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India's Pharmaceutical Industry:

Global Supply Chain and Governance in the Post- COVID-19 World

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Abstract:

COVID-19 has halted the world with significant impacts on human lives and economies. Humanity is facing the biggest challenge since the Second World War. As the world grapples with this pandemic, questions are also being raised about China's role in the COVID-19 outbreak. The issues that are being debated include the current model of the supply chain and the need to diversify from China, global governance, and crisis management in the Post-COVID-19 world. In this context, this paper examines the significant role that India's pharmaceutical industry can play to establish India's rightful place among nations providing global leadership in the Post-COVID-19 world.***

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Keywords: COVID-19 pandemic, pharmaceuticals, PPE, China, India, global supply chain, global governance

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I. Introduction:

COVID-19, the disease caused by the novel coronavirus, has brought the world to a halt. This pandemic is set to become the biggest catastrophe after the Second World War with a devastating impact on human lives and economies. The pandemic combines huge uncertainty on the health side with a precipitous decline in economic activity. How exactly these twin crises will play out is anyone's guess. As of 29 May 2020 globally, COVID-19 has infected more than 5,831,165 and killed more than 360,800 people with the highest fatality in the United States with more than 100,000 followed by the UK, Italy, France, Spain, and Brazil, Belgium, Mexico, and Germany all surpassing the reported deaths in China where the disease originated. Recent trends show a spike in the COVID-19 cases in Africa, Latin America, and South Asia. Governments across the world have imposed social distancing measures, lockdown, and state of emergency to contain the disease and announced economic stimulus packages to protect the economy. India imposed the world's largest lockdown on its 1.3 billion people on 24 March and extended thrice 31 May 2020. However, after keeping the number of cases low for almost two months since the lockdown was imposed, India has witnessed a spike in the eruption of COVID-19 cases in the last week of May with confirmed cases 165, 386 and 4,711 COVID-19 deaths by 29 May.¹

But as COVID-19 began to spread across the world, China after containing the disease at home began to use the pandemic to pursue its geopolitical interests especially in the Indo-Pacific. Over the past decade and half, China's assertive strategic move is evident in the Indo-Pacific, a region which has become a crowded strategic space and the centre of gravity

¹ Johns Hopkins University Coronavirus Resource Centre, https://coronavirus.jhu.edu/, Accessed 29 May 2020.

in the connected world amidst the receding US hegemonic power that provided the stability in the post-World War II period.²

China is blamed for obfuscating the truth about the severity and timing of the outbreak and its human to human transmission, and resorting to aid diplomacy to come out as a saviour. But this has not gone unnoticed and the world is now scrutinising China's move and demanding an impartial inquiry in the outbreak.³ The United States has criticised China for hiding the severity of the outbreak and then coming out with a conspiracy theory against the US. President Trump termed COVID-19 as China Virus. At the G7 meeting held in April 2020, Mike Pompeo, the US Secretary of State, renamed the China Virus as *Wuhan Virus*, after the city where the virus was first detected.⁴

China's role in the World Health Organisations (WHO) has raised questions on the transparency and functioning of the WHO. Suspecting the Chinese geopolitical aim and the reports of WHO working on the behest of China, a growing number of countries including

² For detail on China's strategic move in the Indo-Pacific and the geopolitics, see Rory Medcalf, *Contest for the Indo-Pacific: Why China Won't Map the Future* (Melbourne: Monash University Press, 2020); Brendan Sargent, "Slow-burning China crisis the birth of a new strategic order," *Financial Review*, 3 June 2018, https://www.afr.com/opinion/slowmoving-china-crisis-the-birth-of-a-new-strategic-order-20180603-h10w9d. Accessed 20 May 2020; Ramesh Thakur and Ashok Sharma, "India in Australia's Strategic Framing in the Indo-Pacific,"*Strategic Analysis*, Vol. 42, Issue 2 (2018), Pp.69-83.

³ Evidence that the virus was not man made is quite compelling. See "US spy agency says COVID-19 'NOT man-made'," *The New Daily*, 1 May 2020,

https://thenewdaily.com.au/news/world/2020/05/01/spy-agency-covid-19-not-manmade/?utm_source=Adestra&utm_medium=email&utm_campaign=Morning%20News%20-%2020200501. Accessed 1 May 2020. However, only an inquiry can establish whether the outbreak was the result of an accident.

⁴ Michael D. Shear, "Trump Attacks W.H.O. Over Criticisms of U.S. Approach to Coronavirus," *New York Times*, 7 April 2020,

https://www.nytimes.com/2020/04/07/us/politics/coronavirus-trump-who.html. Accessed 8 April 2020.

the US, G8 nations, Japan, Australia, and India have begun to work on strategies to ward off China's economic and strategic moves and have demanded an independent inquiry into the origins of the virus including the actions of China and the WHO. The US has stopped the WHO funding and Australia's call for an independent inquiry in the origin of the COVID-19 pandemic has received overwhelming support from the international community.⁵ At the very least it would be fair to say that even as the world fights the COVID-19 outbreak, China's actions amid this unprecedented humanitarian crisis are being scrutinised. Such scrutiny is in addition to issues for which China was already under the scanner including human rights violations, international trade practices, and military assertion and challenging the rules-based order in the Indo-Pacific region.

The COVID-19 outbreak raises questions on the current practice of international trade particularly the global supply chains which are heavily dependent on China. Even in the context of the current crisis, many countries have relied on imports of Covid-19 testing equipment, pharmaceuticals, and Personal Protective Equipment (PPE) from China. This is because the world has by default let China become the global manufacturing hub. Several countries including the US, India, several in Europe and others have reported defective Chinese testing equipment and PPE.⁶ In the short run, many of these have little recourse to alternative supply sources with the result that some have started producing these on their

⁵ "Australia receives international backing for independent inquiry into coronavirus," 7 *News*,18 May 2020, https://7news.com.au/lifestyle/health-wellbeing/world-backs-aust-push-for-covid-19-probe-c-1042732. Accessed 20 May 2020.

