

PE/VC: E-PHARMACY - LEGAL SANCTITY?

While the economy is witnessing a fast transition from "offline" to "online" markets and there is a sturdy buzz of "demonetization" and "one click" access to everything, yet laws relating to regulation of most of these e-commerce businesses are in a very nascent stage. The growth in usage of new technology and digitalization to disrupt the marketplace of traditional institutions and intermediaries in the delivery of services have significantly touched upon all industries including pharmaceutical sector wherein the fintech has given rise to a lot of budding e-pharmacies businesses. There are various business models on e-pharmacies which are being adopted by start-ups as well as established players in the market, however the absence of definite legislations regulating these business models has started raising serious concerns over the black hole in our regulatory framework and the Government departments certainly need to gear up and come out with definite regulatory framework for these business models without any further delay. This update is an attempt to analyse the legal sanctity of such existing business models of e-pharmacies in India.

Indian pharmaceutical laws have not kept pace with the developing e-commerce market and the Government has not framed any specific legislation to regulate online distribution/ sale of drugs yet. In fact, we have no laws that can effectively deal with legal issues like sanctity of online pharmacies, distribution of drugs without proper prescriptions, whole sale or retail e-trading of drugs to name a few. The issue gains prominence when we talk about "Schedule X" Drugs i.e. the drugs which cannot be sold without the authorized prescription from medical practitioners and are specifically named under Schedule X of the Drugs and Cosmetics Act of 1940 ("**D&C Act**"). With the recent controversies involving renowned market players, for instance the Snap deal controversy, wherein it was came to the notice of state FDA that the restricted drugs were being sold freely online without any requirement of prescription, and the on-going public interest suit in Bombay High Court, the issue has gained a lot of public visibility.

Existing Legal Framework on E-Distribution of Drugs in India: Indian Laws relating to pharmacies were written prior to arrival computers, let alone internet. There are no dedicated e-health and telemedicine laws in India. Even essential attributes of these laws like regulatory requirements, cyber security data security, etc. are not governed by much needed dedicated laws. Whereas physical means of conducting such businesses are very well regulated under the various pharmaceutical laws and legislations in India, the online mode is still largely unregulated. Other than a circular issued by the Drugs Controller General of India on December 30, 2015 ("**DCGI Circular**"), wherein it has been referred that the online pharmacists should comply with the D&C Act requirements and has directed the state FDAs on take strict action against any unauthorized online sale of drugs, , the law however is silent on permissibility of e-distribution aspect of the same and requirement of specific compliances and restrictions.

Numerous statues carry individual provisions that may be (or at least may be interpreted to be!) applicable to e-health and telemedicine activities in India. For instance, there are many techno legal requirements pertaining to privacy, data protection, encryption, cyber law due diligence, internet intermediary obligations, cloud computing, etc. that are required to be complied with by online pharmacy stores operating in India.

The "Gray" Area: One direct consequence (if not be termed as an "advantage" or "disadvantage") of absence of explicit regulatory framework is that there is no express permission or prohibition to carry out such business models. Hence the legality of online sale of drugs remains unclear and there exists a "gray" zone. Moreover, other than the recent actions taken by respective state FDAs on several such e-commerce businesses, there is no judicial pronouncement on the subject till date.

Critical Concerns: In addition to the issue of ambiguity and applicability of laws, there are several other concerns relating to legal and business viability of e-distribution model for drugs in India. For example, unlike other e-commerce products/services, "pharmaceutical industry" is categorized as "high risk" sector by the Reserve Bank of India and payment gateways generally don't accept online payments for medicines, however the same depends upon case to case basis and quantum of security. Further, the issue of authenticating or checking the validity of scanned copies of prescriptions is not full proof and the possibility of usage of fake or amended copies of prescriptions cannot be overruled. Moving towards the penal consequences, pharmaceutical laws are known for the strictest penalties whether in terms of

monetary penalties or imprisonment for non-compliances. Also, FDAs are witnessed to have been very strict in terms of any non-compliance or complaints against such business activities. States FDAs like Karnataka FDA and Maharashtra FDA have set examples of strict actions like complete shutting down of business activities for any non-compliance. Lastly, drugs and medicines, being essential and critical products, it will require quite some time for Indian consumers to repose their faith and confidence on online models for purchase and delivery of such products. Equally challenging would be live-up to that faith and confidence!

