"There have been as many plagues as wars in history; yet always plagues and wars take people equally by surprise."

-Albert Camus[1]

Dealing with the Coronavirus: Pharma Industry and Government Collaboration in India

Economies prepare for calamities on the scale of targeted terror attacks, but for a calamity on the scale of a pandemic, there is no warning, no preparation.[2] *With the announcement of a nationwide lockdown on March 24, 2020 in India to combat the novel Coronavirus, economic and industrial activity suffered a massive shock. One industry—pharma and healthcare, however, could under no circumstances afford a halt of any sort. The three pillars which hold together the Indian Pharmaceutical Market in India—government and regulators, pharma and healthcare firms and industry associations* [3]*— came together to keep the sector going at full steam as an essential service. This document traces the events that led to large scale coordination and cooperation between the government and industry that kept the pharma and health care sector going in India at a level that there was no shortage of medicines in the country. Indian pharma exports in May 2020, were 15% higher than they were in May 2019!*

The disruption had already started earlier. Dr. P.D. Vaghela who holds the position of Secretary at the Department of Pharmaceuticals said, "Most API manufacturing facilities in a single country had shut down on account of the pandemic. To top it all, the USA and Europe are dependent on India for medicines. A lack of APIs would mean an incapacity to not only produce the required medicines here in India but also to export to countries that depend on us for the finished medicines. We were apprehensive and realized that we needed to make some policy changes and implement them fast."[4] *On a similar note, Dr. Pankaj Patel Chairman, Zydus Cadila, recalls the sense of fear and anxiety that had set in beginning January, 2020 as the virus started disrupting supplies of Active Pharmaceutical Ingredients (APIs) from China in February. "The supply cut-off became a cause for concern over the next several months. We were fearful that the prices of APIs could increase if the situation in China did not improve soon."* [5]

During the first week of the first lockdown, manufacturing capacity [6] *across plants dropped to 10-15% owing to different types of disruptions including the exodus of workers returning to their villages, shutting down of ancillary and related operations, prevention of workers from being able to reach their places of work and large-scale supply disruptions from China.*

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[1] ***Albert Camus*** *was a French existential novelist who wrote, 'The Plague', published in 1948. Although, the novel is set in the 1940's, Camus drew references from the cholera epidemic that killed a large proportion of Oran's population in 1849. The novel, a relevant metaphor for the world's largest pandemic since the Spanish Flu, unfolds into an existential account of the setting in of an epidemic right down to its catastrophic end told through the lens of a doctor, journalist, priest, businessman, social activist and a government clerk.*

[2] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020

[3] Reference to Exhibit 1, Exhibit 2 & Exhibit 3

[4] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020

[5] Interview with Dr. Pankaj Patel, Chairperson, Zydus Cadila; Prof. Arvind Sahay, IIMA; June 17, 2020

[6] *By April, manufacturing capacity increased to 60-70 % which was significantly higher than other industries and by mid-June, the capacity returned to 100% efficiency. In April, India exported pharmaceutical products worth Rs. 11,758 crore while in May, this increased to Rs. 14,959 crore. The industry in May registered a growth of 27.12% over the same time last year.*

For the Indian Pharmaceutical Industry, several plans had already been drafted in context to the pandemic before the lockdown. Prime Minister Narendra Modi met industry leaders and industry association heads on March 21, 2020 via a webinar to assess the situation. The industry indicated that it was prepared and assured Prime Minister Modi that it had adequate stock. Over the course of this meeting, the many challenges and action plans which unfolded over the three-month lockdown period were reviewed. From the drop in manufacturing capacity to the restricted movement of workers and goods; from the supply disruptions in China to potential disruptions in exports and a lack of an established data system in India, a review would help generate ideas for the way ahead. The Indian pharmaceutical industry could use this opportunity to become the pharmacy to the world in every sense of the phrase.

In the words of Dr. P.D. Vaghela, "Crisis situations evoke a systemic change. New systems are established because business is not carried out as usual. Established rules and regulations are changed. Lines of communication were open for anyone to anyone. Age-old issues which required immediate attention were taken up on a priority basis." [7]

The Spread of the Pandemic

On January 23, 2020, nearly two months after the first case of the virus was reported, Chinese authorities announced a lockdown in an attempt to halt the disease. By this time, a significant number of Chinese citizens have travelled abroad as "asymptomatic, oblivious carriers". And in the blink of an eyelid, the virus made its way around the globe. Two days after January 30, 2020, when the WHO declared a global public health emergency of international concern, Dr. Li Wenliang — a whistle-blower doctor who had been silenced by authorities after he attempted to warn doctors about a virus akin to Severe Acute Respiratory Syndrome (SARS) — tested positive for Covid-19 on February 01, 2020. He died six days later. [8]

By the end of March 2020, China saw a 99.72% increase in the number of cases from 27 on December 31, 2020 to 9714 on January 31, 2020. By the end of February, the number of cases had increased to 79,355. [9] **(Exhibit 04)** By the end of March, the number of cases had increased to 33050 in India. [10] **(Exhibit 05)**

In the Prime Minister's first address to the nation on March 24, 2020, he mentioned that at the time, it had taken 67 days for the count of people infected with Corona to reach the first one lakh all over the world. After this, it took only 11 days for another one lakh people to get infected.

In India, the first COVID-19 case was confirmed in Kerala's Thrissur district on January 31, 2020 after a student who had returned home for a vacation from Wuhan University in China, tested positive. On March 4, 2020, a Paytm Gurgaon employee from Delhi, who had returned from a vacation in Italy, tested positive. From across the nation, reports began to trickle in about foreign arrivals into the country carrying the deadly virus with them. The WHO declared Covid-19 a global pandemic on March 11, 2020.

Thirteen days later, what began as a 22-hour voluntary curfew on March 22, 2020 turned into a nationwide lockdown. On March 24, 2020, Prime Minister Narendra Modi addressed over 1.3 billion people across the nation while announcing Lockdown 1.0, a 21-day lockdown period, beginning at

[7] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020
[8] https://www.livemint.com/news/world/a-timeline-of-how-china-misled-the-world-on-coronavirus-outbreak-11585273347248.html
[9] https://ourworldindata.org/
[10] https://ourworldindata.org/

midnight and ending April 14, 2020. This lockdown was extended first until May 03, 2020 followed by a further extension until May 17, 2020 and later, May 31, 2020. **(Exhibit 6)**

When Prime Minister Narendra Modi addressed the nation on May 12,2020, he announced a special economic package of Rs. 20 lakh crore which is equivalent to 10% of India's GDP. Prime Minister Modi urged the nation to become *Atma Nirbhar* and enabled the beginning of a journey towards self-reliance when he said, "The state of the world today teaches us that an *Atma Nirbhar Bharat* or a self-reliant India is the only path." When the crisis started, there was not even a single homegrown PPE kit made in India. However, by May 12, 2020, India was positioned to produce 2 lakh PPE kits and 2 lakh N-95 masks daily.

As of August 11, 2020, the global confirmed cases stood at 20,254,662 with the total confirmed deaths at 738,930 cases. With more than 2.2 million confirmed reported cases, India ranked third in terms of the highest number of cases after the USA and Brazil.

