

AUGMENTING THE FIGHT AGAINST COVID-19: HOW BUSINESSES ARE STEPPING UP - REGULATORY ENABLERS AND MISSES

1. INTRODUCTION

COVID-19 has brought the world to its knees. Countries are at different stages of transmission of the pandemic, trying their best to cope with its growing economic and social impact. Governments world-over are eager for the economy to resume its usual pace, but many of them have been constrained to instead order temporary closure of all non-essential businesses in a bid to contain and prevent the spread of COVID-19.

This is aligned with the advisory from the World Health Organisation and the International Chambers of Commerce, in the following recent joint statement: *"The COVID-19 pandemic is a global health and societal emergency that requires effective immediate action by governments, individuals and businesses. All businesses have a key role to play in minimising the likelihood of transmission and impact on society"*.¹

While governments across the world are taking drastic (but necessary) steps to control the spread of COVID-19, they also face the conundrum of containing its impact on the economy at the same time. The result being that in an uncertain and restrictive global economy, businesses are being pushed to pivot their offering and evolve novel business methods, to ensure self-sustenance, address the needs of the economy and to play a critical role in this fight.

In this article, we attempt to examine the sudden boost to certain businesses and some recent business adaptations, triggered and enabled by the pandemic. We have also identified some material gaps in the regulatory framework governing such activities, which need to be filled in order to enable these businesses to function more effectively and thereby assist better in dealing with the fight against COVID-19.

2. TELEMEDICINE

Regulatory Background

Until recently, there was a lack of clear regulatory framework governing the practice of telemedicine in India. In an attempt to bridge this gap, the Hon'ble Supreme Court of India in 2009², while dealing with a matter of medical negligence, observed that the tendency to give prescription over the telephone should be avoided, except in case of acute emergency.

To abate the pressure created by COVID-19 on the Indian healthcare system, and to improve access to healthcare facilities by making use of advancements in technology, the Ministry of Health and Family Welfare ("MOHFW") on March 25, 2020, issued the Telemedicine Practice Guidelines ("Guidelines"). The Guidelines enable all medical practitioners registered under the Indian Medical Council Act, 1956 ("RMP"), to provide telemedicine consultation to patients from any part of India through video, audio, telephone or

¹<https://www.who.int/news-room/detail/16-03-2020-icc-who-joint-statement-an-unprecedented-private-sector-call-to-action-to-tackle-covid-19>

² *Martin F. D'Souza v. Mohd. Ishfaq* [AIR 2009 SC 2049]

mobile phones, digital data exchange or text (chat, messaging, email, fax etc.) and data transmission systems. The Guidelines have been issued in the form of an amendment to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (“**Ethics Regulations**”).

What is Telemedicine?

Pursuant to the Guidelines, the practice of telemedicine comprises of the following key ingredients:

- delivery of healthcare services by healthcare professionals from a distance/remotely; and
- use of technology for communication between the parties involved in a patient consultation.

Key factors to bear in mind for RMPs on treatment of patients

The Guidelines list out multiple precautions and measures to be followed for safeguarding privacy and security of a patient’s data and records, ensuring accuracy of treatment without a physical check-up, risk mitigation for doctors; some of which have been summarised below:

- the RMP must exercise his/her professional judgment before commencing any telemedicine consultation, to decide whether a physical consultation is more appropriate in the interest of the patient;
- both the patient and the RMP are required to know each other’s identity during telemedicine consultations;
- the RMP must display his/her registration number in all of his/her communications with the patient;
- the patient’s consent is necessary for telemedicine consultations, unless the telemedicine consultation is initiated by the patient (*in which case consent is implied*), the RMP is required to obtain and record express consent from the patient; and
- the RMP must comply with applicable data privacy laws, while handling and dealing with any personal information concerning the patient.

The RMP can also prescribe medicines via such consultations, provided, however, it is done in accordance with the Ethics Regulations and is subject to an appropriate diagnosis or provisional diagnosis having been made in the discretion of the RMP. The RMP is required to share a copy of the signed prescription or e-prescription with the patient.

The Guidelines also define the term “telehealth” as the delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. As per the Guidelines, ‘telemedicine’ denotes clinical services delivered by a RMP while ‘telehealth’ is a broader term for use of technology for health and health related services, including telemedicine. However, since all other aspects of telehealth are specifically excluded from the scope of the Guidelines, it is unclear whether the Government of India intends to issue separate guidelines to deal with such aspects.