⁶ See, for example, Maayan Jaffe Hofman, "As many as 10,000 coronavirus test kits from China found faulty," *Jerusalem Post*, 23 April 2020, https://www.jpost.com/israel-news/as-many-as-10000-coronavirus-test-kits-from-china-found-faulty-625517 and several others available on the internet. Accessed 29 April 2020. This theme is elaborated later in this paper.

 $own^7 - a$ task that is made hard by the prevalence of lockdown conditions in many parts of the world.

Extrapolating from these and similar conditions, many countries including those in the G-7 have underscored the importance of diversification of the supply chain from China. At the level of global governance level, the need for greater political coordination and crisis management have attained a significant focus. In this context, the role of India, the only country with the potential to match China's scale, could be momentous.

At the same time, India has shown substantial empathy for Covid-19 afflicted countries by permitting the export of hydroxychloroquine (HCQ) (a potential antidote for the virus under some conditions) to 55 countries⁸ even though it needs medicine for its own people. It is also exporting Paracetamol to 20 countries. By doing so, India has emerged as a responsible and empathetic member of the global community of nations.⁹

Against this background, it becomes imperative to evaluate India's place in the COVID-19 context. The present paper will first explore the origin of COVID-19, China's actions, and intent. The second section examines India's pharmaceutical industry and its manufacturing capability in the context of *Make in India* initiative and the diversification of the supply

⁷ The most significant example of this is the production of ventilators by General Motors in the US. Joann Muller, "GM begins ventilator production to replenish U.S. stockpile," *AXIOS*, 14 April 2020, https://www.axios.com/general-motors-ventilator-defense-production-act-cbb8a242-a1dd-4c81-a84d-217c23a7bc93.html. Accessed on 29 April 2020.

⁸ "India sending hydroxychloroquine to 55 coronavirus-hit countries," *The Times of India*, 16 April 2020, https://economictimes.indiatimes.com/news/politics-and-nation/india-sending-hydroxychloroquine-to-55-coronavirus-hit-countries/articleshow/75186938.cms?from=mdr. Accessed 29 April 2020.

⁹ India has enough stock of both medications for its needs but could have augmented its stocks had it not permitted exports.

chain. The third section evaluates the current practice of global governance and crisis management amidst the COVID-19 outbreak. In conclusion, the paper makes a critical assessment of current international trade practice and global governance.

II. Origin of COVID-19, China's Actions and Intent

After its drastic containment measures and slowing down of the COVID-19 cases, China emerged in a position to supply the much-needed testing equipment and PPE to the world. According to Chinese state media, China accelerated the production of masks by 12 times compared to the preceding month. As the COVID-19 death toll began to rise in Europe and then in the US, China began to expand its global influence. Already a potent strategic challenger to American primacy, China has taken its geopolitical ambition to the realm of health amidst the humanitarian catastrophe.

China is the world's largest producer of PPE. Before the COVID-19 outbreak, Chinese exports supplied 50 per cent of the world's PPE requirements. In the initial phase of the outbreak, China stopped its PPE exports to the world. But as the COVID-19 cases in China began slowing, its PPE export resumed and China announced an aid package for 82 countries.¹⁰ China has been offering this aid to nations across the world including to the US and America's North Atlantic Treaty (NATO) allies such as Italy, France, Germany in

¹⁰ Michael Walsh, Max Walden and Iris Zhao, "China's coronavirus aid seeking to shift narrative away from Beijing's cover-up, experts say," *ABC News*, 25 March 2020, https://www.abc.net.au/news/2020-03-25/china-coronavirus-aid-seeks-to-shift-narrative-from-cover-up/12072296. Accessed 26 March 2020.

Europe and South Korea, and Japan in the Indo-Pacific region. Indonesia too sent its military transport aircraft to China to get PPE and other medical equipment.¹¹

Despite ramping up the production to meet the world's demand, China's PPE production faced limits to meet both domestic and world demand during the pandemic. China's confirmed cases despite containment of the outbreak in mid-March were among the highest in the world, and there was always a fear of the second wave of outbreak. China's domestic demand is huge as the health workers and government workers need to protect themselves against the virus in the public domain. According to one of the leading Chinese financial service firms, Huachuang Securities, China's healthcare, transportation, and manufacturing industries employ 38 million people. Even if one person uses one mask daily, China will need to produce 38 million masks every day.¹² A similar picture was revealed by China Medical Pharmaceutical Material Association, which estimated that China would need to make about 230 million surgical masks for its domestic consumption alone.¹³ Furthermore, China faced a technical constraint in the production of N95 due to the shortage of nonwoven polypropylene used for the N95 mask.

Also, questions have been raised on the quality of the Chinese PPE. There are reported cases of rejection of the Chinese PPE on the ground of being poor quality and defective. European

¹¹ Bradley Wood, "Indonesia's Covid-19 crisis: China to the rescue?," *The Strategist*, 31 March 2020, https://www.aspistrategist.org.au/indonesias-covid-19-crisis-china-to-the-rescue/. Accessed 2 April 2020.

¹² John Xie "World Depends on China for Face Masks But Can Country Deliver?," *Voice of America*, 19 March 2020, "https://www.voanews.com/science-health/coronavirus-outbreak/world-depends-china-face-masks-can-country-deliver. Accessed 26 March 2020.

¹³ Keith Bradsher and Liz Alderman, "The World Needs Masks. China Makes Them, but Has Been Hoarding Them," *New York Times*, 13 March 2020,

https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html. Accessed on 26 March 2020.

nations, which are among the worst affected by COVID-19, namely Spain, Czech Republic, the Netherlands, Turkey have complained about the faulty Chinese PPE.¹⁴ Spain rejected about 58,000 inaccurate rapid COVID-19 testing kits sent by China and the Netherlands rejected around 60,000 faces masks as defective.¹⁵ Australia too has reported faults with the Chinese PPE as Australian Border force seized 800,000 masks.¹⁶ While the European countries rejected the Chinese supply despite the requirement, the majority of South Asian countries decided to use the Chinese medical kits despite concerns as they had no alternatives given their patchy health system and inability to start manufacturing the PPE. India also reported faulty PPE kits sent by China and rejected 50,000 which failed the quality test.¹⁷ COVID-19 exposes the weakness in the current global supply chain and the over-reliance on China for even small and cheap equipment such as masks.