Cooperating and Competing: Managing in the Wake of the Pandemic

Before the pandemic caught speed in India, industry leaders and associations were putting their heads together with the government in order to address the potential issues that were to face the industry within the few weeks that built up to March 24, 2020. At the time, the industry had an overall inventory of drugs for at least three months. This was expected to increase. [11]

In response to the export restrictions announced on March 03, 2020, the industry vociferously opposed the decision. "Stocks were available and before arbitrarily banning exports, we should have been consulted. This caused a lot of chaos in the global market and did not go down well against India's image as 'Pharmacy of the World." [12]

40% of the generics in the USA come from India which has the largest number of FDA approved plants. The United States is the world's largest market for Indian companies. Jonathan Kimball who is the Vice President at the Association for Accessible Medicines (AAM) Trade and International Affairs in the United States elaborated on the severity of the effect of these restrictions. "The export restrictions upset a whole bunch of people outside India more so because the exceptions to these restrictions were not as clear outside as they were in India. We were in constant contact with Secretary General, Sudarshan Jain of the Indian Pharmaceutical Alliance and his team multiple times a week to ensure that there was a routine dialogue between our two associations. Thanks to this dialogue, we were able to represent Indian pharmaceutical companies' interests in Washington and in front of the media. There was a lot of negative attention in the press in regard to these restrictions. Infact, this point still gets noted by members of Congress. The repercussions of these restrictions continues even today." [13]

According to data by the All India Association of Chemists and Druggists (AIOCD) [14], in April 2020, there was an adequate stock at the distributor level — with the least being for anti-diabetic therapy (four weeks) and highest being for the dermatology segment (eight weeks). Even anti-malarial drugs had 52 days' inventory despite the spurt in sales. This, despite the fact that API/KSM imports from China had slowed in the wake of the Coronavirus. [15]

In a webinar on March 21, 2020, while assuring the Prime Minister and other key government officials that the industry would face no shortage of medicines, Dr. Pankaj Patel said, "The government has

[11] Interview with Dr. Pankaj Patel, Chairperson, Zydus Cadila; Prof. Arvind Sahay, IIMA; June 17, 2020
[12] Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020
[13] Interview with Jonathan Kimball, Vice President, Association for Accessible Medicines (AAM) Trade and International Affairs, USA; Prof. Arvind Sahay, IIMA; July 16, 2020
[14] *All India Association of Chemists and Druggists (AIOCD) has about 800,000 members – stockists, pharmacies and retailers of drugs.*
[15] https://www.business-standard.com/article/economy-policy/covid-19-impact-pharma-players-come-together-for-smooth-production-120041201080_1.html

done well by taking stock of domestic production and inventory regularly and only later allowing exports. There would be no shortage of medicines in the country."[16]

To deal with the fear of a lack of APIs/KSMs on account of the situation in a specific country, Dr. P.D. Vaghela helped form an inter-ministerial group **(Exhibit 7)** which helped frame the four government schemes that would be announced by the government in APIs and medical devices. In a second phase, the group was later converted into a technical group which laid down the framework for the Government's API schemes. In the third phase, the group has become a permanent technical group which is focused on the implementation of these schemes—a long-term action plan which could take over two years to implement. " I am very confident that we will get the API industry back," said Dr. P.D. Vaghela on the Government's move towards *Atma Nirbharta*. [17] Through all the meetings **(Exhibit 8)**, the industry and its associations assured the Prime Minister that the first priority would be the domestic market and that the industry is more than just capable of meeting requirements for both, exports and the domestic market. Leaders and association members ensured the Government that there would not be any shortage of medicines in the country. [18]

Since March 24, 2020, six industry leaders who head Torrent, Cipla, Dr. Reddy's Laboratories, Sun Pharma, Lupin and Zydus Cadila held regular 10:00 AM calls anchored by Sudarshan Jain, Secretary General, IPA,[19] every day of the week, for two straight months. Together, they put their heads together on several initiatives and worked on several issues including the inter-state and intra-state movement of goods, attendance of factory workers, social distancing norms, safety precautions, curfew passes etc. [20]Phones were ringing off the hook at the offices of key government authorities. "Although we compete with each other quite fiercely in the market, we are individually good friends and we all share a harmonious relationship," said Dr. Pankaj Patel who had last been to office on March 17, 2020.[21]

"The first week of the lockdown was characterised by a state of confusion, fear and anxiety. Several clarifications were required to be made to government officials, heads of states, police personnel, port authorities, transport authorities, state border officials, nodal officers etc. A key concern was safety for the employees, managing disruptions in the workforce getting to the factories, closure of packaging factories and obstacles in the movement of raw materials and medicines," said Satish Reddy who is the Chairman at Dr. Reddy's Laboratories.[22]

When it comes to defining essential services, the Secretary of the Department of Pharmaceuticals, Dr. P.D. Vaghela talked about a key panic point. "In the government notifications issued by the Home Ministry in the beginning of the first lockdown, only the functioning of pharmaceutical retailers was declared as an essential service. However, pharmaceutical manufacturing was excluded from the essential services list. After the IPA helped bring this to our notice, we rushed to the Home Ministry requesting them to allow pharmaceutical manufacturing as an essential service. The response from the Ministry was immediate and quick and within no time it was declared that pharmaceutical manufacturing is an essential service. However, ancillary industries and small chemical manufacturers were not listed as essential. Hence, for a several days, there were issues faced on the ground as police officials would not allow ancillary industry workers or chemical manufacturers to go to the factories. This caused a hindrance for the pharmaceutical industry which is heavily dependent on the ancillary

[16] Interview with Dr. Pankaj Patel, Chairperson, Zydus Cadila; Prof. Arvind Sahay, IIMA; June 17, 2020
[17] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020
[18] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020
[19] IPA constitutes 57% of the total production in the country and more than 80% of the R&D expenditure.
[20] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020
[21] Interview with Dr. Pankaj Patel, Chairperson, Zydus Cadila; Prof. Arvind Sahay, IIMA; June 17, 2020
[22] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020

industry for packaging and on chemical manufacturers for certain chemicals. We rushed back to the Home Ministry and brought this aspect to their notice after which these services were also declared as essential." [23]

According to Drug Controller General, Dr. Venugopal G. Somani, "During the initial stage, the most important thing was to stop the spread of the virus. The role of the Ministry of Home Affairs was important since it had to convince people to adhere to the lockdown which was the need of the hour. The disadvantage to this was the slowdown in essential services. However, the biggest question was if manufacturing units are stopped, how will goods be produced?" [24]

On March 29, 2020, the Government constituted 11 Empowered Groups under the Disaster Management Act 2005. Dr. V.G. Somani and Dr. P.D. Vaghela played a crucial role in the setting up of WhatsApp groups to help ramp up production, remove bottlenecks, encourage state representatives of pharma and medical device industry associations to meet state officials and help resolve problems of manufacturers. [25]

Speaking on the need of the hour to establish quick dialogue, Dr. Vaghela opined about the importance of speedy communication in crisis situations. **"**One thing we did from the very beginning was to establish a dialogue with the Chief Ministers. In a crisis, it is important to establish quick communication. While e-mail and video-conferencing did not help me as much as one would think, WhatsApp proved to be a miracle platform in terms of communication. We had a number of WhatApp groups where anyone could be a member to the extent allowed by the platform. When communication is fast, we get to know the ground realities. When trucks were stopped or factories were shut, all the members of the group would instantly find out and action would be taken accordingly. For example, when we had a huge problem in West Bengal where the drivers left the trucks at the borders and just went away, speedy communication was the need of the hour. Communication is the key to success in crisis. Infact, the complaints we received in the control rooms were not even a fraction of the complaints we received on WhatsApp." [26]

Four main groups were created on WhatsApp including Manufacturers Group, India Moves Pharma, Pharma Postal Railways Group and Baddi Group for Himachal Region. At the time, members of the groups were advised to maintain confidentiality of the discussions on the group. **(Exhibit 9)** Together with Joint Secretary, Navdeep Rinwa and Rajnish Tingal, Dr. Vaghela tracked the groups' activities almost round the clock, often addressing issues post-midnight. Several zoom meetings were arranged with chief secretaries of the states and association representatives of states. All the associations were working 24x7 and providing the required inputs.

Most of the issues discussed in these groups eventually trickled down to the Drug Controller General of India (DGCI), Dr. V.G. Somani. "Together with all the State Controllers, I formed a group to communicate the issues discussed on the WhatsApp groups to the manufacturers and distributors who needed to be trained and motivated while at the same time maintain all the precautions. The Resident Commissioner took care of issues at the state level." [27] The CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories. The government body has 121 regular officers including the Drugs Controller General (India), 09 deputy drug controllers, 25 assistant drug controllers

[23] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020
[24] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11, 2020
[25] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11, 2020
[26] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04,2020
[27] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11, 2020

and over 65 drug inspectors. [28] These proved to be a key conduit of data gathering for the government from the industry about the situation on the ground in near real time.