Industry developments after issuance of the Guidelines

With the issuance of the Guidelines, it is evident that the authorities have recognised the benefits of telehealth and telemedicine. Businesses such as Cloudnine Hospitals³ and AIIMS-Bhubaneswar⁴, have launched teleconsultation services after the issuance of the Guidelines. State governments such as the Chhattisgarh Government⁵ have also launched telemedicine services. On account of the clarity provided by the Guidelines,

³<https://www.expresshealthcare.in/covid19-updates/cloudnine-group-of-hospitals-launch-teleconsultation-services/418023/>

⁴<https://www.newindianexpress.com/cities/bhubaneswar/2020/apr/14/telemedicine-starts-at-aiims-2129826.html>

⁵<https://www.hindustantimes.com/india-news/chhattisgarh-starts-telemedicine-service-amid-covid-19-lockdown/story-1N2QrXxcwBwaxHISYS3bGM.html>

existing players in the telemedicine space such as Practo and mfine are also trying to strengthen their businesses⁶ and working on aligning their practices with the requirements prescribed by the Guidelines⁷. The demand for telemedicine consultations has been on the rise since the spread of COVID-19, with an increasing number of patients opting for online consultations, given the imposed lockdown and restriction on movement. What remains to be seen is the manner in which these businesses grow after the pandemic becomes a thing of the past.

3. E-PHARMACIES

Regulatory Background

The Drugs and Cosmetic Rules, 1945 (the "**Rules**") formulated pursuant to the Drugs and Cosmetic Act, 1940 (the "**Act**") regulate the import, manufacture, distribution and sale of drugs and cosmetics in India. The Act and the Rules, however, are silent on the online sale of drugs. In the absence of any regulation, India saw a progressive rise in unregulated e-pharmacy businesses after the initial e-commerce boom. To this effect, the office of the Drugs Controller General of India (DGCI) issued a circular on December 30, 2015 clarifying that the Act and the Rules do not distinguish between the sale and distribution of drugs through conventional means and online. Consequently, entities selling drugs through e-pharmacies were required to obtain a pharmacy license and comply with the Act and the Rules.

With a view to provide for appropriate monitoring mechanisms, the draft amendment to the Rules (the "**Draft E-pharmacy Rules**") were published by the Department of Health and Family Welfare under the MOHFW on August 28, 2018, primarily setting out the requirements and conditions for the sale of drugs by an 'e-pharmacy'. The Draft E-pharmacy Rules are yet to be notified. During the pendency of their notification, the Hon'ble Delhi High Court in December, 2018 passed an interim order in the case of *Dr. Zaheer Ahmed v. The Union of India & Ors.*⁸, clarifying that online sale of medicines without licence is prohibited forthwith until further orders. Subsequently, the DCGI in November, 2019 issued an order directing all States and Union territories in India to prohibit the sale of medicines through unlicensed online platforms till the Draft E-pharmacy Rules are finalized and notified.

Impact of COVID-19 on e-pharmacies

On March 24, 2020, the Government of India declared a country-wide lockdown to prevent the spread of COVID-19, and issued consolidated guidelines on April 14, 2020, *inter alia* to States and Union Territory Governments for implementation of the lockdown ("**Consolidated Guidelines**")⁹. The Consolidated Guidelines had directed commercial and private establishments to shut operations, but the delivery of all essential goods including food, pharmaceuticals, medical equipment through e-commerce were permitted as exceptions to the lockdown. In fact, the police department of the State of Karnataka specifically issued an office memo clarifying that online delivery services and e-commerce retailers *including* e-pharmacies such as Medlife, PharmEasy, 1MG etc., will be allowed to operate¹⁰. The lockdown was further extended till May 03, 2020¹¹ and subsequently extended by another two weeks effective from May 04, 2020. The Government of India also issued new guidelines on May 01, 2020¹² for implementation of the lockdown ("**New Guidelines**"). The New Guidelines permit e-commerce activities in respect of essential goods including pharmaceuticals. .

