

Draft rules on E-Pharmacy

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Manifest pedagogy

Health as a topic has broadly two dimensions to be studied.

1. Health as science
2. Health Governance

The above topic is part of Health Governance. Health governance as a topic is important for mains where in the role of the government towards achieving Universal health coverage is very relevant.

In news

A Division Bench of the Madras High Court recently stayed an order passed by a single judge that banned the sale of medicines online.

Placing it in the syllabus

Issues relating to development and management of Social Sector/Services relating to Health,

Static dimensions

1. E-pharmacies
2. Advantages and Disadvantages

Current dimensions

1. Madras High Court order
2. Draft rules for the operation of e-pharmacies in India

Content

The Madras High Court order on the sale of online medicines

Timeline of the orders:

- In October, the Madras HC had issued a country-wide interim stay order on online pharmacies
- However, the court had also urged the government to pass the draft regulations for e-pharmacies passed by Drug Technical Advisory Body in September
- Suspension of order by Madras HC comes a week after Delhi HC issued an all-India ban on e-pharmacies
- A Division Bench of the Madras High Court recently stayed an order passed by a single judge that banned the sale of medicines online.
- Recently, The Madras High Court has suspended the ban on the sale of online medicines after a group of e-pharmacy companies had filed an appeal requesting for a stay on the court's order asking online pharmacies to shut down operations by December 20, 2018 and the Centre to notify regulations for companies by January 31, 2019.

Draft rules for Operation of E-Pharmacies in India

The Ministry of Health and Family Welfare has introduced the draft to amend the Drugs and Cosmetics Rules, 1945 ("Rules"). The draft rules make provisions for sale of drugs by e-pharmacy. As a result, Part VI-B is inserted into the Rules. **Some of the notable changes brought by the draft rules are as follows:**

Important Definitions under the rules

- **"e-pharmacy"** means the business of distribution or sale, stock, exhibit or offer for sale of drugs through the web portal or any other electronic mode;
- **"e-pharmacy portal"** means a web or electronic portal or any other electronic mode established and maintained by

the e-pharmacy registration holder to conduct the business of e-pharmacy

Registration and Customer Support

- The draft rules make it mandatory that no person shall sell, stock, exhibit or offer for sale drugs through e-pharmacy portal unless registered. E-pharmacy registration holder shall arrange or provide the drugs, as per the prescription received from the customer, within the period specified by the e-pharmacy registration holder at the time of placement of the order through e-pharmacy portal.
- Further an e-pharmacy registration holder shall have a facility for customer support and **grievance redressal for all stakeholders**. The customer support and grievance redressal shall operate for not less than 12 (twelve) hours for all 7 (seven) days of a week. Also the facility shall also have a registered pharmacist in place to answer the queries of customers through customer helpline.

Disclosure of information generated through the e-pharmacy portal

- The information received by the e-pharmacy registration holder from the customer by way of prescription or in any other manner shall not be disclosed by the e-pharmacy registration holder for any other purposes nor shall same be disclosed to any other person.
- The e-pharmacy registration holder shall be duty bound to provide such information to the Central Government or the State Government, as the case may be, as and when required for public health purposes.
- The e-pharmacy portal shall be established in India through which they are conducting the business of e-pharmacy and shall keep the data generated localised: Provided, that in no case the data generated or mirrored

through e-pharmacy portal shall be sent or stored, by any means, outside India.

Application for registration of e-pharmacy

- Any person who intends to conduct the business of e-pharmacy shall apply for the grant of registration to the Central Licensing Authority in Form 18AA through the online portal of the Central Government. The information furnished above shall be supported by the duly notarized affidavit from the applicant. Any application for the grant of e-pharmacy registration of e-pharmacy made in Form 18AA to the Central Licensing Authority shall be accompanied with a fee of fifty thousand rupees and the information and documents as specified in Form 18AA.

Registration

- The detailed conditions for registration for an e-pharmacy registration holder are laid down in the rules. Some of the conditions include being compliant with Information Technology Act, 2000 and the rules therein, details of the patients to be kept confidential, the supply of drugs being made against cash or credit memo generated through e-pharmacy portal, informing the Central License Authority in the case of any change in the constitution of the firm taking place, uploading, e-pharmacy activities not being carried out with respect to any drug referred in e Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), tranquilizers and the drugs as specified in the Schedule X of the Rules.
- Certain information needs to be disclosed on the e-pharmacy portal such as the registration issued, the constitution of the firm including the details of directors, partners, official logo of the e-pharmacy, details of the logistics service provider, return policy

Periodic Inspection

- The draft rules also provide the detailed conditions for registration for an e-pharmacy and provide for periodic inspection of the same. The premise where the e-pharmacy business is conducted shall be inspected every 2 (two) years by the Central Licensing Authority.
- **Procedure for distribution of sale of drugs through e-Pharmacy**
- It is the duty of the registered pharmacist on the behalf of e-pharmacy registration holder to verify the details of the patients, registered medical practitioner and arrange for dispense of the drugs. Further in cases of e-prescriptions the same shall be uploaded on the e-pharmacy portal and shall be kept in record by the dispenser.

