerce marketplaces, it is the third party seller who decides what to advertise for sale or sell on the e-Commerce marketplaces. The

assortment of the products sold through the generic e-Commerce websites are very broad based and includes products like electronics, fashion, furniture, home furnishings, cosmetics etc. With respect to generic e-Commerce marketplaces and e-Pharmacy, usually these e-Commerce marketplaces, in their terms of use and policies, specifically prohibits the advertisement and sale of prescribed drugs or any drugs which are in violation of Drugs & Cosmetics Act. Generic e-Commerce marketplaces are specifically governed under the Information Technology Act, 2000 as 'intermediaries' and have specific rights and duties under the said Act and rules made thereunder. Being generic in nature, these e-Commerce marketplaces can also be misused by its users to engage in prohibited or restricted trades. The Information Technology Act, 2000 specifically deals with such cases where e-Commerce marketplaces are used by third parties for such prohibited cases. With the framing of special statute and rules for the conduct of business of online marketplaces, they have been kept outside the purview of other trade related laws for the products which are specifically sold through the intermediary platform. Such trade related laws, although apply to the third party buyers and sellers.

Concept of Intermediaries:

An Intermediary may be defined as any person who receives, stores, transmits or provides any services with respect to an electronic record, on behalf of another person, is an intermediary. By way of illustration, the following entities have been specifically identified [Section 2(w)] as intermediaries in the Information Technology Act, 2000 ("IT Act"):

1. Telecom service providers, such as Vodafone, Airtel
2. Network service providers
3. Internet Service Providers, such as Airtel, MTNL
4. Web-hosting Service providers, such as GoDaddy
5. Search Engines, such as Google
6. Online Payment Sites, such as Paytm
7. Online-Auction Sites, such as eBid
8. Online-Market Places, such as Amazon, Flipkart, Snapdeal
9. Cyber Cafes

While the intermediary platform is susceptible of risk of misuse by third party users of its platform including pharmaceutical sales over the internet, the principle of safe harbour should be used in dealing with intermediaries. It will be unfair to put the onus on the intermediary for the wrongs of third parties who uses the intermediary platform. Online marketplaces are specifically regulated by a specific statute i.e. **Information Technology Act, 2000** (as duly amended from time to time) under which ***online marketplaces are specifically categorized as 'Intermediaries'***.

By virtue of section 79(1) of the IT Act, intermediaries are exempted from liability for third-party information, data or communication link shared or made available or hosted by the intermediary. The status of an intermediary and the protection endowed on them is limited by the following conditions [section 79(2)]:

- Intermediary should not initiate the transmission of information
- Intermediary should not select who receives the information
- Intermediary must not select or modify the information being transmitted.
- The intermediary's function should be limited to providing access to a communication system over which third party information is transmitted/temporarily stored/hosted

- The intermediary should observe due diligence

Due Diligence to be observed by an intermediary has also been explained in Rule 3 of the Information Technology (Intermediaries Guidelines) Rules, 2011. While the intermediary is responsible for informing its users of its policies including, terms and conditions of usage and providing a mechanism for redressal of grievances, the IT Act does not impose the excessive burden of monitoring all information uploaded to and/or transmitted vide its portal to the public. This view has also been reiterated by the Hon'ble Supreme Court in its recent decision in the case of *Shreya Singhal* v. *Union of India*.

The Rule 4 of the Information Technology (Intermediaries Guidelines) Rules, 2011 states that

- the intermediary, on whose computer system the information is stored or hosted or published, upon obtaining knowledge by itself or been brought to actual knowledge by an affected person in writing or through email signed with electronic signature about any such information as mentioned in sub-rule (2) above, shall act within thirty six hours and where applicable, work with user or owner of such information to disable such information that is in contravention of sub-rule (2)

Further on Government of India, Ministry of Communications and Information Technology Department of Electronics & Information Technology on 18.03.2013 has issued notification to bring Clarification on The Information Technology (Intermediary Guidelines) Rules, 2011 under section 79 of the Information Technology Act, 2000. The clarification states as follows:

- These Rules provide a due diligence framework to be observed by intermediary while discharging his duties. Sub-rule (4) of Rule 3 provides that the intermediary upon obtaining knowledge by itself or been brought to actual knowledge by an affected person in writing or through email signed with electronic signature about any such information as mentioned in sub-rule (2), shall act within thirty six hours and where applicable, work with user or owner of such information to disable such information that is in contravention of sub-rule (2).

