

## Flipkart's e-Healthcare Advent: Legal & Regulatory Concerns To Watch For

written by Rajesh Sivaswamy | April 22, 2022



### Online Pharmacy Legality

Flipkart has entered the e-pharmaceutical industry with its new “Flipkart Health Plus” application, which will act as an intermediary marketplace platform to address the issue of medicine and healthcare service accessibility across the country through its investment in the “SastaSundar.com”, an online pharmacy and digital healthcare platform. While entering the healthcare sector, especially under the advent of the e-pharmaceutical sector, there are various legal and regulatory concerns over the same since there are no dedicated laws for e-health and telemedicine laws. The regulations that govern the online sale and purchase of prescription medications are governed by the laws that govern drugs and technology in general. Unfortunately, legislation has not kept pace with technical changes, resulting in ambiguity.

In India, the Central Drugs Standards Control Organization [“CDSCO”] is in charge of approving, regulating, and licensing pharmaceutical companies. The retail selling of medications is governed by-

- Drugs and Cosmetics Act, 1940
- Drugs and Cosmetics Rules, 1945
- Pharmacy Act, 1948
- Indian Medical Act, 1956
- Code of Medical Ethics Regulations, 2002
- Pharmacy Practice Regulations, 2015

There are two types of models used in India to categorize the online pharmaceutical industry: organized and non-organized.<sup>1</sup> The organized sector follows the process of prescription confirmation, electronic record maintenance, and customer advisory.

The non-organized sector does not follow such a process and simply delivers the medicines, which raises legal and regulatory concerns, which will be discussed here because “Flipkart Health Plus” falls into the non-organized sector according to the Flipkart Health Plus Chief Executive Officer, Prashant Jhaveri, who stated that it will work as an intermediary marketplace initially.

The main legal and regulatory concerns are:

- The legality of the online sale of medicines
- Monitoring of online sale of medicines
- Deceptive marketing
- Drug abuse and quality standards
- Inter-state legal contradictions
- Sale of schedule H and schedule X drugs
- Privacy concerns

### Status Of Online Sale Of Medicines

There are no explicit rules present about the permission to conduct such an e-commerce business, nor any restrictions over the same. Online sale of medicines come under the ambit of the Information Technology Act, 2000 as well as the Indian Medical Act, 1956. However, the legality of the online sale of drugs remains unclear, since these legislations do not permit or prohibit e-pharmaceutical sales in India.

It is unclear how these regulations will apply to the electronic pharmacy

paradigm because they do not recognize the online pharmacy business. For example, the onerous licensing standards and registration criteria mentioned in the Drugs and Cosmetics Act and the Pharmacy Act are not being followed by online pharmacies.

#### Online Sale and Monitoring of Pharmaceutical Medicines

The physical method of sales and monitoring of medicines is well regulated under the Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945, and Pharmacy Act, 1948. However, for online stores, they do not provide any specific regulations.

To combat this, the Ministry of Health and Family Welfare issued a notification on 28<sup>th</sup> August 2018<sup>2</sup> to amend the Drugs and Cosmetic Rules, 1945. The suggested amendments include:

- Provision for sales of the drug by e-pharmacy
- Definition of 'E-Pharmacy Portal'
- Definition of 'Sale by way of 'E-pharmacy'
- Provisions for registration, its conditions, and its validity
- Provisions for Redressal Monitoring Mechanism for such e-pharmacy

These inclusions are welcomed; however, they do require implementation into the current legislation as well for a definitive regulatory framework for the proper functioning of e-pharmacies in India.

#### Deceptive Marketing

Deceptive marketing is routinely used by online drug marketers to commit fraud and conceal the risks linked with the prescriptions they sell.

Furthermore, marketers use targeted marketing to reach out to the most vulnerable elements of society, such as the elderly, the disabled, and those with poor socioeconomic standing. The increased use of social media and online advertising likely compounds this situation.

#### Drug Abuse and Quality Standards

Those who buy medicines from online pharmacies usually self-medicate. The growth of online pharmaceuticals, particularly non-prescription medications, can be ascribed to the expansion of e-commerce enterprises. For instance, doctor-written prescriptions should not be used again; but it is common for individuals to reorder the medicines from online pharmacies using an old prescription note -- increasing the danger of misuse.

Online pharmacies also frequently fail to meet high-quality standards and sell pharmaceuticals that have not been approved. For instance, it's probable that the supplies are not stored at proper temperatures to be effective as per the quality standards set in Section 8 of the Drugs and Cosmetics Act. As a result, poor monitoring during storage and transit endangers the patient's health.

#### Inter-State Legal Contradictions

Every state in India has its own set of legal rules and regulations governing the sale of drugs and medicines. Certain medicines may also be prohibited in some states. For example, in the state of Uttar Pradesh, Atorvastatin (a common drug used to treat cardiac ailments) is prohibited. However, on its border, Delhi has permitted the sale of the same. Complications arising out of such regional challenges could hamper operations.

As a result, the Drugs and Cosmetics Act is not followed. Due to the vastness of the market and the free operation of e-commerce businesses, it is extremely difficult to monitor such violations and hold e-pharmaceutical companies like "Flipkart Health Plus" accountable for the source of the

medicines and the customers to whom they are delivered.

#### Sale of Schedule H and Schedule X Drugs

Medicines in Schedules H and X of the Drugs and Cosmetic Acts cannot be delivered to customers without a valid prescription, and doing so is a crime under the Drugs and Cosmetics Act.

It's often challenging for e-commerce healthcare services to verify such prescriptions and also keep a record of patients with the doctor and hospital details. This may lead to patients ordering such medications across multiple e-pharmaceutical platforms, increasing drug abuse cases.

#### Privacy Concerns

In the absence of strict data protection legislation, websites may be willing to disclose online patient information to hospitals and doctors who may market to these individuals. Because advertising generates cash, search engines frequently allow non-verified suppliers to advertise as well.

The Information Technology Act of 2000, on the other hand, establishes a key legal framework for cyber laws by emphasizing privacy, data security, and confidentiality. Unfortunately, the majority of internet pharmacies are unaware of their intermediary and due diligence responsibilities, and as a result, are considered in violation. Aggregators that sell medications online are classified as 'intermediaries', and as such, they should be governed by the Information Technology Act.

Sections 43A and 72 of the Information Technology Act impose liability on body corporates that handle personal data for failing to implement secure practices and disclosing information to third parties in violation of the user's contract, without their consent, or with the knowledge that the disclosure may result in wrongful gain or loss to the consumer, may be relevant in dealing with this.

#### Endnote

E-pharmacies are illegal. But they cannot be prohibited because the concept of purchasing medications online has risen in popularity for the joy of convenience. And so, they must be legalized and strictly regulated.

As a result, the Drug, and Cosmetics Act must be updated to include online pharmacies. Since e-commerce is the way of the future, traditional chemists will certainly engage with internet forums to improve efficiency, and old models will be recast to produce a more efficient method of working.

Rural populations will have faster access to consultations and prescriptions if e-pharmacies flourish. This will necessitate major efforts to increase technology penetration in such sectors.

As a result of continuing public interest litigation and multiple examples of unlawful internet marketing of forbidden pharmaceuticals in India, the government may impose harsh limitations or even a ban on such operations shortly.

Rather than enforcing a blanket limitation or prohibition, the government is considering starting a pilot project to monitor and control online drug sales. Furthermore, the CDSCO is interacting with international drug regulatory agencies such as the European Medicines Agency and evaluating their models to gain a better understanding of how medicines marketed through e-commerce portals are monitored in these countries.

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