

Legislative Control of Online Pharmacies

Newspapers and the Electronic Media carry daily advertisements of online pharmacies inducing the reader to purchase medicines by uploading the doctor's prescriptions. While this certainly saves time, most users of these online pharmacies may be mindful of the genuineness, storage conditions, and source of the medicines so dispensed.

Presently, these online pharmacies or e-pharmacy portals operate on the marketplace or inventory model in compliance with The Information Technology Act, 2000 and the e-commerce guidelines of the Government of India, with registered pharmacies or chemists as channel partners of these portals and the source of the medicines.

While the brick and mortar "Chemist" as we generally refer to these shops, are regulated by The Drugs and Cosmetics Act, 1940 and the Rules framed thereunder (the "Act"), the Act does not explicitly regulate the online pharmacies. The Government of India has by Notification dated August 28, 2018 proposed the Draft Drugs and Cosmetics Amendment Rules, 2018 (Draft Rules) to include provisions for regulation of the online pharmacies/e-pharmacies, by including a new Part VIB in the extant Drugs and Cosmetics Rules, 1945.

A brick and mortar Chemist is required to have a drug license issued by the Licensing Authority, for dispensation of drugs with the mandatory requirement of a Registered Pharmacist who is a person registered under the Pharmacy Act, 1948, or a matriculate or equivalent with four years' experience of selling drugs, or a degree holder from a recognized University who has one year's experience of dealing in drugs. The need of a Registered Pharmacist arises only when the Chemist is a pharmacy engaged in compounding medicines against a prescription. The Draft Rules purport to impose similar conditions on the E-pharmacies.

Under the Draft Rules, an E-pharmacy means the business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode. E-pharmacy portal is defined as a web or electronic portal established and maintained by the E-pharmacy registration holder to conduct the business of e-pharmacy.



Dipak Rao
Senior Partner
E: dipak@singhania.in

The E-pharmacy portal is to be established in India and the data generated or mirrored through the portal is prohibited from being sent or stored by any means outside India.

Every person who intends to operate the E-pharmacy, including an individual, HUF, Company, Partnership, LLP is required to apply for registration with the Licensing Authority to sell, stock, exhibit, or offer for sale drugs through E-pharmacy. The conditions for registration are:

1. Compliance with the provisions of The Information Technology Act,2000.
2. Cash or credit memo to be generated through the portal and should reflect:
 - a) serial number and date,
 - b) the name, address and sale license number of the licensee dispensing the drugs,
 - c) the name, quantity, batch no., date of expiry and name of manufacturer of the drug dispensed.
 - d) name and address of the e-pharmacy registration holder along with signature/digital signature of the Registered Pharmacist Incharge.

The registration would be for a period of three years, renewable within three months of expiry.

The E-pharmacy is prohibited from dealing with narcotic and psychotropic drugs referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985, Tranquilizers and Drugs specified in Schedule 10 of the Drugs & Cosmetics Rules, 1945.

The obligations of the E-pharmacy registration holder for operating the E-pharmacy portal are:

1. Orders for retail sale received through e-pharmacy portal.
2. Dispensation of drugs against prescription of a registered medical practitioner received from the customer through the portal.
3. Details of drugs dispensed including patient details to be maintained on the portal.
4. Portal to disclose:
 - a) registration certificate.
 - b) constitution of the registration holder.
 - c) logo, if any, of the portal.
 - d) types of drugs offered for sale and availability.
 - e) supply channels or vendor lists.
 - f) details of registered medical practitioner, if any.
 - g) name and registration details of Registered Pharmacist who validates the prescription before dispensing the drugs.
 - h) details of the logistic service provider.
 - i) return policy of dispensed drugs.
 - j) Contact details of the E-pharmacy – email, landline and mobile numbers, address.
 - k) Procedure for submitting grievances on the portal and redressal mechanism
5. Facility for customer support and grievances redressal available for at least 12 hours every day for all 7 days of the week.
6. Details of the patient to be kept confidential and not disclosed to any other person except the Central or State Government.

The Registered Pharmacist is under an obligation to verify the details of the patients, registered medical practitioner issuing the prescription and then to arrange to dispense the drugs in accordance with the prescriptions.

The E-pharmacy registration holder who has received the prescription on the portal shall dispense and make arrangements for supply of drugs from any retail or wholesale licensed premises under the Drugs & Cosmetics Act, 1940.

The Licensing Authority shall have powers to monitor the information on the E-pharmacy portal periodically as well as physically inspect every two years, the premises from where the E-pharmacy business is being conducted.

The Draft Rules have given the public a forty five days window for objections/suggestions which would be considered by the Central Government, after which the same would be re-notified in the Official Gazette and become effective.