- The Indian intermediaries have implemented these Rules. However some Industry Associations have requested for a clarification on the words "…..shall act within thirty-six hours…" as mentioned in sub-rule (4) of Rule 3. It is clarified that the intended meaning of the said words is that the intermediary shall respond or acknowledge to the complainant within thirty six hours of receiving the complaint/grievances about any such information as mentioned in sub-rule (2) of Rule 3 and initiate appropriate action as per law. Further, the Grievance Officer of the intermediary shall redress such complaints promptly but in any case within one month from the date of receipt of complaint in accordance with sub-rule (11) of Rule 3. The intermediary should have a publicly accessible and published grievance redressal process by which complaints can be lodged.

Although the intent of the Information Technology Act 2000 as amended from time to time and its rule, is to provide immunity to the Intermediaries provided Intermediary abide by Section 79 of Information Technology Act and The Information Technology (Intermediary Guidelines) Rules, 2011, however it seems either FDA is not fully aware of this or does not appreciate the intent of the aforesaid legislation related to Intermediary. Therefore it is recommended that FDA may be educated about the role and responsibility of the Intermediary.

Regulation of generic e-Commerce platforms:

For any sale of prescription drugs over generic e-Commerce marketplaces, the safe harbour provisions provided to them under IT Act should be used and promoted within the regulatory framework. This would provide a reasonable precaution against misuse of e-commerce platforms for any illegitimate transactions. To support intermediaries in preventing the misuse of their platform by third parties, the Government need to have a proper guideline for the regulator or the administrator to provide appropriate information to intermediaries in taking down and removing the advertisements for sale of prescribed drugs under the parameters of IT Act. This is also in line with the recent ruling of Hon'ble Supreme Court of India in Shreya Singhal vs. UOI (2015) in a similar subject matter i.e. dealings of regulators and law enforcement agencies with intermediaries for any misuse of its platform by third parties.

Further Government should in fact consider using e-commerce to play an important role in reaching out to the rural and sub-urban consumers specially in case of OTC drugs / medicines and basic necessities which otherwise are not accessible conveniently to the rural population.

With the above background, FICCI would like to propose the following:

1) Intermediaries (i.e. generic e-Commerce marketplaces) which are not designed for the sale of prescribed medicines and who prohibits the sale of prescribed drugs on their site, guidelines may be issued to all the state FDA to follow the Information Technology Act 2000 and The Information Technology (Intermediary Guidelines) Rules, 2011 and aforesaid notifications dated 18.03.2013 and notify Intermediary about the listing/ offer for sale which may be contravention of the law. Intermediary should act within the time stipulated under Information Technology Act 2000 and The Information Technology (Intermediary Guidelines) Rules, 2011.

2) Drugs regulator shall make available the names of manufacturers, importers and the brand names of all the drugs and medicines whether prescribed or not approved or licensed by the drugs regulator on its website and such information shall be updated periodically. It is further proposed that the list of all licensed pharmacist should also be made available and updated on the regulator's website.

3) Drugs regulator shall engage in consumer education series to educate consumers to buy prescribed drugs only on the prescription of a licensed medical practitioner.

4) **Suggestive Guidelines for Reinforcing Due Diligence for those Intermediaries who wants to specifically allow sale of prescription drugs are as follows:**

- Orders of scheduled drugs should require a valid prescription of a registered medical practitioner
- Orders should be processed from a physical licensed premise
- Orders should be dispensed by a Registered Pharmacist in a licensed premise

- In a market place model there should be a team of Qualified Pharmacist and Pharmacologists for Validation of Prescription. The email id and phone no should be accessible for the users to report any adverse effect or solve any drug related query.