Control rooms were also created across the Ministry of Health, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, and Niti Aayog to facilitate pharma industry issues. "To ensure that the control rooms ran smoothly, we did not get into staggered employee attendance. It was crucial that employees came to work and collectively worked on removing bottlenecks," said Dr. Vaghela. [29]

When it came to the challenges at the level of the factory workers, the pharmaceutical industry supported its workers as best as they could according to Dr. V.G. Somani. While certain states reserved the right to deduct the salaries of employees as well as take disciplinary action, if the employees of essential service organizations did not report to their duties, one shoe could not fit all. " There were clear cut instructions from the Government that if a worker could not come to the factory, his wages should not be cut. This was said keeping in mind the fact that many workers came to factories from across borders. The government ensured workers across Daman, Vapi, Baddi and other areas that their wages would not be cut even if they did not work in the factory." [30]

While most communication with the state officials was largely handled by the joint-secretaries, Dr. Vaghela and Dr. V.G. Somani had to intervene in situations which required immediate and urgent attention. Affected areas including Baddi, Daman and Goa required personal intervention along with the issue of congestion at Nava Sheva where it was required to intervene and talk to several authorities including custom officials. These crisis situations could not be resolved in a single meeting and required multiple meetings to arrive at conclusions.

Stressing the urgency of communication during a crisis, Secretary Vaghela, at the Department of Pharmaceuticals (DoP) said, "I was a very integral part of conferences held on alternate days in the morning at 9:00 AM with the Cabinet Secretary, Home Secretary, Chief Secretaries and the Health Secretary. During the course of these conferences, I would update these officials with the on-ground realities and raise concerns put forth by the industry to them." [31]

Amitabh Kant from the National Institution for Transforming India (NITI) Aaayog also got the industry and academia together. He pushed the Ministry Of Chemicals & Fertilizers, Ministry of Health, facilitated by the Ministry of Commerce to create a scenarios where Atma Nirbhar India took shape.[32]

By April 12, 2020, the three leading industry associations — the Indian Pharmaceutical Alliance (IPA – representing large Indian manufacturers that supplied 60% of medicines in India and 80% of exports), the Indian Drug Manufacturers' Association (IDMA – representing medium and smaller firms) and the Organisation of Pharmaceutical Producers of India (OPPI – representing multinational firms) were holding meetings every day in the evening. [33]

Sudarshan Jain who is the Secretary General at the Indian Pharmaceutical Alliance (IPA) appreciated the tremendous cooperation and coordination among all the stakeholders when he said, "All Pharma associations have worked in an integrated manner with the Government of India towards providing a safe and continuous supply of medicines. The Government of India has been very quick and responsive

[28] https://main.mohfw.gov.in/sites/default/files/CHAPTER%2014.pdf;https://cdsco.gov.in/opencms/opencms/e/About-us/who/
[29] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020
[30] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11, 2020
[31] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04,2020
[32] Interview with Dinesh Dua; Chairperson, Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) & CEO, Nectar Lifesciences Limited; Prof. Arvind Sahay, IIMA; June 17, 2020
[33] https://www.business-standard.com/article/economy-policy/covid-19-impact-pharma-players-come-together-for-smooth-production-120041201080_1.html.

to the needs of the industry. We deeply appreciate the prompt communication on the part of the Department of Pharmaceuticals (DoP) in regard to the exemption of pharmaceutical industry manufacturing, distribution, ancillary and support operations as essential goods and services during the initial period of lockdown."

K.G. Ananthakrishnan, Director General, Organisation of Pharmaceutical Producers of India (OPPI) described the ease with which the three bodies communicated their concerns to each other and the government. "All three of us know each other very well and we held several conversations multiple times a day and put our heads together on several issues. This reduced in May but we still make it a point to hold weekly meetings." [34] According to Sudarshan Jain, "With all the firms having helped one another to pool resources, the crisis has brought us together." These industry associations contributed to the creation of pandemic relevant literature for factory workers, employees, doctors and medical staff besides making several recommendations to the various departments. **(Exhibit 10)** It was essential that the workers function under utmost precaution. [35]

According to Dr. Pankaj Patel, Chairman, Zydus Cadila, "We have 100,000 plus people working across plants in different parts of India in the industry. If an employee would be unable to come to work, we would inquire after him. We explained to them that the plant is the safest place they know. Buses would be sanitized, segregation in the canteen would be maintained, glass partitions were created across the floors etc. If we discovered that he is infected, we would attempt to contact trace his interactions in order to prevent further spread. We wanted to motivate our employees to serve the nation while at the same time express our concern for their safety."[36] **(Exhibit 11)** Parallelly, the IPA came out with Best Practices protocol for Employees safety in manufacturing and also put together a protocol in case any personnel is found COVID positive. These protocols were endorsed by the Indian Council for Medical Research (ICMR) and widely disseminated in the industry.

The Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) worked around the clock with the three ministries to ensure that remote areas of India like Derabassi, Punjab, Baddi, Solan, H.P. Haridwar, Rishikesh, Uttarakhand, Sikkim and many more pharma clusters got relief. The organization coaxed the Minister of Civil Aviation and the Minister of State for Commerce & Industry, Hardip Puri to permit passenger airlines to be utilized as Cargo Airlines. [37] **(Exhibit 12)**

By May, manufacturing capacity had increased by 60-70%. According to Daara Patel, Secretary General of the Indian Drug Manufacturers' Association (IDMA), "This was mostly because of the efforts big companies put into in terms of efforts to retain and provide for factory workers. From logistics to stay, these companies retained their workers in lieu of complete safety and hassle-free accommodation." The IDMA however, could not employ these mechanisms since they cater specifically to small and medium-sized companies who require a lot more "hand-holding". These grassroot companies do not have the muscle of the IPA or the OPPI. The IDMA in a sense became the public liaison office of the medium and small firms during the crisis." [38]

[34] Interview with K.G. Ananthakrishnan; Director General, Organisation of Pharmaceutical Producers in India (OPPI); Prof. Arvind Sahay, IIMA; July 03, 2020.
[35] https://www.business-standard.com/article/economy-policy/covid-19-impact-pharma-players-come-together-for-smooth-production-120041201080_1.html

[36] Interview with Dr. Pankaj Patel, Chairperson, Zydus Cadila; Prof. Arvind Sahay, IIMA; June 17, 2020
[37] A Review of the efforts put in by the Pharmaceuticals Export Promotion Council of India; Ulhas Joshi; June 07, 2020
[38] Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020

By May 13, 2020, when the lockdown was extended until June 01, 2020, drug manufacturing reached near normal levels across the country and transportation and ancillary services were recovering with the only major challenge being operations at ports.[39]

At this point, Sudarshan Jain, Secretary General of the Indian Pharmaceutical Alliance (IPA) lauded Prime Minister Modi's vision on *Vasudhaiva Kutumbakam* and *Atma Nirbharta*. "During these unprecedented times, the pharmaceutical industry worked with the government in an integrated manner and continued to operate with vigour to drive local expertise and truly live up to its title as the *Pharmacy to the World*. The Prime Minister very rightly mentioned in his address to nation that it was only the 'local' which came to our help during these unprecedented times." [40]

K.G. Ananthakrishnan and Daara Patel applauded the Government's work during the lockdown period when they mutually shared a common opinion. "From the ministers to the secretaries and joint secretaries; from the different industry associations that normally have different agendas to regulators like the Drug Controller General — people worked extremely well during the crisis situation. Action plans were formulated and implemented at the speed of light and all our concerns were addressed in an organized manner." [41]

By June 25, 2020, manufacturing plants across the country returned to operating at 100% efficiency. Most of the supply issues were resolved and the number of calls between the three key pillars of the pharmaceutical industry reduced significantly. The intense back and forth meetings, video conferences and calls subsided to a couple of calls a week. [42] **(Exhibit 13)**

Managing the Crisis-1: Drop in Manufacturing Capacity and Restricted Movement of Workers & Goods

The early days of the lockdown saw transportation and other operational challenges. The sudden halt in the intra-state and inter-state movement of workers and in the transportation of goods, disrupted the factory operations and supply chains across the country. Factories located in Daman and Baddi [43] in Himachal Pradesh saw reduced operations. Manufacturing capacity had dropped to 20-30% in the first week of the lockdown at the end of March 2020 and facilities held an inventory for about 30-45 days. In Mumbai, for example, goods were lying with CMF agents who were mostly located in Bhiwandi which is a textile town. Labourers would come into Bhiwandi from neighbouring towns and with borders shut, very few or none could attend work. There were no tempos or couriers to transport these goods to the retailers. Gradually, the stocks began depleting. Because of hindrances in transport, there were no raw materials reaching the factories.

