<u>Achilles' Heel: Ramifications of COVID-19 on Healthcare and Pharmaceutical Industries</u>

written by Rajdev Singh | June 9, 2020



How did COVID 19 Affect Health Care and Pharma Industries? The Director-General, WHO, on $22^{nd}-23^{rd}$ January 2020, convened an Emergency Committee (EC) $\frac{[1]}{[1]}$ to assess the public health emergency of international concern and on 11^{th} March 2020, COVID-19 was characterized as a pandemic due to the alarming increase of spread and severity. [2] The world was not ready to combat the precarious situation involving the closure of business and institutions alike.

For a long time, the People's Republic of China (PRC) has held the monopoly as the world's largest consumer and supplier of spare parts, chemical, toys, lighting, base metals or oil involving majority of the consumer durables prevalent in the world consumer market and now due to disruption of the supply chain, the world leaders are looking for alternatives. To look at it differently, India is much better suited, being a labour-

intensive country, and being geographically positioned, to replace China provided various industries collectively work towards the common objective of strengthening and rivigorating our Healthcare and Pharmaceutical sector during the COVID-19 situation. The article will focus on the challenges and impact on the healthcare and pharmaceutical sector and the benefits extended by the Government.

The Impact - How did COVID 19 Affect Health Care and Pharma Industries? It is appropriate to say that COVID-19 pandemic is a jolt which at present has brought the economy to its knees and at the epicentre of this unprecedented global pandemic is the healthcare sector, with medical workers toiling hard to rescue the affected, while vaccination is being tested as a means to tackle this deadly virus.

The impact is multilayered as on one hand, Medical tourism, which is a principal source of revenue generation for India has been staggered due to prohibition on both inter and intra cross-border movement. Moreover, hospitals are holding back on performing and providing services such as outpatient division (OPD) and stalling the surgeries of in-patient Division (IPD), leading to further loss of economy owing to various government notifications and advisories.

While on the other hand, the dependency of the Indian pharmaceutical industries on China for Active Pharmaceutical Ingredients (APIs) for the

production of their medicine formulations is estimated to be around seventy percent. [3] Due to the ongoing pandemic, the Indian Department of Expenditure, vide Office Memorandum [4] has declared the pandemic to be Force Majeure. Scarcity in raw materials due to lack of supply and heightened demand has affected the supply chain majorly. Non-performance by the contracting parties may lead to invoking the Force Majeure clause inherently present in the contract.

Force Majeure and commercial import and export contract
The word Force Majeure_ (FM), is essentially a common law concept originated
from a French word meaning superior force and can be traced to the
Napoleonic Code, Roman law. It is relevant to mention at this juncture that
common law jurisdictions, have witnessed rather rigid and narrow
applicability of the concept of 'frustration of contracts' due to
impossibility, as compared to civil law jurisdictions. Essentially FM
(Section 32 of the Indian Contract Act, 1872) deals in supervening
impossibility[7] in the contractual provision while Frustration (Section 56)
deals with the rule of positive law, in supervening impossibility,
irrespective of the absence of contractual provisions.

In the case of Satyabrata Ghose, [8] the Hon'ble Supreme Court suggested that "impossibility" under Section 56 does not mean in the physical or literal context. It refers to change in circumstances that completely upset the very foundation upon which the parties rested their bargain. The Supreme Court in Energy Watchdog v. Central Electricity Regulatory Commission [9] clarified that "if the fundamental basis of the contract remains unchanged and no frustrating event occurs, except for a rise in coal prices, it could not be held that a mere increase in prices constituted a force majeure event." As regards China, all commercial transactions between China and India shall be governed as per Article II[10] of the bilateral treaty between the countries. The Import, Export, and Foreign Exchange Regulations in force, from time to time, in their respective countries, shall be followed. Disruption of Supply Chain in the Global market

India is globally well poised specifically for manufacturing of Active Pharmaceutical Ingredient (API) but the drawback is that with the current system of work, dependency of Indian pharmaceutical companies on Chinese APIs is a cause for serious concern which needs to be addressed, including dependency on homegrown units. The Indian government, in order to realise the shortcomings, decided to set up a taskforce to review the internal API sector by involving several key representatives from the pharmaceutical industry and NITI Aayog[11] on 19th February, 2020.

During the pre-COVID-19 crisis period, there was no disruption in the supply chain as commercial contracts were being honoured and no greater need was felt by Indian pharmaceutical industries to be self-reliant and to try to manufacture the same within the country instead of exporting the raw materials from China. It is now an opportunity for these industries to be immensely benefitted from this havoc, albeit if only all the cards are played right.