- There should be no listing and sale of Schedule X drugs and other risky drugs (Schedule H-1). There should be adequate checks and balances in place to prevent sale of any schedule X drugs.

- It should be clearly mentioned to the user that the platform is a market place and their order will be processed by a local licensed pharmacy. The details of the pharmacy should be shared with the users using Email and SMS

- Create a Prohibited Products program : A Prohibited Products Program can be made up of (1) the Prohibited Products Classifier, which is the technology behind the program, (2) up-front seller vetting, (3) seller investigation and enforcement, (4) ongoing monitoring of the regulatory landscape, and (5) ongoing manual audits.

    1. Prohibited Products classifier:
        a) The Prohibited Products Classifier (PPC) is an automated tool which can be used to monitor all products sold on such sites. The tool can search the product catalogue, identify products that match a set of keyword-based rules. It uses machine learning technology to determine if the product should be allowed on the site.
        b) Products flagged by the tool can then manually reviewed by a dedicated team that works 7 days a week to confirm that the product is actually restricted and not a false positive. Intermediaries should perform this extra step because the rules cast a broad net when searching the site for products that may be illegal or otherwise violate the policies, which means lot of legitimate products are picked up during the sweep by an automated tool.

    2. Seller Vetting
        a) In addition to searching the catalogue for problematic products, a number of measures to be implemented to vet the sellers. For instance, a machine learning model can be used to identify sellers that are more likely to sell products that violate the policies. In certain categories, such as Health & Personal Care, Beauty and Grocery, pre-approval is required for all new sellers. The pre-approval process can be discussed in more detail separately.

    3. Enforcement against sellers
        a) In addition to removing a seller's listings of restricted products, audits of third-party sellers can be performed and enforcement action against seller accounts with multiple violations to be taken, such as removing their selling privileges.

    4. Monitoring of regulatory developments
        a) Monitoring a variety of sources to keep up to date with regulatory developments and to update the set of PPC rules to reflect these developments.

    5. Manual audits:

a) Manual audits of the site to be conducted regularly in order to ensure that the PPC rules are correctly identifying products that should be restricted, and are not incorrectly removing products that are appropriate for sale.

6. Regular correspondence with FDA and other regulators:
    1. The Intermediaries to partner with the DGCI and FDA in their investigations by providing information about third-party sellers and products on our site.

7. When the gaps are identified in the rule coverage (for example through an audits and FDA contacts), the existing rules can be updated and, when needed, create new rules to address these gaps

While proposing the above guidelines we have tried to address the key concerns faced by the regulator for this segment

1. Sale of medicines without prescription leading to significant cases of drug abuse
2. High levels of self-medication leading to wrong usage, resistance building to antibiotics and adverse reactions and drug interactions
3. Sub-standard and counterfeit medicines
4. Poor documentation for sale of scheduled drugs
5. Drugs may not be labelled, stored, or shipped correctly
6. Chances of medication errors
7. Growth of generic e-Commerce marketplaces without the threat of penal actions for the misuse of their platforms by third parties by selling prescribed drugs.
8. Enhanced information on regulator's website for all stakeholders to check which brand of drugs and cosmetics are licensed and who are licensed pharmacist.

Annexure A
Status of E Pharmacy / Online Pharmacy in other Countries

United States

The online pharmacies are permitted in US but Pharmacy must be domiciled within the US. Online pharmacies must be registered with the 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.

Prescription drugs can only be sold if the patient submits valid prescriptions. A prescription is only considered valid if issued by an authorised medical practitioner. Online pharmacies will have to build robust systems in place to verify the accuracy of drug prescriptions that on the face appear to be issued by authorised medical practitioners (e.g. frequent orders of opioids might indicate that patient suffers from drug-abuse and is likely getting his prescriptions from an unethical medical practitioner).