Elaborating on the various issues faced during the first week, Satish Reddy, Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA) drew a description of the most common scenes. "Factories were facing issues obtaining curfew passes for all their workers. There was much chaos and confusion with several instances being reported where transporters would provide the

[39] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

[40] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/modis-self-reliance-call-need-of-the-hour-pharma-industry/articleshow/75717066.cms

[41] Interview with K.G. Ananthakrishnan; Director General, Organisation of Pharmaceutical Producers in India (OPPI); Prof.Arvind Sahay, IIMA; July 03, 2020; Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020.

[42] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020.

[43] *Baddi is an important hub with more than 400 pharmaceutical large and medium enterprises operating. These include both the APIs and formulation manufacturing units . There are large as well medium enterprises in these areas.*

necessary papers and authorization handed down to them to police officials who would stop workers and transport carriers alike. Despite written authorization, vehicles were stopped, papers were torn up and vehicles were seized. With administrative authorities not permitting inter-state movements of the workers on a regular basis, a fear psychosis had set in." [44]

In another problem regarding drivers, Daara Patel who is the Secretary General of the Indian Drug Manufactures' Association mentioned that, "Trucks were stopped right on the highway. The officials at these points would allow the driver to go ahead but only without his helper. It is not possible for a driver to manage everything without a helper."[45] Several instances of drivers and helpers being manhandled were also reported. "Police officials were not aware that pharmaceuticals are essential. Most small pharmacies in rural or far-off locations operate with one or two people. If one was stopped by the police, the other one would not show up at the pharmacy. Consequently, in rural and far-off areas, there were small pharmacies and retailers who remained shut for a couple of days. However, by and large, pharmacies and chemists remained open in high-density areas." said Daara Patel. [46]

In his first message to the industry, Dr. P.D. Vaghela urged the industry to call back the workers and begin production immediately. It was crucial that workers continued working in factories and that the supply chain remain activated. Appeals were made by associations and firms to landlords and resident welfare associations to allow tenants and residents who work in the pharma sector to attend their work. [47] "Nobody anticipated a complete lockdown. This resulted in a challenge for the manufacturing sector because workers were not reporting for duty. Even if they were willing to work, they were not allowed to go to the factories," said K.G. Ananthakrishnan. [48]

At the time, the Government of India insisted that labourers be paid their total wages keeping in mind the fact that many workers had to cross borders to attend factories and since curfew passes posed a problem, it would not make sense to cut their wages at a time they required them the most. However, workers stopped going to the factories since their wages had already been paid. [49]

The main issue at the time lay in the fact that although the Government orders **(Exhibit 14)** to ease the industry's issues were well in place right from the very beginning, the interpretations of these orders took on disruptive forms. The Government would pass orders to State officials who would communicate these orders to local officers who would then implement them as best as he understood them. By April 2020, manufacturing capacity had increased to 60-70% which was significantly higher than other industries and by mid-June, it returned to 100% efficiency. **(Exhibit 15)** Communication regarding the movement of goods across intrastate and interstate borders was at its highest from the end of March to the end of May.

Managing the Crisis-2: API Disruptions, Export Restrictions and an Opportunity

[44] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020; Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020

[45] Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020

[46] Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020

[47] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

[48] Interview with K.G. Ananthakrishnan; Director General, Organisation of Pharmaceutical Producers in India (OPPI); Prof. Arvind Sahay, IIMA; July 03, 2020.

[49] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020

The API supply disruptions from China in February had highlighted the dependence of the Indian pharma industry on imports. Set against a volatile socio-political scenario,[50] the Indian pharmaceutical industry needed to secure its supply of APIs and Key Substance Manufacturers (KSMs) in the wake of the Coronavirus.[51] As of 2020, China, the world's second largest pharmaceutical market, produces 40% of the world's active pharmaceutical ingredients.[52]China has to its advantage economies of scale, free land, low cost utilities like water, steam, power and negligible financing costs along with the support of the Chinese government in the form of financial incentives, infrastructure and regulatory policies. **(Exhibit 16)**

Dinesh Dua, Chairman of the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) and CEO of Nectar Lifesciences Limited set the present in context to the past. "Until 2000, China was way behind us in APIs and were no match for us. At the time, Chinese Americans wanted to return to China after stealing the technology from America. They had left China for the USA to escape China's communist regime. When they returned, the government of China facilitated them and created pharma parks the size of 20,000 hectares. With infrastructure well in place, China was willing to supply India the same APIs at 20-30% lower prices. Consequently, the domestic pharma producers shifted focus to the manufacture of finished medicines (formulations) and the focus shifted to regulated markets. Many companies which started out as domestic API companies catapulted themselves into formulation companies and within no time, China became India's leading destination for the import of APIs." [53] The percentage of API imports from China spiked from 1% in 1991 to 70% in 2019.[54]For certain life-saving antibiotics like cephalosporins, azithromycin and penicillin, the import dependence is as high as 90%. [55] **(Exhibit 17)**

On the several attempts that have been made to revive the domestic API manufacturing industry in India, Dinesh Dua opined, "It has been ten years since I have been a crucial advocate of the campaign to bring API/KSM manufacturing back home. The earlier NDA disposition did not react to the proposition but then UPA-I under the late Anant Kumarji, who was then the Minister of Chemicals & Fertilizers reacted to it. I personally reached out to him and at an industry get-together in 2018 in New Delhi he stated that the year of APIs was upon us. Unfortunately, he passed away and the idea was stashed away until the pandemic forced it back into existence." In January 2020, API imports from China began to reduce as factories in China began to close due to the Chinese New Year and the spread of Covid-19 in Hubei. On account of the Chinese New Year holidays, there had been no supply from China to India over the 25 days preceding February 18, 2020. [56]

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[50] *Before the killing of 20 Indian Army personnel including a Colonel-rank officer along the Line of Actual Control (LAC) in Galwan Valley in June 2020 and right after the Chinese government facilitated India to airlift 323 citizens from Wuhan, Prime Minister Modi had written to President Jinping in early February 2020 to offer assistance in terms of medical supplies. In response, Chinese Foreign Ministry spokesman, Geng Shuang said that this gesture fully demonstrated New Delhi's friendship with Beijing. And yet, the attack in Galwan Valley was the biggest since the 1967 border clash at the India-China border in Sikkim and the first combat casualties since 1975.*

[51] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/coronavirus-niti-ceo find-ways-to-reduce-drug-import-dependence-on-china/articleshow/74218051.cms

[52]https://www.optimainsights.org/reports/69-china-api market#:~:text=Covering%2040%25%20of%20global%20APIs,has%20huge%20opportunities%20for%20growth.&text=China%20is%20the%20second%2Dlargest,annual%20rate%20of%2017%20percent.
https://www.cphi.com/content/dam/Informa/cphi/europe/en/2020/zone-pages/HLN19CPW-SP-API-article.pdf

[53] Interview with Dinesh Dua; Chairperson, Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) & CEO, Nectar Lifesciences Limited; Prof. Arvind Sahay, IIMA; June 17, 2020

[54] Reviving the Domestic API Industry in Context of the Recent Corona Outbreak; February 2020; IPA-PwC Collaboration

[55] China Supplies 80% of Pharma Raw Materials; Times of India, Ahmedabad; June 19, 2020

