# A Comparison of Healthtech Regulations: India

Thought Leadership • February 13, 2023

First Published by Asia Business Law Journal

By: Safir Anand

Intellectual property (IP) and intellectual capital (IC) drive companies to create jobs and market advantages, as well as propel innovation. Proper protection of IP rights for the ability to monetise and enforce eventual successful valuation are key goals in India.

With multiple IPs combined, brands can create a world of their own, attracting customers to join a developed and advanced ecosystem. This has triggered a trend of uniqueness, layering IP on multiple levels. But not all IP can be protected statutorily, and much has to be protected strategically. In this article, the author explores prevalent IP issues that impact and enable the country's competitive healthtech sector.

## E-PHARMACIES

With the advent of technology, the e-retail business has surged and is expected to grow quickly. Markets N Research predicts the global e-pharma industry will grow nearly three-fold from USD50.5 billion in 2021 to USD142.7 billion by 2028. Among the major players, India is the Asia-Pacific's fastest growing market. Lower prices, doorstep services, around-the-clock availability and easy accessibility are major contributors to the rise of the e-pharma industry.

The Federation of Indian Chambers of Commerce and Industry notes many startups entering the e-pharmacy space. During the pandemic, e-pharmacy was one of the few performing businesses, with 50-60% growth in overall gross merchandise value. Clearly, the sector has huge potential to attract foreign direct investment.

The sale of drugs via e-pharmacies falls under the purview of the Drugs and Cosmetics Act, 1940, and the Information Technology Act, 2000. But the Drugs and Cosmetics Act doesn't distinguish between online and offline pharmacies. Hence, to date, India has no specific legislation or rules to regulate the e-pharmacy industry, with the exception of the Ministry of Health and Family Welfare's Draft Rules to Regulate the Sale of Drugs through E-pharmacy, approved with the introduction of the Draft Drugs and Cosmetics (Amendment) Rules, 2018, providing sector-specific e-commerce regulations. These draft rules mandate all e-pharmacy holders be registered with the Central Drugs Standard Control Organisation, the country's apex drug regulator and central licensing authority. Once notified, these rules shall regulate e-pharmacies to obtain their licences in the prescribed

manner, apart from laying down the procedure for distribution or sale of drugs through e-pharmacies. The licences issued will remain valid for three years and registration can be renewed.

# TELEMEDICINE GUIDELINES

The government published the Telemedicine Practice Guidelines in 2020 to legalise virtual consultations by professionals. This was a welcome move, especially during the health crisis, assuring steady medical services. The guidelines, formulated by the public policy thinktank NITI Aayog, were notified under the Indian Medical Council (Professional Conduct, Etiquette, and Ethics Regulation, 2002) and issued by the Ministry of Health and Family Welfare. Salient features include:

- Only registered medical practitioners (RMPs) are entitled to provide telemedicine consultations;
- RMPs are allowed to use text, video or audio-enabled solutions for consultations;
- Onus is on the doctor to decide whether teleconsultation will suffice, or if in-person review is needed, based on the complexity of the patient's situation;
- RMPs have to verify the patient's identity by name, age, address, email, phone number, registered identification, or other manner;
- RMPs need to be sure about the patient's age before prescribing any medication. The practitioner can ask for the patient's proof of age if in doubt;
- If the patient initiates the telemedicine consultation, their consent is implied;
- If a physical examination is critical information for consultation, RMPs should not proceed until a physical examination can be arranged;
- All RMPs are to complete a mandatory course within three years of the release of the guidelines;
- Certain drugs listed cannot be prescribed through telemedicine; and
- Doctors must follow existing ethics and confidentiality regulations under the Indian Medical Council Regulations, Information Technology Act, and any future data protection and privacy laws. The Personal Data Protection Bill treats health data as sensitive personal data and places restrictions on its movement and use.

# MEDIARIES OR NEMESIS?

Counterfeiting is prevalent but the world of pharmaceuticals is among the most struck by it. One effective anti-counterfeiting play would be making the intermediary liable, targeting suppliers of counterfeit products. But counterfeiters often act through third parties that are perhaps unaware their services are used for illegal activities. Such third-party engagement renders the liability of intermediaries a cutting-edge matter in IP law worldwide. Intermediaries may include both principal groups: online (i.e., e-commerce websites) and offline intermediaries.