Validity of registration and renewal

- The registration issued to any person shall be valid for a period of 3 (three) years and shall be renewed subject to a fee of INR 50000 (Rupees Fifty Thousand). Provided that if the application for renewal of registration is made before its expiry or if the application is made within three months of its expiry, the registration shall continue to be in force until orders are passed on the application. The registration shall be deemed to have expired if an application for its renewal is not made within six months after its expiry.

Prohibition of advertisement of drugs through e-pharmacy

- Further, the draft rules stipulate no e-pharmacy shall advertise any drug on radio or television or internet or print or any other media for any purpose.

Suspension or cancellation of registration

- Where the e-pharmacy registration holder contravenes any provision of the Drugs and Cosmetics Act, 1940 and this Part, the Central Licensing Authority, shall, after

giving the e-pharmacy registration holder an opportunity to show cause as to why such an order should not be passed, shall, by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary or cancel the registration

- Finally under the draft rules the Central Licensing Authority and the State Licensing Authority shall have the power to monitor the data with regard to drugs available with e-pharmacist, types of drugs offered for sale, supply channels etc. to ensure compliance with the Drugs and Cosmetics Act, 1940.

Why E-commerce in medicine is required

It is required because it has the following benefits;

- The major benefit is that it makes medicine more accessible, which is especially useful for people who require ongoing treatments for conditions such as type 2 diabetes.
- Patients can set up an automatic system and regular shipping to their place of residence, which would work well with Amazon's Prime membership service.
- They would also save on travel expenses and be less likely to miss their prescriptions, as they would always have them on hand.
- In short, there would be an overall improvement in the supply chain.
- **Access to Information** – E-commerce provides for the immediate release of information to hospitals, providers, insurers, and patients. This is especially important in areas of the world where health care access is limited.
- **Open Communication** – E-commerce platforms provide the unique opportunity to increase communication among doctors, hospitals, and most importantly, between health care providers and their patients.

- **Improved Outcomes** – Having the ability to connect with patients to help with chronic disease management, medical regimen compliance, and general questions help keep people healthier and more engaged in their health care management.
- **Efficiency** – Introducing technology can help address many of the redundant and time-consuming tasks that medical professionals have to undertake to provide care.

What precautions need to be taken?

1. Misuse of pharmaceuticals can have devastating effects but can be overcome by offering counseling to buyers prior to their checking out.
2. Design a website for checking the legality of e-pharmacy.
3. Make guidelines for consumers for safely accessing e-pharmacies and explains how to buy medicines safely from e-pharmacies.
4. Specific and clear-cut rules should be made for selling, prescribing, dispensing, and delivering prescription drugs through e-pharmacies.
5. List of illegal and blacklisted e-pharmacies should be provided to help out consumers and stop them using such fake websites.
6. The government should make a common logo for legally operating e-pharmacies to distinguish them from illegal one.
7. Make guidelines for online drugs importation and re-importation for legislators and consumers.
8. It is mandatory for e-pharmacies dealing with online drugs importation and re-importation to be registered and to get a license for the same from regulating body.
9. As the power of drug regulation is distributed between Central and State government, the role of Central government and State government should be well defined.
10. E-pharmacies' should not use the data generated from

online business for commercial purpose.

11. Using public-private tie-ups leveraging characteristics of internet based technologies and engaging private sector service providers can be the basis of an encyclopedic policy to address this planetary public health concern.
12. Government schemes like National Rural Health Mission can aid in promoting proper procedures to acquire drugs, prevent self-medication through campaigns on television, radios and social media.
13. Watch should be kept on the importation of banned drugs through e-pharmacies outside India which don't come under Indian jurisdiction.
14. Each and every activity and transactions made through e-pharmacies must be under the regulatory scanner to prevent it from underworld and smuggling.
15. E-pharmacy must establish its server in India as if it is outside the boundaries of India, it is difficult to control and regulate it.
16. To ensure efficient running of e-pharmacies great compliance and strict adherence to laws is required. So, regularly check whether epharmacies follow it or not.