⁶ <https://yourstory.com/2020/04/curefits-diagnostic-vertical-carefit-telemedicine-mukesh-bansal>

⁷ <https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/indian-healthcare-companies-see-big-boost-with-govt-move-on-telemedicine/articleshow/74885564.cms>

⁸ W.P.(C) 11711/2018 and CM APPL. 45307/2018

⁹ https://www.mha.gov.in/sites/default/files/PR_Consolidated%20Guideline%20of%20MHA_28032020%20%281%29_1.PDF

¹⁰ Memo No. 02/CP-BLR/Covid-19/2020 issued by the Police Department of Government of Karnataka dated March 26, 2020

¹¹ https://prsindia.org/files/covid19/notifications/2737.IND_Extension_Lockdown_Order_April_14.pdf

¹² https://prsindia.org/files/covid19/notifications/IND_Extension_Lockdown_May_1.pdf

It is evident that in this unprecedented situation created by the COVID-19 pandemic, e-pharmacies are playing a crucial role in meeting the healthcare needs of the public. Allowing e-pharmacies to operate during this hour of need, further acknowledges the utility of this business model.

Inevitably, on March 26, 2020, the MOHFW acknowledged that retail sale of drugs and delivery to the doorstep of consumers is essential during COVID-19 and issued directions thereon (“**Notification**”). In terms of this Notification, any person holding a license under the Rules is permitted to sell any drugs, except the drugs specifically prohibited, by retail with doorstep delivery of the drug, subject to certain conditions. One of the conditions laid down in the Notification is that the drugs can be supplied at the doorstep of only those patients located within the same revenue district, where the license holder is located. This condition creates ambiguity on the operation of e-pharmacies that have an online-only presence but no brick and mortar stores. The aforesaid geographical limitation on the sale of drugs also defeats the very purpose that e-pharmacies intend to serve through their business models.

On one hand, the Government of India through the Consolidated Guidelines and New Guidelines, allowed the sale of pharmaceuticals, being an essential commodity, by way of e-commerce and on the other hand, the Notification imposes conditions which may not suit the business model of all e-pharmacies.

The current situation has brought the issue of doorstep delivery of medicines to the fore and highlighted the importance of fast tracking the finalisation and notification of the Draft E-pharmacy Rules. The steep rise in the business of e-pharmacies during COVID-19 is proof of their necessity. E-pharmacies are experiencing a shortage of manpower owing to an exponential increase in customer orders and are hiring aggressively to meet the high demand. Some of them are finding innovative solutions to their problem of achieving last mile delivery¹³. For instance, e-health platform- Medlife has partnered with Uber for the delivery of medicines to its customers¹⁴.

4. MAPPING SERVICE APPLICATIONS

While the COVID – 19 pandemic has affected people in a myriad of ways, it is evident that some of us are more severely affected than others. Daily wage earners, migrant workers, etc., have been displaced and are struggling to meet their basic needs. The Central and State Governments in India are converting schools, stadiums etc., into public night shelters and public food shelters to cater to the needs of the underprivileged. Some of these spaces are also being converted into isolation centres for suspected COVID-19 patients.

To help the public avail the benefit of these government initiatives, mapping service applications are now showing locations of these shelters on GPS¹⁵. This is a great example of technology-based businesses using their expertise to help people during these times of need.

It is imperative that such information which is made available through the mapping applications is accurate and reliable. The Government of India is also taking measures against the spread of any misinformation or fake news. For instance, the Ministry of Electronics & Information Technology issued an advisory on March 20, 2020 urging social media platforms and other intermediaries under the Information Technology Act, 2000 (“**IT Act**”) *inter alia* to initiate awareness campaigns on their respective platforms for its users for restricting the upload and circulation of false news or misinformation concerning COVID-19, and to take immediate

¹³https://www.business-standard.com/article/companies/online-pharmacies-on-hiring-mode-as-orders-during-covid-19-lockdown-120041401021_1.html

¹⁴<https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/uber-partners-medlife-to-deliver-medicines-in-5-cities/articleshow/75208152.cms>

¹⁵https://www.business-standard.com/article/current-affairs/google-govt-map-food-and-night-shelters-for-public-during-lockdown-120040601364_1.html

action to disable and remove such false or misleading user content (“**MEITY Advisory**”)¹⁶. Subsequently, the Supreme Court of India by its order dated March 31, 2020 in the case of *Alakh Alok Srivastava v. Union of India*¹⁷, too, acknowledged the menace of fake news and held that any person who circulates a false alarm or warning as to a disaster and issues any fake news will be held liable for imprisonment which may extend to 1 (one) year or with fine. This principle is further reinforced through the COVID-19 regulations passed by various states under the provisions of The Epidemic Diseases Act, 1897, which prohibit all persons, institutions and organisations from using print or electronic media for dissemination of any information regarding COVID-19 without prior permission or clearance from the state government authorities identified in the respective regulations. This has been done with an intent to avoid the spread of rumours and unauthenticated information regarding COVID-19. Any violation of the provisions of these regulations is a punishable offence under Section 188 of the Indian Penal Code, 1860.