In 2019, the Department for Promotion of Industry and Internal Trade released a new draft e-commerce policy proposing data localisation and streamlining of the operations of e-commerce companies in line with the US Food and Drug Administration rules and local regulations. This was an anti-counterfeiting measure. At that time, several e-commerce companies such as Flipkart and Amazon raised concerns over the guidelines, and the department has since circulated a 2022 draft of the policy among government departments and concerned ministries.

# DATA PROTECTION

The Information Technology Act, 2000, was unable to keep up with technology advancement. Data protection has become more complicated as the number of devices to monitor and protect expands daily.

But India does not have any specific legislation for data protection. Data breaches result mostly from inadequate data protection measures. Amazon's Alexa feature of listening to conversations, and Google accessing the healthcare information of millions of people, have raised public alarm.

Since the EU's General Data Protection Regulation, 2018, was enforced, India's Digital Personal Data Protection Bill, 2022, has finally been tabled in parliament, prescribing compliance requirements for all forms of personal data, broadens individual rights, introduces a central data protection regulator, and institutes data localisation requirements for certain forms of sensitive data.

# THE BRAND

In addition to trade name protection for a brand, protection can be availed for packaging, labels, logos, get-up (the appearance of goods and their packaging), layout and combinations of colours of pharmaceutical products. Also, unique tablet designs can be registered as 3D trademarks, for instance, in the shape of an alphabet letter, distinct colour combination and specific numerals, or distinctive shapes of containers, bottles and kits. The Trade Marks Act, 1999, provides specific provisions for the prohibition of the registration of names of chemical elements or international non-proprietary names.

# COPYRIGHT

For the protection of various aspects of pharmaceutical products, the following can be protected under copyright:

- Packaging, labels, get-up, layout, colour schemes of the pharmaceutical products;

- Advertisement text and graphics as published in a particular journal, article, medical book, or anywhere else; and
- Any literary work regarding efficacy, general precautions, side effects or important safety information.

## PATENTS

India only recognised process patents for inventions relating to food, drugs and chemicals until the product patent regime was introduced in 2005. Now it is imperative for pharmaceutical companies to protect their inventions from any unauthorised commercial use by acquiring patent rights on the invented product or process.

Pharmaceutical patents can be classified under the categories of new chemical entities, formulations or compositions, synergistic combinations, new forms of known substances, kits, product-by-process; and process or method of manufacturing. However, the process for medicinal, surgical, curative, diagnostic, therapeutic or other treatment of humans or animals is not patentable under the act.

## DOMAIN NAMES

Apart from listing products on official websites, several companies operate product-specific websites for their flagship products, dispersing product-related information, manner of use, general precautions, side effects, or important safety information.

As domain names serve the purpose of source identifier, they are treated as equivalent to trademarks in India. Hence, domain name registrations confer the companies with proprietary rights over the mark.

## WELL-KNOWN MARKS

A petition or application for declaring a mark as well-known may be filed under the amended Trademarks Rules, 2017. Earlier, there was uncertainty around the process and timelines, but now a committee decides such applications and the process is more streamlined.

Indian courts have on several occasions also observed that goods associated with a trademark do not have to be in the market for a certain number of years to acquire distinctiveness. A trademark can acquire distinctiveness overnight, so adjudication is on a case-by-case basis. Hence, pharma brands acquiring substantial market share as popular, famous and well-known are eligible for the process.

# CUSTOMS REGISTRATION

The law allows holders of specific IP rights – including trademarks, copyright, patents, designs and geographical indications – to record their rights with Indian customs for seizure of counterfeit goods at port.

Import of branded goods is notified to the respective rights holder and if the goods are found to be counterfeit they are seized, with a heavy penalty imposed on all parties facilitating the import. The seized counterfeit goods are ultimately destroyed under the rights holder's supervision.

## KEY CONTACT



**Safir Anand**

Senior Partner

View Bio of Safir Anand

## RELATED PRACTICES

PATENTS