III. Diversification of Supply Chain: "Make in India" and India's Pharmaceutical Industry

¹⁴ "Coronavirus: Countries reject Chinese-made equipment," *BBC*, 30 March 2020, www.bbc.com/news/world-europe-52092395. Accessed 2 April 2020.

¹⁵ "China's coronavirus supplies are being rejected-how do we ensure quality in pandemic?," *ABC News*, 4 April 2020, https://www.abc.net.au/news/2020-04-04/china-coronavirus-covid-19-medical-supplies-recalled-regulation/12105110. Accessed 10 April 2020.

¹⁶ "Australia seizes faulty coronavirus protective equipment imported from China," *ABC News*, 2 April 2020, https://www.abc.net.au/news/2020-04-01/coronavirus-chinese-ppe-border-force-intercepted/12085908. Accessed 10 April 2020.

¹⁷ "India will reject all faulty PPE Kits Donated by China , Say Govt Sources; 50 K of 1.7 Lakh Kits Failed Checks," *News* 18, 16 April 2020, https://www.news18.com/news/india/india-will-reject-all-faulty-ppe-kits-donated-by-china-say-govt-sources-50k-of-1-7-lakh-kits-failed-checks-2580529.html. Accessed 29 April 2020.

With the spike in the COVID-19 cases, the extent of the world's dependency on China began to be exposed.¹⁸ In the first G7 meeting during the COVID-19 outbreak, the diversification of supply chain and over-reliance on China emerged as significant issues. Japan became the first country to take steps in this regard and announced the economic package to the Japanese companies to move its businesses from China to countries such as India, Vietnam, and Malaysia. Moreover, Chinese actions during the genesis and transmission of the virus referred to above are compelling the world to work on the diversification of supply chains.

Amid the above scenario, it becomes important to examine the issue of the supply chain and India's capability and potential. Since India embarked on economic liberalisation in the 1990s, subsequent Indian governments have taken significant steps in this direction. But India' manufacturing sector got a serious policy focus in 2015 with the Modi government's *Make in India* initiatives.¹⁹ A noticeable trend over the past decade is the growing joint-production in the defence sector with the US and its allies such as France and Israel, in addition to New Delhi's long-term defence partner, Russia.²⁰ This trend has both economic and geopolitical implications.

Amidst the debate surrounding mitigating over-reliance on China, it is imperative to examine India's pharmaceutical industry and its capability to rise to the occasion. Today, India's

¹⁸ Lizzie O'Leary, "The Modern Supply Chain Is Snapping", *The Atlantic*, 19 March 2020. https://www.theatlantic.com/ideas/archive/2020/03/supply-chains-and-coronavirus/608329/ Accessed 29 April 2020.

¹⁹ Raghbendra Jha, "Modinomics: Design, Implementation, Outcomes and Prospects," *Asian Economic Policy Review*, Vol.14, Issue.1 (2018), Pp. 1-23.

²⁰ Raghbendra Jha, "Trump Meets Modi," Australian Outlook,28 February 2020,http://www.internationalaffairs.org.au/australianoutlook/trump-meets-modi/. Accessed 29 April 2020; Ashok Sharma, "What's Behind the new US-India defence pact?," *The Conversation*, 17 June 2015, https://theconversation.com/whats-behind-the-new-us-indiadefense-pact-42944. Accessed 29 April 2020.

pharmaceutical industry is ahead of many nations. With the constant focus for almost six decades, India has developed its capability to be one of the leading players in the pharmaceutical world. India's manufacturing capabilities in the pharmaceutical sector has immense leverage.

India's pharma industry statistics are impressive. India is the world's largest producer and exporter of generic medicine and accounts for around 60 per cent of all vaccine production globally. India is the third-largest producer of drugs by volume accounting 10 per cent globally. India's pharmaceutical industry boasts of 3,000 pharmaceutical companies connected with a network of 10,500 manufacturing plants. India's domestic market was US\$ 18.12 billion in 2018 registering a growth of 9.4 per cent over than the 2017 figure.²¹ According to the estimates of Indian Pharmaceutical Alliance (IPA), the spending of Indian consumers is expected to triple in 2020 from the previous year spending of about lper cent of their total income on medical expenditure. Indian pharmaceutical market, domestic and abroad, is worth \$38 billion annually and employs around 2.7 million people directly or indirectly. India provides 40 per cent of generic drugs demand for the US and 25 per cent of all medicine for the UK. India leads the world in providing antiretroviral drugs used to fight AIDS (Acquired Immune Deficiency Syndrome) with Indian pharmaceutical firms exporting more than 80 per cent of their output of these drugs. Indian Diaspora community boasts of talented doctors across the world. India has the highest number of Indian Diaspora medical professional practitioners in the foreign medical group category in the Anglosphere nations²² India's credentials in the eradication of smallpox through public

²¹ Invest India, "Indian pharmaceutical – a formula for success," ,https://www.investindia.gov.in/sector/pharmaceuticals. Accessed 29 April 2020.

²² For detail, see Ashok Sharma, *Indian Lobbying and its Influence in US Decision Making: Post-Cold War* (New Delhi: Sage Publications, 2017).

intervention, despite its patchy healthcare system, is recognised internationally including by the World Health Organisation (WHO).²³ Nevertheless, China is a larger producer and exporter of pharmaceuticals than India.²⁴

The Indian pharmaceuticals market is one of the largest in the world – the third largest in terms of volume and thirteenth largest in value terms. Indeed, India has become a major manufacturing hub for pharmaceuticals with a large raw material database and trained workforce. The Pharmaceutical Exports Council of India estimates that in 2020 this industry is likely to grow at a compound annual growth rate (CAGR) of 22.4 per cent with a value of \$55 billion. Generic drugs constitute 70 per cent of the Indian market, whereas over the counter drugs and patented drugs constitute 21 per cent and 9 per cent respectively.²⁵

India is also a very large exporter of pharmaceuticals (value \$19.13 billion in 2018-19) and is expected to grow up to reach \$20 billion in value by 2020. In 2018-19 India's largest export markets were in the US (\$119.18 million), Russia (\$10.33 million), UK (\$9.83 million), South Africa (\$3.63 million), and Nigeria (\$1.71 million). India is the largest supplier of

²³ "India has tremendous capacity in eradicating coronavirus pandemic: WHO," *The Economic Times*, 24 March 2020, https://economictimes.indiatimes.com/news/politics-and-nation/india-has-tremendous-capacity-in-eradicating-coronavirus-pandemic-who/articleshow/74788341.cms?from=mdr. Accessed 29 April 2020.