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

Brazil

Brazil-based pharmacies may fill online orders, but with the restrictions. Pharmacy has to be licensed in Brazil. An Internet pharmacy must post its ANVISA (Brazilian Health Surveillance Agency) permit number on its website. An Internet pharmacy must post its ANVISA permit number on its website, which provides a link to a searchable database of licensed Internet pharmacies These pharmacies must be open to the public, with a pharmacist present during all hours of operation.

Canada

Canada-based pharmacies may fill online orders, but with the restrictions. The licensed pharmacy selling drugs over the Internet must be the website of a brick and-mortar pharmacy with a physical street address. However, there is no national licensure for pharmacies — it happens at the provincial level. According to Health Canada, any licensed pharmacy that offers Internet services must meet the standards of practice within its own province.

Great Britain

Internet Pharmacies are permitted in Great Britain but that must be registered with the GPhC. The GPhC operates an internet pharmacy logo scheme to identify legitimate online pharmacies so that

the public can be sure they are purchasing safe and genuine medicines online. The logo not only provides a visual means to help patients identify whether a website is connected to a registered pharmacy, but it will also provide a direct link to the GPhC website. By clicking on the logo, visitors can verify the registration details of both the pharmacy and the pharmacist(s) behind the website.

China

Internet pharmacies are permitted in China. Online pharmacies are mandated to display certification on their websites; customers can check the pharmacy domain name/registration # with the CFDA database. Chinese online pharmacies operate on a market-place model. Recent news from Reuters/Bloomberg appears to indicate that Chinese regulators will soon allow online sale of prescription drugs although the time-frame for regulatory clearance is unclear.

Outcomes of the Discussions

Key Concerns raised	Suggestions on how to address the concern	Changes Required (if any)
1. Distinguishing between ePharmacy and generic eCommerce websites	Specific rules to be created for eCommerce platforms which specifically sell or provides marketplaces to sell prescription based medicines. Rules for generic eCommerce websites which do not permit sale of prescription medicines: (a) Those eCommerce websites which do not permit sale of prescription medicines shall specifically provide in their terms of use that sale and purchase of prescription medicines are not allowed. (b) These eCommerce websites shall be treated as 'intermediaries' under Information Technology Act, 2000 (as amended for this definition in 2008). (c) Such eCommerce websites shall comply with intermediary take-down process as provided under Information Technology (Intermediaries Guidelines) Rules, 2011. (d) These rules should have retrospective effect.	State level FDA officers should be made aware of this distinction between ePharmacy and generic eCommerce platforms. Appropriate take down guidelines should be created for FDA officers to send take down notices and information request format to generic eCommerce platforms.
2. Fake Sites	Registry of the E pharmacies should be created. There can be a logo and registration no which a user can cross verify from the regulator's website. This could be an important measure to fight against the illegally operating online pharmacies. The European Union has issued a common logo for legally operating online pharmacies/retailers in the EU Member States. This certificate should be provided by the DGCI in the central government [Snapdeal Comments: IN-CERT (under DoT) to be notified of fake sites and IN-CERT should immediately block the same through ISPs gateway.]	Certificate & Registration process for ePharmacy marketplaces should be created
3. Abuse of drugs	Schedule X and other habit forming drugs could be restricted from being made available for purchase an E Pharmacy model in Phase 1 All the other prescription drugs should only be dispensed against a scan copy of prescription of a Registered Medical practitioner. Audit trail (including the address and name of the patient) should be digitally stored to prevent abuse and ensure tracking in case there is any adverse event [Snapdeal Comments: certain drugs to be taken out from prescription categories and classified as the so called OTC drugs viz. Viagra, morning pills (like iPill etc.)]	List of drugs which are habit forming and have risk of abuse should be created and not allowed for sale through E Pharmacy. Notification clarifying that the model is compliant as long as there is a prescription
4. Role of Pharmacist may be compromised. May increase the risk of medication error.	E pharmacy – should have a team of Qualified Pharmacist and Pharmacologists for validation of Prescription and for handling any drug related queries or adverse event from the patients. Address/phone/other contact information should always be clearly disclosed. Name and photograph of all the technical team could be displayed on the website. Final check should be done through a pharmacist at the dispensing location, who would operate subject to the current regulation only	Requirement for applying for E Pharmacy registration should be defined
5. Liability	In E-Pharmacy, orders should be processed only from a physical licensed premise and should be dispensed by a Registered Pharmacist in a licensed premise. The drugs should only be sold on a bill with proper documentation of the batch no	Current laws adequate to cover these - Liability of the Seller (Physical Licensed Pharmacy)