[56]https://timesofindia.indiatimes.com/business/india-business/prices-of-key-pharma-ingredients-could-rise-if-coronavirus-outbreak-in-china-prolongs/articleshow/74195762.cms

Much before the first lockdown was announced, most industry leaders voraciously voiced their discontent on a potential ban on exports citing a dent to India's image as, Pharmacy of the World. But, for the Government, this ban was being considered keeping one key issue in mind. 13 Active Pharmaceutical Ingredients which were largely manufactured abroad could not be imported as the respective cities were under total lockdown. This could potentially result in a catastrophic effect on the production of India's most essential medicines. The Government needed to focus on domestic production.[57] On March 03, 2020, export restrictions were placed on 13 critical APIs[58] and its formulation by Amit Yadav, Directorate General of Foreign Trade (DGFT) to protect the domestic availability in the anticipation of shortages of drugs. [59]

In a move to promote domestic manufacturing of critical bulk drugs, the Government of India, on March 21, 2020, announced a Rs. 9,940 crore package to boost domestic production of bulk drugs and medical devices, and exports. The approved scheme would promote bulk drug parks for financing common infrastructure facilities in three bulk drug parks spread across a total of 1600 acres of land with a financial investment of Rs. 3,000 crore in the next five years. [60]The major contenders for these parks would be Telangana, Andhra Pradesh, Baddi in Himachal Pradesh, Gujarat and Maharashtra. [61]The package would also create a production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Intermediates and Active Pharmaceutical Ingredients (APIs) in the country with financial implications to the tune of Rs. 6,940 crore for the next eight years. [62]The government identified 53 APIs under the scheme.[63]

Praising the new policy, Dilip Shanghvi, Managing Director, Sun Pharma said, "The new policy is a bold announcement by the government and will give the necessary fillip to the API industry in India. I would like to congratulate the Government as this will safeguard healthcare security and create an ecosystem for a strong Indian API industry." Adding further to this, Satish Reddy said that, "India has the capability and competence to manufacture all APIs. The announcement by the government will help revive the API industry in the country and regain the dominance over the years. The investment in creating bulk drug parks is an important step for the development of industry. " [64]

Commending the Government's decision to focus on domestic API manufacturing, K.G. Ananthakrishnan was all praise for the step towards *Atma Nirbharta*. "Although it will take us a couple of years to become self-sufficient, it is better late than never. It is important though that alternative sources from Europe and other countries be kept open to manage the situation." [65] On April 06, 2020, the Government took cognisance of the industry and its associations' requests as Amit Yadav, Directorate General of Foreign Trade (DGFT) lifted export restrictions on 13 critical APIs and their formulations barring Paracetamol. The rising cost of APIs and KSMs and solvents soon became a cause of concern for the industry and representations on the rising costs were made on April 30, 2020 to the Government of India. [66]

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[57] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020

[58] The 13 APIs and their formulations include paracetamol, tinidazole, metronidazole, acyclovir, vitamins B1, B6 and B12, progesterone, chloramphenicol, erythromycin and clindamycin salts, neomycin and ornidazole.

[59] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

[60] https://www.business-standard.com/article/pti-stories/industry-players-applaud-govt-s-move-to-boost-manufacturing-of-apis-med-devices-120032200611_1.html

[61] Interview with Dinesh Dua; Chairperson, Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) & CEO, Nectar Lifesciences Limited; Prof. Arvind Sahay, IIMA; June 17, 2020

[62] https://www.business-standard.com/article/pti-stories/industry-players-applaud-govt-s-move-to-boost-manufacturing-of-apis-med-devices-120032200611_1.html

[63]https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/eight-global-pharmaceutical-firms-evince-interest-in-indias-plan-to-ramp-up-api-production-mansukh-mandaviya/articleshow/76201809.cms

[64] IPA Press Statement on Promotion of Domestic Manufacturing of APIs and KSMs Policy; Mumbai, March 21, 2020

[65] Interview with K.G. Ananthakrishnan; Director General, Organisation of Pharmaceutical Producers in India (OPPI); Prof. Arvind Sahay, IIMA; July 03, 2020.

[66] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

Nearly a month later, on May 21, 2020, the Central Government removed restrictions on the export of active pharmaceutical ingredients (APIs) for Paracetamol, making it export-free [67] with immediate effect. **(Exhibit 18)** By the beginning of June, India was planning to attract foreign majors to ramp up the production of active pharmaceutical ingredients. This drew interest from eight companies as it considered extending SOPs to existing domestic entities. The move was also a step towards reducing the dependence on China. [68] The Government was actively looking for alternative sources for bulk drugs, which are used to make medicines, to avoid any crisis in the domestic market given the national sentiment towards China. Any further reliance on this dependency would be a risk in times on uncertainty. But, just as any decision has its downsides, the downside to this one would be price and capacity restraints.[69]

On June 30, 2020, the Government of India announced a ban on nearly 60 Chinese apps. At the time, the rising tension on the LAC in Galwan Valley and other parts of Eastern Ladakh in Northern India remained a cause for concern and pharma industry experts became increasingly concerned about any potential ban on the import of APIs and KSMs from China. Import dependent sectors in India include pharmaceuticals, automobiles, electronics, telecommunications etc. Automobiles and pharma companies have invested deeply in building a supply chain that traces back to China significantly and disrupting this chain could adversely affect their competitive situation in export segments.[70]

Managing the Crisis -3: Halted Movement of Exports & Imports

After the government announced export restrictions on the export of 13 crucial active pharmaceutical ingredients and their formulations in lieu of preserving domestic capacity on March 03, 2020, exporters had lined up applications seeking licence to ship restricted active pharmaceutical ingredients by March 16,2020. The government had received as many as 200 applications from pharma firms in a span of 10 days after it tightened their export norms. [71]

With containers stuck in transit for days together, companies were worried about the drugs, mostly vitamins and hormones which have a limited shelf-life of around 18-24 months. If the restrictions were to be prolonged, buyers would not accept the product and the same formulations could not be utilised for domestic consumption. Manufacturers and exporters had mostly manufactured these listed items before the outbreak of the pandemic and had committed to ship the consignments to customers in mutually agreed upon timelines. The reference notification imposing restriction on the export of the listed items with immediate effect would severely impact the industry as many consignments had already been lined up for export in the warehouses and ports. [72]

After industry associations raised concerns that the pandemic had caused challenges in clearances at port offices and many products were losing shelf life and going below the threshold of 60% , the Government took a call. Under the existing rule, imported drugs that have less than 60% shelf life remaining are not allowed into the country. However, given the supply chain disruption this rule was relaxed by the Central Drugs Standard and Control Organisation (CDSCO) in a circular issued on April 17, 2020 by Dr. Venugopal G. Somani. **(Exhibit 19)**

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[67] https://www.businesstoday.in/current/economy-politics/govt-lifts-bans-on-export-of-paracetamol-apis-immediate-effect/story/405265.html

[68] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/eight-global-pharmaceutical-firms-evince-interest-in-indias-plan-to-ramp-up-api-production-mansukh-mandaviya/articleshow/76201809.cms

[69] Government Looks Beyond China to Source APIs; Business Standard, June 20, 2020

[70] Stopping China; Indian Express; June 20, 2020

[71] https://economictimes.indiatimes.com/news/economy/policy/exporters-line-up-for-restricted-active-pharmaceutical-ingredients licence/articleshow/74642481.cms

[72] https://www.financialexpress.com/industry/pharma-body-seeks-relaxation-on-api-exports-for-committed-drug-orders/1889370/

The lack of truck drivers amid the lockdown had several thousands of tonnes of cargo, including essentials stuck at various ports across the country. Reports in the first week of April 2020 suggested nearly 40,000 containers were stuck at Chennai and Container Freight Stations (CFS). [73]Congestion at India's largest container port, Nhava Sheva required immediate action based on clear communication. By July, the supply disruptions were mostly erased. The intensity had died down on account of movement across the nation being resumed.