²⁴Hueling Tan, "China's pharmaceutical industry is poised for major growth," *CNBC*, 19 April 2018, https://www.cnbc.com/2018/04/19/chinas-pharmaceutical-industry-is-poised-formajor-growth.html. Accessed 29 April 2020.

²⁵ India Brand Equity Foundation, "Pharmaceutical Exports from India," March 2020, https://www.ibef.org/exports/pharmaceutical-exports-from-india.aspx. Accessed 20 April 2020.

generic pharmaceuticals (20 to 22 per cent of global export volume) and has one of the lowest manufacturing costs in the world – lower than that of the US and about half that in Europe.²⁶

The success of the Indian pharmaceutical industry can be traced to the 1960s when the Indian government supported the nascent industry with favourable policies. But it was the Indian Patent Act of 1970 that became the catalyst for the growth of India's pharmaceutical industry. The Act allowed only process patents for chemical entities including pharmaceuticals, and the duration for the pharmaceutical patent protection was made short. These two provisions enabled generic medicine producers to develop alternative processes for products that were already in the market. Despite unsubstantiated charges of counterfeiting on the process of reverse engineering, employed by generic medicine firms, international firms were unable to prove whose products the Indian generic medicine manufacturers were reverse engineering. But India's signing of the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)²⁷ with provisions such as data exclusivity put constraints on India's generic drug producers and opaqueness on the future of generic medicine sector. However, the Indian pharmaceutical industry overcame the TRIPS Agreement. India's TRIPS membership required it to compromise with its previous agreement on intellectual property rights. India used the transition period provided under the Transitional Agreement of TRIPS²⁸ to adapt to the changed patent laws to protect its budding pharmaceutical industry. India was able to take advantage of the exemptions granted the TRIPS for the developing countries to build its

²⁶ Ibid.

²⁷ TRIPS was enacted on 1 January 1995.

²⁸ Article 65.3, Part VI — Transitional Arrangements, TRIPS, https://www.wto.org/english/docs_e/legal_e/27-trips_08_e.htm. Accessed 20 April 2020.

indigenous pharmaceutical industry. The leverage that India got under TRIPs was used to build its budding Pharmaceutical industry, enhance R&D competence, and ensure India's emergence as the world's leading generic medicine producer.

Another contributing factor is India's pool of lawyers who are western educated, well versed with the English language, and the Anglo-American judicial systems. This goes back to the colonial era. Not only Indian lawyers but the majority of the top politicians during the Indian national movement were lawyer politicians and many received education in the UK. Indian legal experts have an international outlook to deal with intricate global issues and this was useful in exploiting the suppleness of the TRIPS provisions.²⁹

Indian companies adapted to the new circumstances and some of the leading firms spent heavily on R&D. The focus on R&D, quality, and flexibility increased their acceptability in the global market. For example, firms such as Ranbaxy and Dr Reddy's developed better generics and used the Novel Drug Delivery System (NNDS) to reach the international market.³⁰ Soon the Indian pharmaceutical products began to get market approval in the US and the UK. Indian companies focused on their business models to develop the pharmaceutical industry. The cost-effectiveness and developing innovative strength helped the Indian pharmaceutical firms to dominate the international market.³¹ The NNDS facilitated international cooperation with the pioneer producers in the western countries and Indian

²⁹ H. Juan, "Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?" in Kung-Chung Liu and Uday S. Racherla, eds., *Innovation, Economic Development, and Intellectual Property in India and China* (Singapore:Springer, 2019), Pp. 251-269.

³⁰ Biswajit Dhar and KM Gopakumar, "Effect of Product Patents on the Indian Pharmaceutical Industry," http://wtocentre.iift.ac.in/Papers/3.pdf. Accessed 20 March 2020.

³¹ D. Jane Bower and Julian C. Sulej, "The Indian Challenge: The Evolution of Successful New Global Strategy in the Pharmaceutical Industry," *Technology and Strategy and Management*, Vol. 19, issue.5 (2007), Pp. 611-624.

firms. India soon became the destination of research collaboration, contract research, and joint ventures especially with the leading drug companies in the US and the UK. Patents from Indian pharmaceutical companies are also on the rise. ³²

However, India relies heavily on China for Active Pharmaceutical Ingredients (API) for around 70 per cent which is used in medicine production. India faced a shortage of API because of lockdown in the Chinese provinces of Hubei and Shandong which account for 25 per cent of API output. But as the outbreak slowed down, China restarted its API production and resumed export to fulfil the demands of 189 countries. But during the pause in the API production in China, the Indian pharmaceutical industry's dependency on imported API from China was exposed. Before the COVID-19 outbreak, the price of Indian medicines increased by 25-30 per cent, because of China's clean-up measures on polluting industries which mainly targeted pharmaceutical and chemical industries. This lessened the margins for Indian pharmaceutical firms.

In a move to mitigate the dependency on China for the API and protect its \$39 billion drug production, the Indian government set up a panel under the Drugs Controller General of India (DCGI). The DCGI has been observing the situation since February 2020 with any API shortage repercussions. India pumped \$1.2 billion to boost its domestic production of the API. Also, the Indian government decided to give guaranteed purchase agreements for existing domestic API manufacturing factories calculated on the demand of Indian pharmaceutical firms.³³ This move is to handle the below-par capacity utilisation of active

³² Dhar and Gopakumar, n.30.

³³ "India to boost drug ingredient output to pare China reliance," *The Economic Times*,14 April 2020,

plants and sop up the price differential to bolster the capacity utilisation of domestic pharmaceutical firms.³⁴

India's pharmaceutical industry is riding high on improvements in domestic access to market, strong domestic demand for medicine, increase in the domestic spending on health insurance and healthcare, improved access to medicines in the domestic market, frequency of chronic diseases, and growing export demand for India's medicine especially generic drugs and vaccines. Furthermore, the spike in domestic demand is attributed to growing awareness on health, the expanding bracket of the middle class which has a continuously growing disposable income to spend on health insurance and health care.