	and signature of the Registered Pharmacist. Generic eCommerce websites shall not be liable for sale of prescription drugs on their platform if such eCommerce websites have prohibited the sale of such drugs in its terms of use and has complied with its take down obligations under Information Technology Act, 2000.	should be same as it exists in the current market, and Intermediary (Market Place) should be same as already defined under the IT Act
6. Fake Prescription by a Quack Doctor may be fulfilled. No Verification of Registration no of the registered Medical practitioner.	In the marketplace model, since the dispensation is done by the local pharmacy only, there is no change required in the process/ act. Currently In offline model there are no additional check and balances to address this problem. In Phase II, E Pharmacies / Industry association should closely work with state medical councils / Medical Council of India to create an electronic tool to verify the registration no of the doctor with his details. They can also report if there is any discrepancy. This could be an effective measure to catch hold of fake doctors.	No Change Required
7. Substitution	E Pharmacy should fulfill the orders as per the prescription of the registered Medical Practitioner. In phase 1, Substitution could be completely dis-allowed, till the relevant laws are modified later	No Change Required
8. Data Privacy	E Pharmacy should have proper tools in place to protect the confidentiality of the data	Presently data privacy already covered under the IT Act. For the next level, Need to introduce a uniform system for maintenance of Electronic Records by the E Pharmacies in the country. http://www.nhp.gov.in/electronic-health-record-standards
9. Transportation of drugs / Home Delivery of drugs	At present, in Phase 1 as an added precaution, we could restrict operations only within the same state from where dispensation takes place. For nationwide delivery, guidelines for the delivery of the drugs should be clearly defined similar to Good distribution services. Presently, the same rules that are followed for B2B transportation can be applied to cover interstate B2C deliveries. Once the drug has been dispensed it should be packed by the pharmacist in tamper proof pack. For drugs requiring special temperature requirement a Cold Chain should be appropriately maintained.	Need to define clear standards and Liabilities for home delivery of the drugs
10. Refilling of the Prescription	Refilling should be allowed on same prescription only for chronic conditions. Refilling should be allowed for not more than 6-12 months after the date on which such prescription was issued. It should not be refilled more than five times.	Stamping should be limited to Schedule X drugs and other habit forming drugs. Refilling of the prescription for chronic conditions should be allowed. (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1306.22)
11. Telemedicine,	No new change required wrt ePharmacy. Current laws can continue and	No Change required.