Reliefs extended by the Government of India

The Hon'ble Supreme Court through various judgments has clarified that adequate medical facilities[12] and public health services[13] for the people is an essential part of the obligations undertaken by the government in a welfare state. Further, it was held by the Apex court that "The Government is

required to assist people, and its endeavour should be, to see that the people get treatment and lead a healthy life. A healthy society is a collective gain and no Government should make an effort to smother it..."[14] In light of the same, attempt is being made by the government through notifications and circulars to revive various businesses adversely affected by the pandemic. The Directorate General of Foreign Trade (DGFT) operating under the Ministry of Commerce and Industry, Government of India has made notable exemptions keeping in mind the current situation, which are as follows:

- Extention of the Foreign Trade Policy 2015-20[15] and Hand Book Procedure 2015-20[16] by granting exemptions of one year among other things on the validity period of status certificates, Duty-Free Import Authorisation and Export Promotion Capital Goods Authorization for import purposes, dates of filing of various applications and returns, etc.
- There has been an amendment in Schedule 2 of Indian Trade Classification (Harmonised System) of Export Items, 2018 to ban the export of essential medical supplies such as masks, gloves, etc.[17]
- Restrictions have been imposed on the export and formulation of API[18] although subsequently the same was allowed to be exported freely[19].
- Restrictions have been imposed on the export of artificial respiratory apparatus or oxygen therapy apparatus or any other breathing appliance such as the ventilators.[20]
- Electronic passes[21] and licenses have been made available during the national lockdown for ease of doing business.
 Conclusion

In a nutshell, the Indian Pharmaceutical Industry has huge potential and should work towards increasing the target market as this pandemic has opened multiple opportunities for India. It is relevant to understand that in order to be able to replace China, Indian manufacturers have to work towards quality, quantity as well as marketability of the API. The Indian Government has to work in multiple dimensions.

On one hand, it has to come up with a liberal trade approach to encourage export of API to the global market so that, India can emerge as a global choice, and on the other hand, it has to aim towards reducing the financial backlog and crisis of the manufactures so that they can focus on increasing the production and also increase the horizon of activities they are involved in. The other direction in which the government should strive towards is providing better employment benefits for those working in the healthcare sector. The government should aim towards striking a balance so that there is multidimensional growth of the country.

- [1] the International Health Regulations (IHR 2005)
- [2] https://www.who.int/news-room/detail/27-04-2020-who-timeline---covid-19
- [3]

https://www.europeanpharmaceuticalreview.com/article/117413/the-covid-19-pand emic-and-the-indian-pharmaceutical-industry/

- [4] Office Memorandum No. F.18/4/2020-PPD, issued by Department of Expenditure Procurement Policy Division, Ministry of Finance, Government of India.
- [5] https://www.merriam-webster.com/dictionary/force%20majeure#h1
- [6] Code Civil, Articles 1147 and 1148, French Law.
- [7]

https://www.scconline.com/blog/post/2020/04/06/a-tale-of-two-things-of-frustration-force-majeure-clauses-in-the-time-of-covid-19/

- [8] Satyabrata Ghose v Mugneeram Bangur and Company & Anr 1954 AIR 44, 1954 SCR 310.
- [9] Civil Appeal Nos.5399-5400 of 2016.
- [10] https://mea.gov.in/bilateral-documents.htm?dtl/7721/Trade+Agreement
- [11] https://pib.gov.in/PressReleseDetailm.aspx?PRID=1603775
- [12] Paschim Banga Khet Mazdoorsamity v. State of West Bengal & Anr. (1996) 4 SCC 37.
- [13] State of Punjab v. Ram Lubhaya Bagga (1998) 4 SCC 117.
- [14] Mahendra Pratap Singh v. State of Orissa and Ors AIR 1997 Ori 37
- [15] DGFT Public Notice No. 57/2015-2020 dated 31.01.2020.
- [16] DGFT Public Notice No. 67/2015-2020 dated 31.01.2020.
- [17] DGFT Notification No. 44/2015-2020, dated 31.01.2020.
- [18] DGFT Notification No. 50/2015-2020, dated 03.03.2020.
- [19] DGFT Notification No. 03/2015-2020, dated 06.04.2020.
- [20] DGFT Notification No. 52/2015-2020, dated 19.03.2020
- [21] DFGT Trade Notice No. 59/ 2019-2020 and 62/ 2019-2020, dated 28.03.2020 Contributed By Rajdev Singh, Partner & Deiya Goswami, Associate King Stubb & Kasiva,

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