

E-Pharmacies in India

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E-commerce provides ease of access and even before the COVID-19 outbreak, it was a significant, and expanding, mode of conducting business in India. There is a demand for online sale of medicines too, but the dangers of counterfeiting are higher on the Internet and the fallout of spurious drugs can be lethal. Despite such challenges, the nascent e-pharmacy market in India is estimated to surpass USD \$3.5 billion by 2022. However, the absence of specific guidelines to govern this industry has meant that e-pharmacy operations have come under legal scrutiny time and again.

On 8 May 2020, a prominent organisation representing brick-and-mortar chemists moved the Delhi High Court (South Chemists & Distributors Association & Anr. v. UOI & Ors. W.P.) alleging the central government was promoting / favouring online pharmacies through India's COVID-19 contact tracing app named 'Aarogya Setu'. The mobile application provides a link to a website the name of which is quite similar to its own - www.aarogyasetumitr.in - and the website lists only e-pharmacies and telemedicine services in a stated effort to 'bring healthcare services to the doorstep of all Indians in the time of the COVID-19 crisis'. Per the plaintiff organisation, the portal's name was likely to mislead users into believing it was a government mandated website. Moreover, medicines procured through local pharmacy stores could also be home delivered securely during the ongoing COVID-19 situation, and the portal's implication that e-pharmacies were somehow better placed to serve the health needs of people was false. The said portal was alleged to be discriminatory as well as illegal and it was demanded that it be immediately delinked from the Aarogya Setu App. The court has asked the government to file its reply and listed the matter for further hearing on 29 May 2020.

While we wait to see how this dispute plays out, it is instructive to look at statutes that govern the sale of pharmaceuticals in India. Principal legislations are the Indian Medical Council Act, 1948, the Pharmacy Act, 1948, the Drugs and Cosmetics Act, 1940 (the Act) and rules framed under i.e. the Drugs and Cosmetics Rules 1945 (the Rules). The Act and Rules regulate the import, manufacture, distribution and sale of drugs – they, inter alia, prohibit not only the manufacture, distribution and sale of drugs

that are not of standard quality, are misbranded, adulterated or spurious but also the stocking, exhibition and offering for sale of such drugs and medicines. A license for conducting business is also a pre-requisite for pharmacies and premises in respect of which the license is to be granted must be adequately equipped for storing drugs and medicines. The Rules further mandate that prescription drugs must be sold under the supervision of a registered pharmacist who is required to maintain a record of the prescription provided.

In terms of e-pharmacies, absent specific regulation, they have been operating in a 'grey area'. Some outfits have independent websites / apps; they stock medicines in independent warehouses and upon receiving orders based on valid prescriptions deliver medicines to end-consumers. Others simply function as aggregators / intermediaries and connect neighborhood retail pharmacies to end-consumers – they claim to fall under the ambit of the Information Technology Act 2000, which governs liabilities of intermediaries in the face of e-commerce offences / disputes.

Be that as it may, the rapid upward trajectory of the e-pharmacy business in India speaks of a gap that exists in the market. However, it is not a gap that traditional pharmacies are happy for online pharmacies to fill. In September 2018, a pan Indian organization representing brick and mortar retail chemists, observed a nationwide strike to protest against the online sale of medicines by e-pharmacies without valid licenses, as well as against discriminatory prices offered via discount schemes. This triggered the introduction of an amendment to the existing Rules via a notification dated 28 August 2018 titled Sale of Drugs by E-Pharmacies (the Amendment), the salient aspects of which are:

- registration for conducting business is a must for e-pharmacies;
- a registered pharmacist must verify the details of the prescription, registered medical practitioner and arrange for the dispensation of drugs;
- 'Narcotic' and 'psychotropic' drugs as defined in the Narcotic Drugs and Psychotropic Substances Act, 1985 may not be sold by e-pharmacies;
- patient details must be kept confidential;

- advertising is prohibited on radio, television, internet, print media etc.; and
- data generated with respect to online transactions must be stored in an e-pharmacy portal located in India, and include information on the constitution of the e-pharmacy / ownership details / official logos / logistic service providers / return policies, etc.

Though progressive in nature, the Amendment is yet to be implemented. Meanwhile, four months post the Amendment proposal, in *Dr. Zaheer Ahmed v The Union of India & Ors.*, the High Court of Delhi restrained the online sale of medicines sans a valid license and issued directions to competent authorities to restrict such sales. Around the same time, the High Court of Madras in *The Tamil Nadu Chemists and Druggists Association v Union of India* also granted a permanent injunction blocking online sale of medicines by e-pharmacists sans a valid license and observed that the government should notify the Amendment (which would enable such licensing) at the earliest and no later than 31 January 2019. Despite the aforesaid directions, the Amendment is still to be notified as governing law. Meanwhile, yet another direction was issued on 28 November 2019, this time by the Drug Controller General of India (India's drug regulatory body), prohibiting the sale of medicines through unlicensed online platforms across India till the draft rules to regulate e-pharmacies are finalised.

In jurisdictions where e-pharmacies are more established, such as the US, the EU and the UK, common safeguards include mandatory registration for online pharmacies. Further, use of a particular logo or seal certifies that the website is a legitimate channel for online sale of medicines and often links to a list of all legally operating online pharmacies / retailers. Other practices, for example in the US, require e-pharmacies to provide a street address, require a prescription, and have a licensed pharmacist to answer questions.

India would do well to formalise a regulatory framework for e-pharmacies keeping in mind global benchmarks. In light of the ongoing pandemic and disputes such as the one we began this article with, one hopes this will happen sooner rather than later.