

Draft e-pharmacy rules are progressive, adequately address concerns of offline players



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Atul Pandey, Arjun Bhagi, 31 JANUARY, 2019

E-pharmacies have made life very convenient for consumers, who can now order medicine from the comfort of their homes. However, these e-pharmacy companies themselves are facing a lot of inconvenience of late owing to important legal developments in this sector. This article gives you a primer on the regulatory framework for sale of medicines in India, how e-pharmacies are facing legal challenges in recent times, and what lies ahead for the industry.

Legal regime for sale of medicines in India

The Drugs and Cosmetics Act, 1940 (“Drugs Act”), and the Drugs and Cosmetics



Rules, 1945 (“Drugs Rules”), regulate the sale of drugs in India. These laws prescribe stringent conditions for sale, stockpiling and distribution of medicines. To get a sense of how deeply regulated the medical sector is, it would be helpful to understand the permissions required by a bricks-and-mortar store to dispense medicines. The medical store located in your nearby market is required to obtain a licence from the state food and drugs authority to sell, stock, exhibit or offer for sale or distribute medicines. The Drugs Rules also specifies that certain medicines can only be supplied by these medical stores against the prescription of a registered medical practitioner. Offline medical stores are displeased since certain e-commerce entities are operating without obtaining licences, whereas the offline stores have to mandatorily obtain licence for operations and maintain periodic compliance under the Drugs Act and the Drugs Rules.

Legal regime for online sale of medicines in India by e-pharmacies

The Drugs Act and the Drugs Rules pre-date the age of internet boom, and the government has still not updated these laws to provide for the sale of drugs through a digital medium (like an app or a website). Accordingly, online sale of drugs through a digital platform (offered by e-commerce entities) is neither expressly permitted nor expressly barred under the current regulatory regime in India.

An e-pharmacy acts as a place of meeting between a registered pharmacist (having valid registration under Drugs Act and Drugs Rules) and the end-customers. An end-customer uploads the prescription of the website on the e-pharmacy, against which the assigned local registered pharmacist makes the supply of medicines to the end-customer. A section of the e-pharmacies takes the view that they are mere digital facilitators and are, accordingly, outside the purview of the Drugs Act and the Drugs Rules. However, a conflicting view is also prevalent in the market. A section of e-commerce companies is of the view that, in addition to facilitation, they are also conducting ‘exhibition’ or ‘offer for sale’ of drugs on their website, which mandates a licence under Rule 59 of the Drugs Rules.

Owing to this legal uncertainty, investors for a long period had taken a cautious approach in channelising their investments into e-pharmacy companies. In 2015, the government finally intervened and clarified that the Drugs Rules do not distinguish between the conventional and over-the-internet sale/distribution of drugs. This gave some relief to the investors, and they asked their investee companies to commence compliance under the Drugs Rules.

Despite these developments, the offline retailers continued their resistance to the growth of e-pharmacy sector on the grounds that the operations of e-pharmacy companies remain illegal till an amendment is brought to the Drugs Rules.

The Government made an important move in August 2018, by introducing draft amendments to the Drug Rules (“E-Pharmacy Rules”). The E-Pharmacy Rules, once implemented will give legal recognition to e-pharmacies by making registration

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mandatory for all e-pharmacy companies. Existing and new entities in the e-pharmacy business will be required to pay a registration fee of Rs 50,000 and the process is completely online. The registration of an e-pharmacy shall be valid for a period of three years.

Recent legal trouble for e-pharmacies

While the e-pharmacies found a renewed lease of life with the announcement of the E-Pharmacy Rules, they received a body blow from the Delhi High Court and the Madras High Court. A single-judge bench of the Madras High Court had directed authorities to stall online sales of medicines as an interim relief to the plea of offline retailers. A similar order was issued by a single-judge bench of the Delhi High Court on 12 December 2018 in response to a public-interest lawsuit. Later, a division bench of the Madras High Court stayed the order of its single-judge bench, providing much relief to e-pharmacy companies. However, even this relief was short-lived, as a division bench of the Delhi High Court, through its order on 8 January 2019, decided not to intervene in the stay on online sale of drugs imposed by its single-judge bench. To conclude, there are presently two conflicting views of the High Courts dealing with the issue of online sale of medicines, and e-commerce companies are facing difficulty in operating amid this uncertainty.

Separately, the recent changes introduced by Press Note No 2 of 2018 to the Indian Foreign Direct Investment policy is also a worrying factor for such e-pharmacies that have foreign direct investments. E-commerce entities will have to re-align their structures to ensure that their sourcing and ancillary support activities are in compliance with the amended foreign direct investment policy which comes into effect from 1 February 2019.

What lies ahead for e-pharmacies?

The central government has stated before the Delhi High Court and the Madras High Court that it proposes to finalise and implement the E-Pharmacy Rules by 31 January 2019. The timing of the implementation of these rules is a crucial factor, as it will give direction to the ongoing cases before the Delhi High Court and the Madras High Court that deal with the ban on sale of online medicines.

There have been concerns that rights to regulate e-pharmacies should stay with the state government. We are of the view that the E-Pharmacy Rules correctly envisage a centralised process of e-pharmacy registration, as operations of e-pharmacies on a digital platform are not restricted to geographical boundaries of states. Registrations at state-levels would impede the growth of this sector in our opinion. It is also important to mention that mere registration requirements do not take away the supervisory powers of the state government. The E-Pharmacy Rules expressly empower state governments to monitor the e-pharmacies regarding drugs availability, types of drugs ^

offered for sale, supply channels or vendor lists, details of registered pharmacists, registered medical practitioner (if any) and any other requirements of the Drugs Act and the Drugs Rules.

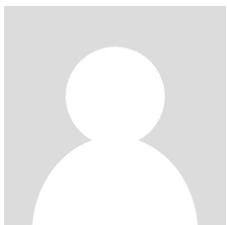
There is no doubt that there has been considerable delay in issuing a policy for e-pharmacies. The delay can primarily be attributed to the stiff opposition received from bricks-and-mortar pharmacies. There is also the fact that sale/dispensation of medicines requires great care and action, as it deals with human lives, and the concern that whether e-pharmacies are sufficiently equipped to provide the necessary degree of care to the end-customers.

Having said that, it is important to note that e-commerce has invaded every sector of business, and medicines should be no exception. Most e-pharmacies presently operate with strict protocols to ensure that drugs are dispensed through a registered pharmacist in compliance with the Drugs Act and the Drugs Rules. The E-Pharmacy Rules mandate compulsory registration, set out the process for operations, protect data privacy, provide for monitoring of data by authorities, prohibit advertisement of drugs and provide for a complaint redressal mechanism. In our opinion, the draft E-Pharmacy Rules is progressive and adequately addresses concerns of offline pharmacies in relation to drug epidemic and drug abuse.

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