The Indian pharmaceutical industry has been growing at 7 to 8 per cent annually as per the IPA assessment. This has been happening despite the Indian economy's underperformance when GDP growth rate went below 5 per cent. Before the worldwide COVID-19 breakout, in January 2020, the Investment Information and Credit Rating Agency (ICRA) estimated the growth of the Indian pharmaceutical industry at 11 to 13 per cent in 2020-21. This has been attributed to the strong demand from the domestic market due to the growing affordability and accessibility of healthcare. Also, this growth is due to lower pricing pressure for the US market, few limited competition products, new launches and an increase in market share for the existing products.³⁵

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-toboost-drug-ingredient-output-to-pare-china-reliance/articleshow/75128876.cms?from=mdr. Accessed 2 May 2020.

³⁴ "Indian government moves on APIs, as Chinese supplies are returning," *the pharmaletter*, 1 April 2020, https://www.thepharmaletter.com/article/indian-government-moves-on-apis-as-chinese-supplies-are-returning. Accessed 2 May 2020.

³⁵ "Indian pharma industry likely to grow at 10-13 per cent in FY'21: ICRA," *Economic Times*, 28 January 2020,

Subsequent Indian governments have taken concerted measures to bolster the pharmaceutical industry. These range from regulating the industry to encouraging private players for innovation and research, investment-friendly policies to attract foreign bidders to encouraging export in the new markets. Recently, India's pharmaceutical industry got a boost from the launch of Ayushman Bharat (Health Insurance Program) under the Modi Government. To address the lack of healthcare facilities, in February 2018, the Government of India announced the creation of 150,000 Health and Wellness Centres (HWCs) by transforming the existing Sub Centres and Primary Health Centres to deliver Comprehensive Primary Health Care (CPHC) bringing healthcare closer to the homes of people and covers free essential drugs too. Again under Ayushman Bharat, PM Modi launched the world's biggest health scheme widely known as Pradhan Mantri Jan Arogya Yojna or PM-JAY on 23rd September 2018 under Ayushman Bharat Yojana (ABY). The ABY intends to make medical treatment affordable to 40per cent of Indian citizens numbering around 500 million people including 100 million families at risk for secondary and tertiary care hospitalization across public and private hospitals in India. PM-JAY is the world's largest health insurance/ assurance scheme fully financed by the government.³⁶

India will need to focus on enhancing expenditure in the health sector to boost this sector. India's spending on health is around 1 per cent of GDP when compared with other developing countries such as China which spends 2.5 to 3 per cent of its GDP on the health sector. Moreover, only around 30 per cent of Indians are covered under health insurance. Also, the need is to invest in the healthcare infrastructure and training medical professional

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-pharma-industry-likely-to-grow-at-10-13-per-cent-in-fy21-icra/articleshow/73697191.cms?from=mdr. Accessed 2 May 2020.

³⁶ Ayushman Bharat, About Pradhan Mantri Jan Arogya Yojana (PM-JAY), National Health Authority, Government of India, https://pmjay.gov.in/about/pmjay. Accessed 2 May 2020.

which is per capita population is very low. India has only 29 skilled health care workers for its every 10,000 people when compared with 41 in China and 111 in the United States.³⁷

As the Indian government wants to expand the medical facility and make it more affordable and accessible to the masses especially its vulnerable section, the Indian pharmaceutical industry particularly generic medicine producers have to deal with the reduction in prices of their products which are already the lowest in the world. The industry is also facing the challenge as the US market is reaching its peak due to price attrition and increased regulation and scrutiny. The US market has been the biggest contributor to India's leading pharmaceutical firms in recent years. The US receives about 30 per cent of India's exports of pharmaceuticals which helps the US save around \$20 billion annually on healthcare spending. However, India's progress in innovation is not very exciting when it comes to innovation and inventing new drugs. The government will need to support the investment in research with a focus on the private-public partnership. To be competitive, India will need to invest in research in the pharmacy sector. This is rightly explained by Mr. Bhadorai at McKinsey "A talent pool with advanced skills is also limited in India, with only 2,000 Ph.D. students enrolled in pharmacy institutes, compared to over 15,000 Ph.D. students enrolled in the United States," ³⁸

A study by the IPA-*The Indian Pharmaceutical Industry – The Way Forward*- provides a visionary strategy for the Indian pharmaceutical industry until 2030. The study points to the challenges and spots some of the steps that need to be taken to solidify India's leading status

³⁷ Nick Easen, "India: a global pharma powerhouse," *Raconteur*, 16 December 2019, https://www.raconteur.net/healthcare/india-pharmaceutical-industry. Accessed 2 May 2020.

³⁸ Ibid.

in the pharmaceutical world and expand further in the domestic and world market. ³⁹ According to the IPA report, India's pharmaceutical sector has created 2.7 million jobs both directly and indirectly at CAGR between 7 and 8. With this growth rate, the sector is estimated to be worth up to \$90 billion by 2030. However, the IPA report aims higher growth for the sector which can be achieved at a CAGR of up to 11per cent or 12per cent making the industry worth \$120 to \$130 billion by 2030.⁴⁰

The IPA aims to provide high-quality medicines at an affordable price as part of a scheme to implement universal healthcare schemes in the country. To be the world leader in innovation, the IPA sets a goal of three to five molecular entities launched or in late clinical trial phases and 10-12 innovation launches per year by 2030. To elevate India's position as the global drug supplier by volume, the IPA looks to establish a market in the US generics space and developing trade with other countries. Also, the pharmaceutical industry can enhance its revenue contribution to the economy from the current \$11 billion and contribute to the holistic development of India.⁴¹

The IPA points to the challenges that India's pharmaceutical industry has to deal with. The lack of stable pricing and policy create frequent and unexpected changes to domestic pricing policy in India and create an uncertain environment for investments and innovations. The Indian pharma sector will need to address the lack of capabilities in the innovation space,

³⁹ Victoria Rees, "The potential of the Indian pharmaceutical industry," *European Pharmaceutical Review*, 28 October 2019, https://www.europeanpharmaceuticalreview.com/article/103336/the-potential-of-theindian-pharmaceutical-industry/. Accessed 2 May 2020.