Managing the Crisis-4: Access to Data

The three pillars agreed on a common bottleneck that they encountered at one point or another. Data collection was a herculean task during this lockdown especially since the automatic data updating system which would work effectively in normal circumstances, did not function as effectively on a day to day basis. Data was not available in a single place and needed to be collated from companies and states. The government required industry associations and companies to submit state-wise data on capacity utilization and labour utilization.

Other issues in data collation included getting information on stock updates for key import locations. India was mostly dependent on secondary information coming in from Indians based in key import destinations. [74] There were also several other data points which required collation. "It was not possible to repeatedly ask an official to arrange for curfew passes for companies as and when the situation arose. In order to arrive at some conclusive data, we would ask the companies for their assistance in gathering the required data from the field and share this with the officials who would then construct a plan of action in accordance to the number of curfew passes required per area in totality," said Daara Patel in reference to issues in data collation.

In other instances, many companies did not share data out of a sense of fear. "Other than the police, no one has a network as large as us. The common notion is that a regulator is a cop. Hence, many people are afraid to provide them with data. However, a regulator functions like a facilitator who ensures the larger good of the public," said Dr. V.G. Somani, Drug Controller General. His office and its 20 regional offices were instrumental in being able to get most of the required data together in one place for the government and industry to take a decision.

When it came to compiling and calculating the factors that define the difference in the cost of production of APIs manufactured in India and China **(Exhibit 7)**, Dr. P.D. Vaghela talked about the difficulty in accessing the data. "To arrive at the figure of 20%, difference in cost of production of APIs in India vs. China, we needed to scan through data. But, this data was not easily available. Fortunately at the time, we had access to some data studies carried out by KPMG, Ernst & Young and other research organizations. However, we did not have data studies specifically for APIs in a specific country. The only way to get data was to request for secondary data for Indian API manufacturing plants based out of a specific country. We could not get hold of any primary data."

Managing the Crisis-5: Testing Kits

"When the pandemic hit the nation, there was not a single test available in the country as of March 19, 2020. We needed to figure out a way to make test kits available in the country indigenously by

[73] https://www.business-standard.com/article/economy-policy/govt-allows-imported-drugs-with-residual-shelf-life-of-under-60-120041800913_1.html

[74] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020

encouraging kit manufacturers to manufacture them. It was also crucial that these kits were tested for accuracy, " said Dr. Venugopal G. Somani. [75]

By April 19, 2020, Indian pharma majors were gearing up to develop or import testing kits.[76] At the time, Cadila Healthcare and Biocon were in the process of developing indigenous testing kits or rapid antibody testing kits. Some, such as Eris Lifesciences, Mylan, and Gland Pharma, among others, imported the required kits from international suppliers. [77] India, at the time had 641 test labs across the country. [78]

In the beginning, several companies received the go-ahead signal from the Government to import rapid antibody test kits from China. Consequently, around 50,000 kits came in from India's neighbouring country at the time. The Indian Council of Medical Research (ICMR) had advised state governments to stop using Coronavirus [79] testing equipment from two Chinese companies on account of adverse reports about the quality.[80]By the end of May, testing machines and personal protective equipment (PPE) were being made in India. Prime Minister Narendra Modi had set a target to conduct one lakh tests per day before May 31, 2020. By May 29, 2020, the figure had already been surpassed as 1,22,000 tests were being conducted per day. [81]

Managing the Crisis-6: Drug Approvals, Clinical Trials, Research & Development

In terms of drug approvals Dr. Venugopal G. Somani, Drug Controller General of India talked about how everyone began in absolute darkness, "At the time, it was unclear which medicines would work in combating Covid-19. So, we began with the medication that we used to treat MARS and SARS. After all, these medicines had received approval. But, these did not work. Then, we tried Hydroxychloroquine[82] based on limited data. The evidence was not convincing. Statistically, it seemed like it was unlikely it would work. However, numerically, it seemed to be working just fine. We started out with only two domestic manufacturers of the drug. Although its application is used in Malaria, the drug was mostly an abandoned drug which suddenly became as valuable as diamonds or gold. The drug was only available with rheumatologists or orthopaedics. Together with Azithromycin, Hydroxychloroquine worked miraculously in the first phase to cure Covid-19. To encourage manufacturers, we had to take a lot of steps to ensure the drug's availability in the country." [83]

Somani further added that, "The drug, which is a Schedule H1 drug used to be available only 20% in the market. However, during the pandemic, the Government had a 50% reserve of the drug while every chemist and drug retailer has 60% availability. While it is a prescription drug, stores were required to keep a record of each purchase to as to avoid unnecessary purchases. When the production of the drug

[75] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11,2020
[76] *There are two kinds of testing for the pandemic. One is the real-time Polymerase Chain Reaction Kit that uses throat or nasal swabs and provides results in a few hours while the other is an Antibody-based Rapid Testing Kit that uses blood samples and provides results in a few minutes.*
[77] https://www.business-standard.com/article/current-affairs/indian-pharma-majors-step-in-to-develop-import-coronavirus-test-kits-120041900657_1.html
[78] https://www.cnbctv18.com/healthcare/india-is-pharmacy-of-world-provided-medicines-like-hydroxychloroquine-to-countries-will-remain-so-mos-health-choubey-6033091.htm
[79] https://www.jagranjosh.com/general-knowledge/timeline-of-covid-19-1586178638-1
[80] https://www.business-standard.com/article/current-affairs/indian-pharma-majors-step-in-to-develop-import-coronavirus-test-kits-120041900657_1.html
[81] https://www.cnbctv18.com/healthcare/india-is-pharmacy-of-world-provided-medicines-like-hydroxychloroquine-to-countries-will-remain-so-mos-health-choubey-6033091.htm
[82] *Hydroxychloroquine and chloroquine are two medications that have been used for many decades to treat malaria and auto-immune conditions like rheumatoid arthritis and lupus. India is the largest manufacturer and exporter of the drug.*
[83] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11,2020

was ample, it began to be exported. The drug would provide relief to the entire world and we were ready to help." [84]

India has a total installed capacity to manufacture 40 tonnes of API of Hydroxychloroquine which translates into 200 million tablets of 200 mg. India required around 24 million tablets per year as in April 2020 for malaria, lupus, and rheumatoid arthritis. Each COVID-19 patient needed at the time, a 14-tablet course. During the same time, the Ministry of Health and Family Welfare had placed an order for around 10 crore tables of Hydroxychloroquine with Ipca Laboratories and Zydus Cadila. The centre at the time, had already procured around 100 million tablets and states together had procured 60-70 million tablets. This alone could take care of more than one crore people in the country.

Zydus' production would be sufficient for more than 7 lakh individuals. [85]Zydus alone received orders from the central and many state governments for roughly 15 crore tablets for April 2020. [86]Dr. Pankaj Patel had said that his company would manufacture 30 tonnes of Hydroxychloroquine active pharmaceutical ingredient which would be equivalent to 15 crore tablets in May 2020.[87] Zydus Cadila used to earlier manufacture 2-4 tonnes of active pharmaceutical ingredients every month for domestic supply as well as for exports but in April 2020, the company would meet its increased domestic target of 20 tonnes or 10 crore tablets. The target for May 2020 would be 30 tonnes or 15 crore tablets, which the company was confident about achieving.[88]

Adding further to this, Dr. Patel said, "When we received a call from government authorities telling us that we needed to export Hydroxychloroquine, we decided that we needed to manufacture all the material in India and so we hired plants across the country to make sure the additional capacity would be built up. At the time, we were one of two companies whose capacity geared up to 30,000 units a month." [89]

In terms of pricing, Dr. Patel mentioned that pricing would not be higher than normal and that contrary to belief, the company was supplying the drug at a lower price to the government. Zydus manufactures Hydroxychloroquine tablets in Ahmedabad, Sikkim and Baddi as of April 2020.[90]In India, each 400 mg tablet was priced at around Rs.13 at the time. It was recommended by the ICMR as prophylaxis for asymptomatic healthcare workers involved in the care of suspected or confirmed cases. They were recommended to take 400 mg twice a day on day one, followed by 400 mg once weekly for the next seven weeks. The total cost of this course, which comprised nine tablets came to only Rs. 117. [91]

