

Pharma & Healthcare Update

November 05, 2018

ONLINE SALE OF PRESCRIPTION MEDICINES IN JEOPARDY

- *Madras High Court has ordered the government to ensure that no prescription medicine is sold online without a license*
- *The Government had recently published draft of rules to regulate online sale of medicines which imposed a requirement to obtain registration to sell medicine online*
- *Therefore, the timing and intent of the order puts a question mark on present business models for online sale of medicine*

Recently, the Madras High Court ordered the Government to ensure that no prescription medicine should be sold in India without a license until further orders.¹ As a direct consequence of this order, it is expected that the Central as well as State Drug Licensing Authorities will increase enforcement efforts. Existing online pharmacy business owners may expect an increase in investigations and inquiries from the regulator in the near future.

HISTORICAL BACKGROUND

The law that regulates sale of medicines in India i.e. the Drugs and Cosmetics Act, 1940 ("DCA") is more than 70 years old. Therefore, the law as it exists today does not contemplate that medicines can be offered for sale, and be sold over the internet. However, with the help of technology, it has become possible for sellers to sell, and patients to buy, medicines over the internet.

For undertaking sale of prescription medicines, the following is the minimum requirement under current law:

1. Original prescription signed by a registered medical practitioner;
2. A licensed premise where medicines can be stocked, offered for sale, and sold; and
3. A registered pharmacist, under whose supervision the medicine is to be dispensed to the patient or the patient's carer.

In 2016, a government appointed committee had investigated the legality of online sale of medicine in the context of, amongst other things, the requirements stipulated above. It had found that the Information Technology Act, 2000 recognized digital signatures, and therefore an electronic document with digital signature could qualify as a prescription for the purpose of law. However, it had raised doubts about the operation of websites that offer medicines for sale without a separate license. The issue at hand was whether offering a drug for over a website requires a specific license by itself, in addition to any premise-specific license the website owner must obtain for stocking of drugs. It had also raised doubts about genuineness of a transaction that takes place online because the registered pharmacist would not know the bona fides of the recipient of the prescription medicine, since the recipient is not seen by the pharmacist.

In consideration of the committee's observations, the Government had published draft of the rules on August 28 2018 to regulate sale of medicines over the internet. The said draft rules:

- A. Gave validity to e-prescriptions;
- B. Introduced a requirement to register the e-commerce website over and above the requirement to obtain a premise-specific license to stock medicine; and
- C. Made the website owner accountable for sale of spurious medicines or any other non-compliance of the law.

FACTS AND CIRCUMSTANCES OF THE CASE

It is in this background that the Madras High Court heard the petition. The petitioner, an association of brick-and-mortar retail and whole sale pharmacies, had approached the Court to "block link of all websites" that sell prescription medicines in violation of law "till the licenses are granted to sell medicines through online".

The petitioner appears to have been able to prima face convince the Court that online sellers were not following the requirements stipulated under 1 – 3 above. The petitioner appears to have claimed that though the draft rules for regulation of sale of medicines over the internet were under consideration of the government, online sale of prescription medicines was "still in existence without obtaining proper licenses".

The Court appears to have been concerned by the apparent seriousness and public interest involved in the issue put forth by the petitioner. After preliminary assessment, the Court was pleased to order that the Government should stall online sale of prescription medicines without license on immediate basis.

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We believe that the order of the Court appears to be a knee-jerk reaction to lop sided claims of the petitioner and is bound to be watered down by the next hearing date (i.e. November 9, 2018) once businesses involved in the online sale of medicine make their case. In our view, it is possible today to undertake sale of prescription medicines over the internet in full compliance of law. One must appreciate that if there was an existing requirement to obtain a separate license before undertaking online sale of medicine, the Government itself would not have proposed an additional registration requirement under the draft rules. Furthermore, the online sale of medicine is a major business today, unlike a few years ago. The government is not blind to its existence. If it was per se illegal to sell prescription medicines over the internet, the government would have itself stopped it long ago, especially after an expert committee had examined its legality and given its recommendations.

Therefore, we strongly believe that the premise of the petitioner that the online sale of prescription medicines cannot be performed without breaking the law, or is being performed without a valid license, is totally without basis. It is hoped that the Court will also confirm this position during the course of the hearing of the petition.

Until such clarification from Court arrives, it is worth nothing that the language employed by the Court in its order was not generic to online sale of medicine, but specific to online sale of prescription medicine without license. Therefore, those companies who are undertaking online sale of prescription medicines under appropriate license should not be affected by this order. However, those companies who do not have a license, or have a regulatory short-coming in their processes, may face investigation or possible closure as direct consequence of the actions taken by the Government under the Court's order.

– **Darren Punnen, Anay Shukla & Dr. Milind Antani**
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¹ Order dated October 31, 2018 in *The Tamil Nadu Chemists and Druggists Association v. The Union Of India. And Others.*, WP/28716/2018 (Mad HC)

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