⁴⁰ Indian Pharmaceutical Alliance, "The Indian Pharmaceutical Industry : The Way Forward," June 2019, https://www.ipa-india.org/static-files/pdf/publications/position-papers/2019/ipa-way-forward.pdf. Accessed 2 May 2020.

⁴¹ Ibid.

mitigate the dependency on external markets for intermediates APIs, and enhance its standard and competitiveness in the world market and comply with quality inspections. India being subjected to the highest number of FDA inspections since 2009 will need to continue investment into upgrading quality standards. As a result, India is at the risk of supply disruptions and unpredictable price fluctuations. Policymakers need to attend to these concerns in order to ensure India's continued success in the pharmaceutical industry.

The significant challenges have been in the form of productivity of R&D expenditure, growing competition in the US generics space and operational risk posed by the regulatory agencies to the Indian pharmaceutical products for maintaining the standard.⁴² Despite being third by volume in the world, India's pharmaceutical industry is 13th in the world in terms of value. To be among the top valued pharmaceutical industry, India will need to invest more in Research and & Development. India's organisational capability and discipline will need to be enhanced to be competitive at the international level. India has an individual entrepreneurial spirit but its organisational level competence will need to be enhanced. This applies to the Indian pharmaceutical industry as well.

According to the IPA, the bold strategic moves into uncharted territories could be taken by improving communication between industry stakeholders and Indian regulators would help to build a stronger platform for pharma while developing more certainty around drug costs, such as policies that provide a framework for pricing, would contribute to a steady regulatory environment. Focus on API manufacturing, so that there is less reliance on imports into the country. This could be time taking but in the long run in India's interests.

⁴² "Indian pharma industry likely to grow at 10-13 per cent in FY'21: ICRA," *The Economic Times*, 28 January 2020, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-pharma-industry-likely-to-grow-at-10-13-per-cent-in-fy21-icra/articleshow/73697191.cms?from=mdr. Accessed 2 May 2020.

Another proposal is to simplify the regulatory approval processes. Investment in emerging R&D fields is much higher than for generic products, according to the report, so creating a more efficient regulatory approach could assist in innovation.

It has been suggested that waiving local clinical trials for drugs approved and marketed in the EU, the UK, Australia, Canada, Japan, and the US could restructure strategy for clinical trials. Similarly, working with other global regulatory bodies could help encourage pharmaceutical growth in India. This is plausible by close cooperation with agencies of countries with large markets.⁴³

The need for a stronger collaboration between pharmaceutical companies, the government, and regulatory agencies backed by concerted efforts by the pharmaceutical companies and the government's intervention in the form of enabling policies and a supportive ecosystem can facilitate the industry achieve Vision 2030.⁴⁴

The Indian pharmaceutical industry is getting a significant boost under the Modi Government's *Make in India* initiative. Pharmaceutical firms have aligned their manufacturing policy and practice⁴⁵ and have contributed to *Make in India* initiatives, economic growth, and employment. The future also lies in India to expand its manufacturing in specialised drugs which is increasing and is priced high. India with its manufacturing

^{43 &}quot;Indian Pharma industry aspiring to grow to \$120-130 billion by 2030: IPA," The
Economic Times, 19 June 2019,
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-
pharma-industry-aspiring-to-grow-to-120-130-billion-by-2030-

ipa/articleshow/69861213.cms. Accessed 2 May 2020.; Indian Pharmaceutical Alliance, n.40.; Rees, n. 39.

⁴⁴ "Indian Pharma industry", n. 43.

⁴⁵ Aparna Banarjee, "The Law and Politics of Pharmaceutical Patents in India" in Kung-Chung Liu and U. Racherla, eds., *Innovation and IPRs in China and India: Myths, realities and Opportunities* (China-EU Law Series Vol. 4) (New York: Springer, 2016), Pp. 143-158.

capabilities base, cost-effectiveness, and years of branding and reputation can fill this gap. Quality medicine at a stable and affordable price, its medicine supply accessible and reliable, will be the key for Indian firms which will be difficult for other nations to match.

The COVID-19 outbreak provides India's pharmaceutical industry a big opportunity and responsibility as well. With the vaccine to cure coronavirus unlikely for at least a year, two medicines Hydroxychloroquine (HCQ) and paracetamol are suddenly in high demand. The drug especially HCQ used for treating malaria patients is considered as key for preventing the coronavirus. India is the biggest producer of these drugs. North America with almost 30 per cent share of India's pharmaceutical exports is the biggest recipient followed by Africa at 17 per cent and Europe at 16 per cent.⁴⁶ But in the wake of COVID-19 India put a temporary ban on the export of these medicines. However, after initial policy missteps on the export of generic medicines, India decided to lift the temporary ban on the export of drugs. India wanted to first secure drugs for its domestic demand given its large population's vulnerability to pandemics and its patchy health care system. Currently, India exports HCQ to 55 countries and Paracetamol to 20 countries. The list of importing countries includes the US and nations in South and Southeast Asia. India has taken some regulatory measures to ensure that pharmaceutical companies comply with government policies such as pricing, production capacity, maintaining the balance between domestic demand and the world demand, and export of HCQ on the case-by-case basis during the virulent disease.

However, some medical experts are sceptical and have stressed that no scientific evidence of any drug including HCQ can cure or prevent a COVID-19 outbreak. Both HCQ has been ⁴⁶ "India relaxes ban on exports of paracetamol, hydroxychloroquine," *The Economic Times*, 9 April 2020,

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indiarelaxes-ban-on-exports-of-paracetamol-hcq/articleshow/75035983.cms?from=mdr. Accessed 10 May 2020.

useful in the treatment of malaria and auto-immune diseases such as rheumatoid arthritis and lupus. Though the clinical trials have been limited and only countries such as France and China have recommended its use in their trial, the European Medicine Agency (EMA) stressed the effectiveness of HCQ in treating COVID-19 has yet to be proven.⁴⁷ According to the Indian Council of Medical Research (ICMR), the medicine so far has been tested as preventive medicine in laboratory studies and in-vivo studies. Two studies are being conducted known as solidarity trail under the World Health Organization (WHO) to test a common HCQ treatment protocol and Chloroquine Accelerator Trial, Welcome Trust, and the Bill and Melinda Gates Foundation for HCQ effectiveness. The medical experts from the ICMR have advised HCQ use with doctors prescription for frontline asymptomatic healthcare workers involved in dealing with suspected or confirmed COVID-19 cases and asymptomatic household contacts of laboratory-confirmed cases.