India manufactures 70% of the world's supply of Hydroxychloroquine. Two key starting materials needed for Hydroxychloroquine production are produced domestically while India gets the active pharmaceutical ingredient that is used to manufacture the drug from China. India exported Hydroxychloroquine API in April-January 2019-20 period worth $ 1.22 billion. [92]The Indian pharmaceutical industry exported formulations made from Paracetamol worth $5.41 billion during

[84] Interview with Dr. Venugopal G. Somani, Drug Controller General of India (DCGI); Prof. Arvind Sahay IIMA; June 11,2020
[85]https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/hcq-productionscaled-up-zydus/articleshow/75112679.cms
[86]https://www.livemint.com/science/health/india-biggest-producer-of-game-changer-hydroxychloroquine-drug-has-enough-capacity-11586266119087.html
[87]https://www.aninews.in/news/national/general-news/pharmaceutical-industry-produces-20-cr-hydroxychloroquine-tablets- this-month zydus-cadila-ceo20200411150740/
[88]https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/hcq-productionscaled-up-zydus/articleshow/75112679.cms
[89] Interview with Dr. Pankaj Patel, Chairperson, Zydus Cadila; Prof. Arvind Sahay, IIMA; June 17, 2020
[90]https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/hcq-productionscaled-up-zydus/articleshow/75112679.cms
[91] https://www.expresspharma.in/covid19-updates/remdesivir-in-india-an-unfolding-story/
[92]https://www.livemint.com/science/health/india-biggest-producer-of-game-changer-hydroxychloroquine-drug-has-enough-capacity-11586266119087.html

April-January 2019-20. The figure stood at $ 5.8 billion in the financial year 2018-19. [93] According to the Foreign Ministry, in April 2020, India had shipped 1.9 million tablets and other forms of Paracetamol to 31 countries including USA, Spain, Germany, Bahrain, Brazil, Nepal, Bhutan, Sri Lanka, Afghanistan, Maldives and Bangladesh.. Consignments of anti-malarial drug Hydroxychloroquine and paracetamol were being sent to 87 countries on a commercial basis.

In May, US-based Gilead Sciences' Remdesivir emerged as one of the most promising drug candidates for the treatment of the Coronavirus which received approval from the USFDA on May 01, 2020. On June 1, 2010, Dr. V.G. Somani granted marketing authorisation to Gilead Sciences' anti-viral drug Remdesivir for the treatment or restricted emergency use of suspected or laboratory-confirmed cases in adults and children hospitalised with the severe disease.

Gilead Sciences signed non-exclusive voluntary licensing agreements with Cipla, Hetero Labs, Jubilant Lifesciences, Mylan and Ferozsons Labs to expand supply in India and Pakistan. [94]At the time, Cipla manufactured Remdesivir under the name, 'Cipremi' at amongst the lowest prices in the world. The price for a 100 mg vial, as of July 2020, was Rs. 4000. The pharmaceutical giant targeted a supply of 80,000 vials within July itself. [95] Stressing the importance of affordable and accessible pricing, Dr. V.G. Somani said," Accessibility and affordability define a quality product. Medicines should be available for the masses, not for the classes."

Later in June 2020, Glenmark Pharmaceuticals launched prescription-based anti-viral drug Favipiravir under the brand name, 'FabiFlu' at Rs. 103 per tablet for the treatment of mild-to-moderate cases after it received the Indian drug regulator's approval. The drug is available as a 200 mg tablet at a maximum retail price of Rs. 3,500 for a strip of 34 tablets. [96]Favipiravir is a generic version of Avigan of Fujifilm Toyama Chemical, Japan, a subsidiary of Fujifilm Corporation. [97]

On clinical trials, Dr. V.G. Somani was confident that most countries will not be able to challenge India's drug protocols. "107 clinical trials are underway of which 10% to 20% have already been completed. These trials are broadly performed on vaccines, respiratory drugs, new drugs and adjunct therapies. The trials are in different phases as we speak. We have a large database of this information. We are also defining our own drug protocols and barring the USA, U.K. and Japan whose criteria for clinical trials involves a completely different process, most countries will not challenge our drug protocols."

Prime Minister Narendra Modi has often stressed the importance of Research and Development in the pharmaceutical sector. In terms of research on vaccines, the country's first indigenous COVID-19 vaccine candidate Covaxin, developed by Hyderabad-based Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV) received the nod for human clinical trials from the DCGI in early July 2020. [98] Covaxin would be tested on over 1,100 people in two phases. The company planned to enrol 375 participants to test COVID-19 vaccine candidate the month of July. [99] Zydus Cadilla had also started Phase 2 trials of its Covid vaccine by early August 2020.

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[93] www.businesstoday.in/current/economy-politics/govt-lifts-bans-on-export-of-paracetamol-apis-immediate-effect/story/405265.html
[94] https://indianexpress.com/article/explained/the-drugs-india-is-fighting-covid-with-6449377/
[95] https://www.livemint.com/news/india/coronavirus-vaccine-cipla-launches-generic-version-of-remdesivir-in-india-11594223346722.html
[96]https://www.businessinsider.in/india/news/fabiflu-covifor-cipremi-medicines-approved-to-treat-covid-19-patients-in-india/slidelist/76507980.cms#slideid=76508438
[97] https://mumbaimirror.indiatimes.com/coronavirus/news/glenmark-launches-covid-19-drug-in-india-after-dcgi approval/articleshow/76481387.cms
[98] https://www.expresspharma.in/covid19-updates/zydus-cadila-gets-dcgi-approval-for-human-clinical-trials-of-covid-19-vaccine/
[99] https://www.livemint.com/news/india/coronavirus-vaccine-cipla-launches-generic-version-of-remdesivir-in-india-11594223346722.html

On the subject of vaccines, Dr. V.G. Somani mentioned that there was a specific task force put in place by the PMO which ensures that vaccines and diagnostics are being developed in a step towards *Make in India.* However, although research on vaccines is well underway, India has not yet discovered any drug of its own. " We do not have drug discovery in India and this aspect has long been neglected. We are coming out with an R&D policy at the national level and look forward to this being unveiled by the end of August 2020," says Dr. V.G. Somani.

Many firms in India including Lupin, Zydus Cadila, Dr. Reddy's Laboratories and Sun Pharma are already spending between 5% and 9% of their revenues on Research and Development, with some spending significant amounts on new molecule development. The pandemic created an impetus for these firms to take the R&D to the next level.

Key problems in Research and Development include issues related to the funding of private entrepreneurs and venture funding. Research is required to be carried out on fiscal policies besides which there should be an environmental ecosystem for research. Often companies want to do research but do not receive permission as quickly as one would like and a lack of transparency only adds to the problems. Elaborating on this thought, Dr. P.D. Vaghela said that, "Research and Development cannot be developed in a short span but the process can be initiated. Although India is brilliant in incremental research [100]in terms of drug discovery, no new drug from India has turned commercially viable. In India we should have focused method where we perform research which aims at launching commercially viable drugs and new medical devices. While patents are also registered in India, in the USA, 3500 commercially viable patents have been registered. Also, multi-national corporations are not interested in research on Indian specific diseases like leprosy. Hence, the global demand for research on related drugs is very minimal. Indian researchers invest a lot more in research on these drugs in comparison to the global demand. "

On utilising the capacity of India's globally renowned academia to arrive at conclusions beneficial for the industry, Dinesh Dua stressed the urgency to promote industry academia collaboration in a big way. " 100% of the innovation in the West in pharma and biotech has come from academia and not from industry. India invests a lot on R&D and yet, we are struggling with drug discovery. This is because we have no support from academia. If academia could be a part of this I could add 10% academia to my R&D team and the value addition would be unthinkable! The pharmaceutical industry in India is controlled predominantly by the Government with academia's contribution almost non-existent or bare minimal." [101]

Also, technology's role in R&D cannot be ignored or side-lined since the best research today requires the tools to place it at the top. In this regard, Dr. P.D. Vaghela said that, "In India we should have focused methods where we perform new research aimed towards launching commercially viable drugs and new medical devices. Technology is becoming smarter and more efficient as we speak. If Indian researchers do not keep pace with these developments, the country will be left behind. Several developed countries already have a huge apparatus to incentivise research and development. If they have the technology to manufacture low-cost qualitative APIs, why will they sell these APIs to us? It is imperative that India forms a robust R&D structure." [102]

Would it be possible not only to supply 40% of the world's supply of generic medicines, but also to be an important source of new molecules for different therapy areas that had hitherto been the almost

[100] *Incremental research refers to the ability to work on the drawbacks of a given product, say stents, and create a better version of the same product.*
[101] Interview with Dinesh Dua; Chairperson, Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) & CEO, Nectar Lifesciences Limited; Prof. Arvind Sahay, IIMA; June 17, 2020
[102] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020

exclusive preserve of pharmaceutical MNCs in the West? How was the Indian pharma industry positioned in 2020?