Accordingly, mapping service applications that are providing information in connection with COVID -19 must verify the accuracy of such information prior to its use. In doing so, to the extent that mapping service applications are intermediaries under the IT Act, the safe harbour they enjoy thereunder may get diluted as they may be required to select or modify the information/content on their platform while ensuring its accuracy, irrespective of whether or not someone reports it. This would also need to be considered by other intermediaries while providing or publishing information regarding COVID-19 on their respective platforms. Various web mapping applications such as Google Maps and MapmyIndia have collaborated with the Central Government and various State Governments in India to help their users locate and access night shelters and food shelters.¹⁸ If such web mapping applications rely solely on government sources for information to provide the aforesaid services, their liability with respect to accuracy of data and information used may be limited.

5. DIGITAL PAYMENT SYSTEMS

The Government of India, as a part of its vision to transform India into a digitally empowered and cashless economy, encourages digital payments and promotes cashless transactions through the use of various electronic payment modes. In this context, the Reserve Bank of India (“**RBI**”) recently issued a comprehensive set of guidelines on the regulation of Payment Aggregators (“**PAs**”) and Payment Gateways (“**PGs**”) (“**RBI Guidelines**”). Further, the directions for opening and operation of accounts and settlement of payments for electronic payment transactions involving intermediaries, issued by the RBI on November 24, 2009 (“**Intermediary Directions**”) continue to be applicable for PGs and other payment intermediaries.

Extensive use of digital modes of payments will encourage social distancing and consequently minimise the spread of COVID-19. Businesses and non-profit organisations are also entering into direct collaboration with different PAs and PGs to raise donations from the public through various initiatives for those affected by COVID-19. In this context, PAs and PGs, through their respective platforms, are allowing their users to directly donate to the Government of India’s relief funds such as the PM CARES Fund.

In the above scenario, PAs and PGs are merely facilitating donations from their users. The manner in which the donations made are utilised, fulfilment of compliances and requirements in relation to these donations is the responsibility of the donee i.e. the respective non-profit organisation or the Government of India, as the case may be. The donee is also required to issue tax certificates to the donors under Section 80(G) of the Income-tax Act, 1961 for the amount donated. However, because of the relevant PA’s or PG’s involvement in the process, this demarcation of the role and responsibility is not always clear to the donor and must be categorically addressed by the relevant PA/ PG as well as the donee organisation.

¹⁶https://prsindia.org/files/covid19/notifications/106.IND_Advisory_False_News_Social_Media_Platforms_Mar_20.pdf

¹⁷https://prsindia.org/files/covid19/notifications/1033.IND_SC_Media_Directions_Apr_1.pdf

¹⁸<https://www.newindianexpress.com/cities/delhi/2020/apr/15/delhi-government-asked-dms-to-identify-paid-isolation-facilities-2130299.html>

Recommended steps for safeguarding the interest of PAs and PGs

In this regard, following are a few measures which PAs and PGs may take to safeguard themselves in the aforesaid arrangements:

- enter into appropriate agreements with non-profit organisation partners to ensure that the responsibilities of both parties are accurately identified;
- for the benefit of users making such donations, the terms of service of the PAs and PGs should clearly state that the manner in which donations will be utilized and the responsibility of fulfillment of compliances in relation to these donations are responsibilities of the donee; and
- ensure that the non-profit organisation (donee) partners specify the terms of collection and use of donations and related compliance on their website as well.

Ambiguity in the regulatory framework

The RBI Guidelines and the Intermediary Directions appear to be structured specifically to enable e-commerce activities and do not contemplate facilitation of donations while specifying the permissible list of 'credits' and 'debits' into the accounts maintained by such intermediaries. Considering the current scenario, it is imperative to broaden the purview of the RBI Guidelines as well as the Intermediary Directions to also address donations necessitated by COVID-19, or other digital payments not specifically involving 'e-commerce'.

6. ROAD AHEAD

The COVID-19 pandemic is a global health and societal emergency that requires effective immediate action by governments, individuals and businesses. Some businesses, as discussed above, have managed to turn adversity into an opportunity, by pivoting their business models to enable the government, common man and other businesses in dealing with challenges posed by the current global situation. For businesses, innovation and adaptation is the need of the hour. This is also a time for the government and regulatory authorities to support the shift in approach to doing business, to take unconventional measures to accelerate revival and to encourage the growth of the economy.

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