After President Trump pushed for HCQ as a game-changer in combating COVID-19, the demand for the medicine increased. According to the Indian Drug Manufacturers' Association India has enough capacity and capability to cater to its both domestic and international demands.⁴⁸ Indian pharmaceutical industry can manufacture approximately 200 million 200mg HCQ tablets every month. India is the leading producer of HCQ fulfilling 70per cent of the world's HCQ needs and is capable of accelerating production to meet the world demands.⁴⁹ India's Intas Pharmaceuticals Ltd. is to supply up to two million HCQ

⁴⁷ "Why the world is hungry for a coronavirus drug made in India," *DW*, 9 April 2020, https://www.dw.com/en/why-the-world-is-hungry-for-a-coronavirus-drug-made-in-india/a-53077879. Accessed 10 May 2020.

⁴⁸ "India relaxes ban", n.46.

⁴⁹ "Why the world is hungry for a coronavirus drug made in India," n.47.

tablets to the WHO-endorsed study to prevent coronavirus using HCQ without any cost on top of two million tablets of matched placebo.⁵⁰

India is going to be a key destination for manufacturing and alternatives when the world looks to diversify the global supply chain from China. India has the advantage of the trust factor. Western countries were ready to trust India as a democratic country with the Anglo-American Judicial system where any litigation can be taken to the Indian courts. This is not the case with China with the Communist authoritarian system. This was further backed by India's closeness to the Political West and the deepening US-India strategic partnership which included a range of issues including pharmaceutical joint-ventures and research and development. India's pharmaceutical industry strength lies in contract manufacturing, research and development, and clinical trials. The trust factor has helped India to emerge as a preferred partner for the joint-collaboration for the global pharmaceutical firms of the US and the West. India's readiness to export critical pharmaceuticals and medical equipment during the COVID crisis has only cemented trust in India.⁵¹

With government support, focus on research and innovations, joint ventures with the world's leading companies, and India's credibility as a reliable supplier to the world in the pandemic situation are going to be crucial. India can become not only by volume but also by value-wise one of the leading players in the pharmaceutical world. This can help Indian pharmaceutical $\frac{50 \text{ "Intas to provide 2 million hydroxychloroquine tablets for WHO study on COVID-19," The Economic Times, 30 March 2020.$

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/intas-toprovide-2-million-hydroxychloroquine-tablets-for-who-study-on-covid-19/articleshow/74891846.cms?from=mdr.Accessed 10 May 2020.

⁵¹ Raghbendra Jha and Ashok Sharma, "Reconstructing Pharmaceutical Global Supply Chains after COVID-19," Australian Outlook ,21 May 2020, http://www.internationalaffairs.org.au/australianoutlook/reconstructing-pharmaceuticalglobal-supply-chains-after-covid-19/. Accessed 21 May 2020.

firms consolidate their position in the US market as well as increase their foothold in new markets.

India's capability to provide drugs in demand for COVID-19 therapies to the world could be one of the defining moments for India to showcase as a reliable and trustworthy supplier but also the scale of its manufacturing capability in the time of crisis. These are testing times for India to siege the opportunity in this increasingly significant realm of global trade, politics, and influence.

IV. Global Governance: Political Coordination and Crisis Management

Amidst the outbreak of the coronavirus, the debates surrounding the global governance and crisis management to deal with pandemics have emerged significantly. The WHO's late deceleration of COVID-19 as pandemics and the world's lack of preparedness despite the warning on the coming of pandemics are evidential.

The role of the WHO is being scrutinised. Questions have been raised on the role of WHO Director-General Tedros Adhanom Ghebreyesus for underplaying the severity of the pandemic and the US legislators have demanded his resignation.⁵² The US has blamed the WHO chief for working on the behest of China and sheltering the Communist regime by underreporting the pandemic outbreak in China. This has raised serious questions on the

⁵² Bradley A. Thayer and Lianchao Han, "China and the WHO's chief: Hold them both accountable for pandemic," *The Hill*, 17 March 2020, https://thehill.com/opinion/international/487851-china-and-the-whos-chief-hold-them-both-accountable-for-pandemic. Accessed 10 May 2020.

integrity of the WHO and the need for a relook at the current global crisis management arrangement. ^{53 54}

The US president Trump has halted the US funding to the WHO, awaiting an official investigation into the global health agency and its response to COVID-19. The Trump administration has accused the WHO of mismanaging the situation and disastrous decision to oppose travel restrictions from China and other nations because of which death toll increased by 20 times.⁵⁵ Earlier, prominent leaders including the Japanese Deputy Prime Minister Aso Taro blasted at global health agency for sheltering China and complying with the Chinese Communists Party's propaganda and said that WHO should be renamed as CHO (Chinese Health Organisation). ⁵⁶ Australian Foreign Minister Thomas Paine has demanded an impartial inquiry in WHO's "mishandling" and spread of the outbreak.

The WHO's alleged incompetency and shielding China on coronavirus outbreak also raises questions on governance structure and reliance on bureaucrats to manage the global health agency. The WHO is heavily reliant on bureaucrats who have no medical background. Also, the bureaucrats take their position for granted. Reforms on both aspects will make the WHO more efficient. In this context, medical experts and professionals with administrative skills

⁵³ Michael D. Shear, "*Trump Attacks W.H.O. Over Criticisms of U.S. Approach to Coronavirus,*" *New York Times,* 10 April 2020, https://www.nytimes.com/2020/04/07/us/politics/coronavirus-trump-who.html. Accessed 10 May 2020.

⁵⁴ Thayer and Han, n. 52.

⁵⁵ " Trump halts US funding of World Health organisations," *New York Times*, 14 April 2020, https://www.nytimes.com/2020/04/14/us/coronavirus-updates.html. Accessed 10 May 2020.

