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Online Pharmacies

Regulation is required

Trademark Use

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Diagnosis: Regulation

Pankaj Musyuni and Aniruddh Singh of LexOrbis investigate the rise of online pharmacies in India, and consider whether more regulation is required

Increased globalisation and health awareness, along with the ease with which patients can self-diagnose and -medicate, has led to the rise of online pharmacies. The sector is rapidly growing, however, and it is necessary to have regulatory control for the benefit of the public. In India, a lack of regulatory control has enabled illegal online pharmacies to proliferate. They have gone on to hijack popular pharma brands and sell counterfeit or sell prescription-medicines.

The laws relating to the regulation of these ecommerce businesses are still at a nascent stage and there are none that effectively deal with the sanctity of online pharmacies, quality of the supplied medicines, distribution of drugs sold under the prescriptions, and more. The absence of definite legislation regulating the business of online pharmacies has raised serious concerns, as many start-ups and established players their business model.

Current landscape

In India, the Drugs and Cosmetic Act regulates the manufacturing, import and distribution of drugs in India, along with safety, efficacy and quality standards before reaching the end consumer. Under Schedule X of the Drugs and Cosmetic Act, a class of prescription drugs is included that cannot be purchased over the counter, but according to a recent case, an ecommerce website sold the drug online freely without any requirement for a prescription. There are many other instances such as this that call for the need for developing specific legislation to regulate the online distribution and sale of drugs.

Drugs, in general, can be broadly categorised under prescription and over-the-counter (OTC). Prescription drugs are prescribed by a doctor for the use of a specific individual under a valid prescription issued by a registered medical practitioner, whereas OTC drugs do not require a doctor's prescription and can be sold at any retailer and grocery store. While the main concern is with the sale of prescription drugs online, some acts provide the basis for better understanding the Indian perspective, such as the Information Technology Act, which provides support for the legal recognition of electronic records and electronic signature. Similarly, the Drugs and Cosmetic Rules also mention that a prescription should be in writing and signed

by the prescriber with his or her usual signature and the date. The Pharmacy Practice Regulations, declared by the Pharmacy Council of India in January 2016, defined a prescription as a written or electronic direction from a registered medical practitioner, or other properly licensed practitioners, such as dentists or veterinarians, to a pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to a patient.

The Information Technology Act and the Drugs and Cosmetic Rules satisfy the legality of a prescription written and signed electronically. The scanned copy of a prescription should be valid and enforceable in the eyes of the law and a doctor can prescribe via an electronic prescription to his or her patients.

The current scenario does not state any specific requirements, compliance, or restrictions necessary for the online distribution and sale of drugs in India. In December 2015, a notification from India's Drugs Controller General stated that strict action would be taken against the unauthorised online sale of drugs and online pharmacists should comply with the Drugs and Cosmetic Act to safeguard public health. Concerns include endangering human life, rendering pharmacovigilance ineffective, restricting effective procedures and mechanisms for drugs recall, compromising storage and packaging conditions, the dangers of online sales of controlled substances, and encouraging drug addiction among young people.

This created a grey area among practitioners, who were unclear on the legal sanctity of drugs sold online. Then in April 2015, an ecommerce website was raided on allegations of selling prescription drugs through its website. These were scheduled drugs, which cannot be sold without a prescription from a registered medical practitioner.

New rules proposed

The drugs consultative committee held its 48th meeting in July and on its agenda made a consideration of the issue of the clandestine export and sale of medicines via the internet by certain web portals in the country in violation of the provisions of the Drugs and Cosmetic Act.

Online pharmacies are not currently illegal but those that do not meet the requirements of the Drugs and Cosmetics Rules, including those relating to sale from licensed premises and maintaining necessary records, are not permitted

A sub-committee was also constituted to examine whether drugs sold online are illegal or are in compliance with existing legislation. Recently, India's minister of state for health and family welfare, informed Rajya Sabha, India's upper house of parliament, that the sub-committee recommended various steps, including the creation of a national portal to act as the nodal platform for transacting and monitoring the online sale of drugs to curb illegal sales.

These steps were laid down in a notice dated 15 March 2017. They include: creating a mechanism to register online pharmacies; placing geographical restrictions on the operation of online pharmacies; developing a means for verifying the authenticity of drugs through a link to the national portal; and allowing existing licensees that carry out retail sales to register on the national portal for online sales.

In view of the current legislative framework, online pharmacies such as NetMeds.com have begun to provide the option to upload prescriptions. By uploading a proper prescription, the online pharmacy may sell the drug without having to violate any laws.

India's health and family welfare ministry issued a public consultation in March of this year on the regulation of drug sales in the country. This notice included for the first time provisions for the functioning of online pharmacies in India. The ministry proposes establishing and developing a robust internet-based structure for regulating the sale of medicine in the country. All manufacturers, wholesalers and online

pharmacists would be required to register with the portal and provide information on medicines and drugs received, sold, returned to the manufacturer or disposed of in any other manner. No retailer/chemist/online pharmacist outlet would be permitted to sell any drug unless it is registered on the portal. Permission for an online pharmacy would be granted only when it has a licensed brick and mortar facility in each of the licensing authority's jurisdiction. This means that the online pharmacy should have a physical presence and the ability to offer face-to-face customer experiences in a particular jurisdiction.

Though provisions are being proposed for strengthening the regulatory mechanism regarding the sale of drugs in the country, and as well as monitoring the operations of online pharmacies, stakeholders such as All India Organization of Chemist and Druggists stand opposed to the proposed establishment of an internet-enabled structure for regulating the sale of drugs in the country.

Online pharmacies are not currently illegal but those that do not meet the requirements of the Drugs and Cosmetics Rules, including those relating to sale from licensed premises and maintaining necessary records, are not permitted. The online sale of drugs becomes illegal only when they are in violation of the existing legislation.

As India is emerging as a significant player in regulatory developments, the future of online pharmacies will become more prominent in near future. [IPPro](#)

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