Telephonic Consultation , E mail Consultation	players can adhere to them	
12. State Licenses, registration of registered medical practitioner and Licensed Pharmacies	Inter State Delivery could be restricted for Phase 1 In phase 2, GDP for sales to customers on the lines of B2B GDP rules can be defined	No Change required
13. Level Playing field	Competition allows innovation and will be beneficial for the end consumers. Level field for all players is essential	No Change required
14. timely and full availability of details of registrations and licenses on DGCI website	DCGI website shall provide prompt and full information w.r.t. Entity name and brand name of drugs, medicines, cosmetics, Ayurveda etc. on its websites. It will be then easy for ePharmacies and generic eCommerce platforms to ascertain who is allowed. DCGI websites to also provide the name, location and registration number of pharmacist. Indian Medical Council to provide the name and registration number of physicians on his website.	
15. prohibited product classifier	a) The Prohibited Products Classifier (PPC) is an automated tool which can be used to monitor all products sold on such sites. The tool can search the product catalogue, identify products that match a set of keyword-based rules. It uses machine learning technology to determine if the product should be allowed on the site. b) Products flagged by the tool can then manually reviewed by a dedicated team that works 7 days a week to confirm that the product is actually restricted and not a false positive. Intermediaries should perform this extra step because the rules cast a broad net when searching the site for products that may be illegal or otherwise violate the policies, which means lot of legitimate products are picked up during the sweep by an automated tool.	Creation of e-commerce portal/ mobile applications which are designed for selling prescribed drugs
16. seller vetting	In addition to searching the catalogue for problematic products, a number of measures to be implemented to vet the sellers. For instance, a machine learning model can be used to identify sellers that are more likely to sell products that violate the policies. In certain categories, such as Health & Personal Care, Beauty and Grocery, pre-approval is required for all new sellers. The pre-approval process can be discussed in more detail separately.	
17. enforcement against sellers	In addition to removing a seller's listings of restricted products, audits of third-party sellers can be performed and enforcement action against seller accounts with multiple violations to be taken,	

	such as removing their selling privileges.	
18. concerns of the doctors community	a. doctors are the first point of connect for the patients, hence held responsible for misuse/ fraud done by anyone b. impact on doctor- pharmacist connect c. state medical councils work separately from MCI act, validity of prescription in every state is not acceptable d. data confidentiality is a big challenge e. fake doctors might go online f. substitution and price differential cannot be explained online	A separate consultation with Indian Medical Association is recommended to further understand the concerns

Glimpses


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For Interme es (E-commerce rketplace
June
New Delhi
FICCI


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FICCI
K K AGGARWAL
SHILPA GUPTA
ADITYA VIJAY BERLIA
GN SINGH


VAIJANATH JAGUSHTE
TABREZ AHMAD
ASHISH CHANDRA
K K AGGARWAL


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ASHISH CHANDRA
K K AGGARWAL
SHILPA GUPTA


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List of Participants

S.No.	Name	Designation	Organisation
1.	Dr. GN Singh	Drugs Controller General India	
2.	Dr. Arbind Prasad	Director General	FICCI
3.	Mr. Aditya Berlia	Co-Chair, Pharma Committee	FICCI
4.	Dr. K. K. Aggarwal	Honorary Secretary General	Indian Medical Association
5.	Mr. Ashish Chandra	General Counsel	Snapdeal
6.	Mr. Prashant Tandon	CEO	1MG
7.	Mr. Atul Ahuja	Vice President-Retail	Apollo
8.	Ms. Jayasree Menon	Head, Government Affairs & Public Policy Emerging Markets	GSK
9.	Mr. Bhaskar Bhattacharya	Partner	Corporate Law Group
10.	Ms. Nilanjana Ghosh Chaoudhary	Sr. Associate	Corporate Law Group
11.	Mr. Ravikiran Veligeti	Manager-Corporate Affairs	Glenmark
12.	Mr. B.R. Sikri	Director	ABS Mercantiles Pvt Ltd
13.	Mr. Ashwini Kumar	Principle Officer Delhi	AIOCD
14.	Mr. Pradip Trivedi		AIOCD
15.	Mr. Vaijanath Jagushte	Hon. Treasurer	MSCDA
16.	Mr. Mohit Bansal	Senior Manager-Public Policy	Amazon
17.	Mr. Tabrez Ahmad	Secretary General	Organisation of Pharmaceutical Producers of India (OPPI)
18.	Mr. Varun Gupta		1MG
19.	Ms. Shobha Misra Ghosh	Head- Health/ Pharma /Insurance education	FICCI
20.	Ms. Shilpa Gupta	Head – Retail / FMCG / Gems & Jewelry	FICCI
21.	Friends from Media		

Media Clippings

FICCI Stakeholder's Consultation on Online Sale of Drugs and Medicines