⁵⁶ "Not WHO! Call it China Health Organisation, miffed Japan on coronavirus pandemic," *ANINEWS*, 4 April 2020, https://www.aninews.in/news/world/asia/not-who-call-it-china-health-organisation-miffed-japan-on-coronavirus-pandemic20200404141658/. Accessed 10 May 2020.

will be more appropriate. To increase accountability, world leaders must take more responsibility in the functioning of the WHO. The political leaders are accountable not only to their domestic constituencies but also to the international community. They are likely to be more accountable in this age of heightened media scrutiny and politicians conscious of their international profile. The G20 virtual meeting in the midst of the COVID-19 outbreak is the right step. The member states expressed their concerns and desire to help each other and work for global efforts to fight the outbreak.

Much of the funding of the global organisations including the WHO comes from the developed countries and most of them are the members of G7 and G20 and wealthy donors such as Bill & Melinda Gates Foundation. But the countries which have funded these organisations have not shown serious interests and leadership in the affairs of these global organisations. The WHO is an important organisation and the world would need to reform the global agency. The increased involvement of funding bodies and nations, a proper corporate structured governance model, and accountability and transparency in the working the WHO would make it a purposeful and effective body.

The COVID-19 crisis has happened in the age of artificial intelligence where the flow of information is unlimited. The pandemic has exposed the world's vulnerability to misinformation, propaganda, conspiracy theory. In addition to the state-backed China's "misinformation", the world health agencies will also need to work on managing the misinformation. In this context, the dissemination of correct information in regards to pandemics, medicine, cure, and practice will be the key areas of governance.

The current pandemic crisis, the lack of preparedness, and the absence of the vaccine show the lack of farsightedness and coordination of the leading developed nations. The experts warned that pandemic is going to be the biggest catastrophe in the short term and climate change in the long run. But the developed nations focused on lifestyle diseases such as cancer and other chronic diseases. As a result, no serious research effort was made to deal in the wake of Severe Acute Respiratory Syndrome (SARS) 1. If the world had invested in the vaccine after SARS 1 in 2002, the world would have been in a better position to deal with SARS 2.⁵⁷

The Western developed nations are dominant in research in the field of cancer and lifestyle disease. But for the vaccine and medical equipment, the world has become heavily dependent on China. The world has invested heavily in China creating over-dependence. China's innovation has been limited and beyond a certain level, the trust factor has been missing in economic interdependence between the US-led West and China. The world is finally waking up to China's geopolitical design when the world is battling the world's biggest humanitarian crisis that originated in China.

The nations across the world first look to safeguard their interests. The actions of the world indicate an inward-looking approach and protectionism in the world during and beyond the COVID-19 outbreak. The reliability of international organisations and dependency on global supply chains for essentials became doubtful. The nations across the world gave priority to their self-interests over the larger regional and global interests during the pandemics. Even the allies could not be trusted as evident in the case of the US outbidding French and German shipments carrying medical equipment by paying three times more than the actual price. Even India which has been praised by many nations including the US and the WHO for its humanitarian help by exporting and ramping up the production for generic medicine such as HCQ and paracetamol considered to be crucial for Covid19 therapies banned the export of

⁵⁷ Private communication with Arun Sharma, Chair, QIMR Berghofer Medical Research Institute, 10 April 2020.

drugs initially considering its domestic needs. Also, national interest overrode the alliance, regional, or organisational interest. In March amidst the fast-growing coronavirus outbreak across Europe, Germany, the leading nation of EU, banned the export of vital supplies of PPE unless for use in aid operations which was meant for its neighbouring nations Austria and Switzerland.⁵⁸ Germany's action of national interests created unease and tension in solidarity in the European Union (EU), the most successful example of regional cooperation. The US outbid its North Atlantic Treaty Organisation (NATO) allies France and Germany for the shipment of medical equipment by three times more than the actual price. The US has been accused of modern piracy for diverting the medical equipment destined for Europe. Another regional institution South Asia Association for Regional Cooperation (SAARC), where the Indian Prime Minister Modi along with its member nations conducted a virtual meeting to cooperate on containing the COVID-19 outbreak was soon marred by the self-interest of the member nations. Survival and national interest became the top priority for many nations. This trend and over-reliance on China for the PPE, China's limitations to ramp up the production, and the cases of defective medical equipment and masks, indicate the world towards inwardlooking approach, protectionism, and nationalism.

But the Post-COVID-19 world will also move towards greater political coordination, crisis management, and crisis communications. The need for political coordination in crisis management for pandemics, natural disasters, and climate change will be the driving force. This trend during the COVID-19 outbreak was visible in the meetings of G20 and G7, and regional organisations such as SAARC where the political leaders expressed their willingness to help each other work towards greater cooperation on the humanitarian crisis and natural

⁵⁸ Jan Dahinten and Matthias Webl,"Germany Faces Backlash From Neighbors Over Mask Export Ban," *Bloomberg*, 10 March 2020, https://www.bloomberg.com/news/articles/2020-03-09/germany-faces-backlash-from-neighbors-over-mask-export-ban. Accessed 10 May 2020.

disasters such as pandemics, environmental issues including global warming. Member states called for greater political coordination to fight the pandemic.

The trend is evident in various nations' approach. Germany and the EU members after the initial scramble for medical equipment to protect their citizens began to work on the larger interests of the EU members. The US began to work with its NATO allies, G7 and G20 members. India lifted the temporary ban on the medicine to the world with priority to the nation worst affected by the COVID-19 outbreak. The same trend was visible in China's case of aid diplomacy by giving PPE to the world which was only after security its domestic needs.

V. Conclusion

The rebooted world is likely to see many nations resetting their relations with China. This will be more visible in the world's relation to China in the trade sector. During the COVID-19 outbreak, the world's over-reliance on China has been exposed. It has shaken the confidence of the US and the Western world, especially the industrialised nations of G7. COVID-19 will prompt them to manage their supply chains to ease over-reliance on China, shifting instead to the developing countries with manufacturing capabilities in Asia, Africa, and Latin America. In this context, India, considered to be the only country to match China's manufacturing scale at least in the medium term, will be crucial. The Indian pharmaceutical sector is expected to play a significant role in this revival of the country's manufacturing sector.