Indian online pharmacies and drug stores in legal tug-of-war

Amid protests by brick-and-mortar pharmacies concerned about the rise of online pharmacies in India and action by state drug control departments against e-commerce companies allegedly involved in the distribution of medicines via the internet, Indian regulatory body the Drug Consultative Committee is currently working on a regulatory framework for online pharmacies in the country. Dr Milind Antani and Anay Shukla of Nishit Desai Associates outline the background to the controversy involving Indian online pharmacies and explain the legal issues such businesses currently present.

14 October 2015 was a particularly hard day in the life of a person in India. If someone needed to buy a medicine on that day, it was not to be found almost anywhere: around 850,000 brick-and-mortar drug retailers shut their shops to express their concerns and mark their protest against the booming online drug retail business.

**Background**

It all started in April 2015 when the Maharashtra state drug control department (‘Maharashtra FDA’) raided the warehouse of one e-commerce giant, and sought to file a criminal case against its CEO. Maharashtra FDA alleged that prescription drugs were being sold through the e-commerce company without a prescription. Around that time, Maharashtra FDA also raided the operations of 27 online pharmacies. The drug control departments of other states followed suit. Gujarat state drug control department raided the office and warehouse of a major online pharmacy. The Karnataka state drug control department cancelled the licences of two major firms for the online sale of drugs without prescription. And the Telangana state drug control department reportedly banned the online sale of drugs.

In the immediate aftermath of these events various drug control departments, the major players in the online pharmacy space united and released a white paper, which made the case for the lawful operation of online pharmacies in a regulated environment. The said white paper was released in the presence of the government authorities. Since then, a number of players have also submitted their formal representations in an individual capacity to the Government of India.

Meanwhile, India's top drug regulation recommendatory body, the Drug Consultative Committee (‘DCC’), met in July 2015 to lay out a roadmap for developing a regulatory regime for online pharmacies in India. The DCC constituted a sub-committee to review existing regulations in India and abroad, and asked the sub-committee to propose a new framework for the regulation of online pharmacies in India. The sub-committee invited comments and suggestions from stakeholders and the general public; the consultation period ran until 31 October 2015.

Online pharmacies pose a potentially huge threat to brick-and-mortar pharmacies as they are in a position to provide double digit discounts to consumers for various reasons, in particular the fact that their costs of maintenance are considerably less than brick-and-mortar pharmacies. At the same time they can pass on the these margins to consumers.

India’s largest united association of brick-and-mortar drug wholesalers and retailers, The All India Organisation of Chemists & Druggists (‘AIOCD’), is aware of the threat. When the sub-committee invited suggestions from the public, the office bearers of the AIOCD met the Health Minister of India. It is reported that the Health Minister could not give assurance to the AIOCD as the organisation would have liked. As a retaliation measure, the AIOCD called a nationwide strike of its members for one day, 14 October 2015. The AIOCD believes that permitting the sale of drugs online will result in widespread drug abuse and lead to the circulation of counterfeit drugs. Hence, the AIOCD demands that online pharmacies be banned.

In the $13.6 billion medicine market in India, online pharmacies have only just begun to appear very recently, and reportedly occupy less than 5% marketshare. The major players in the field may be less than two years old but they are recording double digit growth in this short time period. Some of these businesses have also seen multi-million dollar investments. The major players in the online pharmacy space have now formally united against the AIOCD and formed an association called the Indian Internet Pharmacy Association (‘IIPA’).

The sub-committee is expected to furnish its report by December 2015. A decision on online pharmacies should be taken by DCC by March next year and should be formalised into law by mid-2016.

**The legal angle**

In many foreign jurisdictions, there is a clear distinction between drugs that are required to be sold under the supervision of a registered pharmacist on the production of a prescription and those that may be sold by general retailers over-the-counter (‘OTC’). OTC drugs in
many foreign jurisdictions are, therefore, non-prescription drugs that are sold freely.

OTC drugs have a different meaning in the context of Indian laws. The Drugs and Cosmetics Act 1940 (‘D&C Act’) requires that all drugs must be sold under a licence. Thus, general retailers in India cannot sell drugs. All drugs have to be sold by licensed drug retailers only. This dilutes the concept of ‘over-the-counter’ considerably.

Further, the Drugs and Cosmetics Rules 1945 (‘D&C Rules’) identify certain drugs that can be sold only on the production of a prescription signed by a Registered Medical Practitioner (‘RMP’). These drugs are popularly referred to as ‘prescription drugs.’ Because the concept of OTC is almost non-existent in India, it is easier to classify drugs in India into the categories of prescription and non-prescription drugs than OTC drugs and prescription drugs.

There is no issue in regard to the online sale of non-prescription drugs in India. The issues arise when it comes to the online sale of prescription drugs.

It is important for online pharmacies to accept prescriptions in scanned or electronic form to process purchase orders of prescription drugs, otherwise their business model will lose its ‘mobile’ advantage over brick-and-mortar stores. As has been stated earlier, prescription drugs can only be sold on the production of a prescription that is signed by an RMP. So the question arises as to whether a scanned copy or electronic form of prescription meets the requirements of being ‘signed’ by an RMP.

The Information Technology Act 2000 (‘IT Act’) provides that when a document is required to be signed under law, the document would be deemed to be in compliance with the law only if such information or matter is authenticated by means of an electronic signature. An electronic signature is a means to authenticate an electronic record by a subscriber using a method laid down by the IT Act. Since the D&C Rules require all prescriptions to be signed by the RMP using his or her signature, a scanned copy of the prescription or the prescription in electronic form would be considered valid under D&C Rules only when the RMP affixes his or her electronic signature to it.

Online pharmacies will find it a herculean task to get RMPs to affix electronic signatures given that less than 1% of RMPs in India today have obtained an electronic signature.

Further, the D&C Rules also require that the registered pharmacist, under whose supervision drugs are dispensed, makes a note that the drug has been dispensed on the prescription itself so that the prescription is not over-dispensed. How can such a note be made over a scanned or electronic copy of a prescription?

There are other challenges with online sale of prescription drugs as well but these are manageable with some business structuring. One challenge is related to the place of sale. A licence for sale of drugs is given to the licence holder for a specific premise under the D&C Act and the D&C Rules. This means that the sale of drugs must take place at the licensed premises approved by the licensing authority only. When drugs are sold online, it would be very difficult or rather impossible to determine the place of sale. It is arguable that in the case of the online sale of medicines the place of sale could be the house of the patient where the monies are collected and drugs are handed over to the patient or carer. If so, the online sale of drugs would violate the D&C Rules.

Another challenge is connected to the delivery of prescription drugs. The Pharmacy Practice Regulations 2015 state that all prescription drugs should be handed over by a registered pharmacist himself or herself to either the patient or his or her carer. When prescription drugs are sold online, there is very little scope for the handing over of prescription drugs by the registered pharmacist.

Conclusion

It is hoped that the recommendations of the sub-committee touch upon all the issues and challenges discussed here and more. Both the AIOCD and the IIPA appear to have legitimate grounds for pushing their demands. Some realities need to be factored in as well. A number of small brick-and-mortar drug stores may run out of business if online pharmacies enter into direct competition with them. Similarly, the existing online pharmacies may end up losing investments of millions of dollars should there be a blanket prohibition on the online sale of drugs.

In this tug of war, there is no denying that a country the size of India needs online pharmacies to operate. We are hopeful that the government proposes a solution that does not harm either the brick-and-mortar drug stores or existing online pharmacies, and at the same time, benefits the common man of India. The coming months will decide the fate of online pharmacies in India, and in a ‘remote’ way, of every Indian.