Precautionary Measures to be followed while carrying out such Business without Encroaching the Illegal Territory:

As said previously, the business model of e-distribution of drugs is not illegal in India. Individuals and companies may explore the e-distribution of drugs option, provided that they don't fall foul of the existing pharmaceutical and IT legislations. Hence, set out below are some of the precautionary measures which the businesses should consider and follow to remain within the ambit of law while carrying out such activities :

- Strict compliance/ conservative view would be to hold a **"retail license"** even for e-distribution of drugs. Note that a retail drug license is only issued to persons who possess a degree or diploma in pharmacy from a recognized institute or university. Medibiz controversy in Karnataka also supports the above view.
- Online pharmacies/drugs distribution websites can be categorized as **"internet intermediaries"** within the meaning of Information Technology Act, 2000 (**"IT Act"**) and are therefore required to comply with cyber law due diligence requirements in India.
- As per D&C Act, there is no concept of **"digital prescriptions"**. While as per the IT Act, digital documents have full legal sanctity and this IT Act takes precedence over all other acts where digital documents are in question. Therefore, it is better to obtain a copy of digital prescription as a condition precedent to accepting any order for e-sale/distribution of Schedule X drug. Further, it is advisable to verify the physical copy of the prescription during the time of delivery.
- Arrangements and tie ups should be done only with **licensed pharmacies**. Further, orders should be taken and accepted from the customer(s) either over the phone or internet only from the areas where the pharmacy retail license is applicable.
- Ideally, the medicines/drugs need to be delivered to the customers by a registered pharmacist, not the courier person. However a more feasible option for distribution is to **tie up with a firm which possesses distribution license**. Alternatively, distribution can be carries out by licensed pharmacies directly.
- As far as payment option is concerned, it is recommended to negotiate for prepayment mechanisms with banks and/or other payment gateways. If not allowed, then **Cash on Delivery** is still an available and legally valid option.

ARA LAW View - Way Ahead:

The annual Indian pharmaceutical market is pegged at around USD 36.4 Billion, steadily growing at around 20% per annum. If the Government decides to allow online sale of drugs, it is likely to give a major boost to sales of the sector while also making medicines accessible to remote areas. Also, with the on-going steps towards demonetization of Indian economy, proper regulations and legal framework for such online businesses is a need of the hour.

Pursuant to on-going public interest suits in judicial forums and various instances of unauthorized online sale of restricted drugs in India, there is a possibility that strict regulations or even a ban on such businesses may be imposed by Government in near future. However the Government is also considering launching a pilot project to regulate the online sale of drugs to be equipped with proper regulation mechanism instead of imposing any blanket restriction or ban on the same. The central regulator is also consulting various international drug regulatory agencies such as the US FDA and the European Medicines Agency as well as examining their models to understand how quality and standards of medicines sold through e-commerce portals are monitored in these countries. Once the definite regulations are out, the sector will be better regulated and expected to grow swiftly!

While on the one hand there has been a continuous call for regulations because the existing laws does not have any specific guidelines in place for e-commerce players in the pharmaceutical industry. It is still very clear that 'scheduled' drugs should be sold only by licensed pharmacies against a doctor's prescription. This is in consonance with the DCGI Circular also. Therefore for the time being, any business model on e-sale/distribution of drugs (especially Schedule X drugs) should comply with the above mentioned precautionary measures to the extent possible in order to avoid any serious repercussions under applicable laws.

SNAPSHOTS

LEGISLATIVE SNAPSHOTS

PERMANENT RESIDENCY STATUS TO FOREIGN INVESTORS The Union Cabinet on August 31, 2016 had approved the scheme for grant of Permanent Residency Status (PRS) to foreign investors subject to the relevant conditions as specified in the FDI Policy and other rules notified by the Government from time to time.
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REGULATORY SNAPSHOTS

FUNCTIONING OF STOCK EXCHANGES AND CLEARING CORPORATIONS IN INTERNATIONAL FINANCIAL SERVICES CENTRE (IFSC) SEBI has issued a Circular vide SEBI/HO/MRD/DSA/CIR/P/2016/125 dated 28th November 2016 regarding Guidelines for Functioning of Stock Exchanges and Clearing Corporations in IFSC.
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JUDICIAL SNAPSHOTS

ENTITLEMENT TO 20 PER CENT TAX RATE UNDER SECTION 50B OF THE INCOME-TAX ACT IN CASE OF EXCLUSION OF DEFUNCT ASSETS IN A SLUMP SALE Recently, the Delhi High Court in the case of Triune Projects Private Limited held that the transaction of sale is a genuine slump sale which qualifies for the tax
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CORPORATE RESTRUCTURING SECTIONS NOTIFIED UNDER THE COMPANIES ACT, 2013 On 07 December 2016 the Ministry of Corporate Affairs (MCA) notified the relevant sections of the Companies Act, 2013 ("Act") relating to the capital reduction, winding-up (other than members voluntary winding-up), compromise or arrangement

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AMENDMENTS RELATING TO ANGEL INVESTORS Stock Exchange Board of India (SEBI) vide PR No. 161/2016 corresponding to SEBI Board Meeting dated November 23, 2016, has approved following amendments related to Angel Investors:

1. The definition of startup for Angel Funds investments will be similar to definition of DIPP as given in

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VALIDITY OF ENTRY TAX On November 11, 2016, the nine-judge Constitution Bench of the Supreme Court (vide a split verdict of 7:2) pronounced its judgment on the issue of validity of Entry Tax. The judgment is of immense significance as it not only examines the power of the state legislatures to levy such taxes, but also clarifies the import

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