The Denouement: IPM Production and Exports during January to May 2020

As of 2020, India is the largest provider of generic medicines globally, occupying a 22% share in global supply by volume. It also supplies 50% of the global demand for vaccines. India has 550 US FDA approved plants, the most outside the USA. Indians pay 70% less than the global median prices to buy medicines. The country also has one of the lowest manufacturing costs at almost 50% of Europe.[103]The industry is broadly divided into Active Pharmaceutical Ingredients and Formulations. **(Exhibit 20)**

Access to affordable HIV treatment from India is one of the greatest success stories in medicine. India is one of the biggest suppliers of low-cost vaccines in the world. Because of a low price and high quality, Indian medicines are preferred worldwide. India is often referred to as, 'The Pharmacy of the World'.[104]India holds 12% of all global manufacturing sites catering to US market. The cost of manufacturing in India is approximately 33% lower than that of the US. 100% Foreign Direct Investment (FDI) is allowed under the automatic route for greenfield pharma.[105]

The total size of the industry, as of 2020, including drugs and medical devices was around Rs.3,01,000 crore ($ 43 billion). During the same period, the growth rate was 7-8% in the drug sector and 15-16% in the medical device sector. [106]India is the source of 60,000 generic brands across 60 therapeutic categories. The country manufactures more than 500 different Active Pharmaceutical Ingredients (APIs) and is the third largest market for APIs on a global level. Branded generics occupies 70%-80% share of the retail market. In terms of the formulations industry, India is the largest formulations exporter expected to experience double-digit growth over next 5 years from 2020.

India is home to more than 3,000 pharma companies with a strong network of over 10,500 manufacturing facilities. The domestic pharmaceuticals market turnover reached $ 20.03 billion in 2019, up by 9.3% from 2018, growing as penetration of health insurance and pharmacies rise. [107] Indian consumers are spending nearly 1% of their total income on drugs and pharmaceuticals. [108]

As per the Union Budget 2020-21, the allocation to the Department of Pharmaceuticals has been $ 44.47 million. [109]The Department of Pharmaceuticals aims to make the country a hub for end-to-end drug discovery under its 'Pharma Vision 2020'.[110]

In January 2020, the Indian pharmaceutical market's Moving Annual Total (MAT) grew by 11% and 10% at the Total Sales Audit (TSA) and Secondary Sales Audit (SSA) level respectively. On month, the market grew by 9% and 8% at the TSA and SSA level respectively while in February 2020, the Indian pharmaceutical market's MAT grew by 11% and 10% at the TSA and SSA level respectively. On month, the market grew by 9% and 8% at the TSA and SSA level. In March 2020, the Indian pharmaceutical market's MAT grew by 11% at both, the TSA and SSA level respectively. On month, the market grew by 5% and 7% at the TSA and SSA level respectively while in April 2020, the Indian

[103] Reviving the Pharma Ancillary Industry, May 2020; IPA & Accenture
[104] https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf
[105] https://www.investindia.gov.in/sector/pharmaceuticals
[106] https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf
[107] https://www.investindia.gov.in/sector/pharmaceuticals
[108] https://www.raconteur.net/healthcare/india-pharmaceutical-industry
[109] https://www.makeinindia.com/sector/pharmaceuticals
[110] https://www.investindia.gov.in/sector/pharmaceuticals

pharmaceutical market's MAT grew by 9% at both, the TSA and SSA level respectively. On month, the market grew by 12% and 9% at the TSA and SSA level. **(Exhibit 21)**

Sun Pharmaceuticals holds 5.5% of the total pharmaceutical market share followed by Mankind at 4.7% and Cipla at 4.4%. Zydus Cadila and Lupin Limited individually hold 3.9% of the total market share followed by Intas at 3.2% and Alkem at 2.9%. Abbott and Pfizer individually hold 2.4% of the total market share while Dr. Reddy's Laboratories, Glenmark Pharma and Ipca Labs hold 2.3%, 2.2% and 1.6% respectively.

The top twenty pharmaceutical companies registered a MAT growth rate of 8.24% in May 2020 over the eleven months from May 2019 while the total pharmaceutical market registered a 6.44% growth rate during the same period. Aristo Pharma Mankind registered a growth rate of 18.73% in May 2020 over the eleven months from May 2019 while Mankind registered a MAT growth rate of 12.34% during the same period. Pfizer registered a growth rate of 10.59% in May 2020 over the eleven months from May 2019 while USV registered a growth rate of 10.01% during the same period. Zydus Cadila, Dr. Reddy's Laboratories, Sun Pharma and Cipla registered growth rates for the same period at 9.95%, 9.94%, 7.82% and 3.84% respectively.

The top twenty pharmaceutical companies registered a growth rate of 4.31% in March 2020 over March 2019 while the total pharmaceutical market registered a 7.71% growth rate during the same months. In March 2020, Abbott, Alembic, Ipca Labs and Mcleods Pharma registered growth rates over March 2019 at 49.22%, 36.12%, 34.69% and 32.80%. Cipla, Sun Pharmaceuticals, Mankind and USV registered growth rates over March 2019 at 22.10%, 17.72%, 17.21% and 16.69%. **(Exhibit 22)**

The top twenty Indian pharmaceutical brands include Abbott's Mixtard, Sanofi's Lantus, USV's Glycomet -GP, Franco's Dexorange, Abbott's Thyronorm and Novomix. **(Exhibit 23)** In terms of therapy areas, during the lockdown, two areas saw a significant increase in sales. Cardiac products grew by 13.12% in April 2020 over April 2019 while Anti-diabetic products grew by 10.46% over the same months. However, the total growth in therapy areas declined by -10.96% in April 2020 over April 2019. **(Exhibit 24)** In terms of product portfolio, the Indian pharmaceutical industry has a total of 11,340 products as of April 2020 of which Intas has 1009 products followed by Cipla which has 1000 products. **(Exhibit 25)**

Exports in the Indian Pharmaceutical Industry increased from 10.23% in 2010-11 to 18.75% in 2018-19 while imports increased from 3.77% to 5.65% during the same period. [111]The Indian pharmaceutical industry supplies a significant percentage of global supply of medicines including vaccines, APIs and finished products. As of 2020, India accounts for 20% of global exports in generics by volume, making it the largest provider of generic medicines globally. Indian vaccines are exported to 150 countries.[112]

India exported pharmaceuticals to the tune of Rs. 1,33,910 crore with a recorded growth of 10.72% in 2018-19 while the country exported 549 million kgs of total pharmaceuticals worth Rs. 140,535 crore with a 4.95% increase over the previous year in 2019-20. Of the total value, Drug Formulations & Biologicals formed 80.4% of the total exports while Bulk Drugs & Drug Intermediates formed 19.59% in 2019-20. India exports pharmaceuticals primarily to the USA, China, Germany, Brazil, Bangladesh, South Africa, UK, Russia and Nigeria among 200 countries.

The import of drugs in 2018-19 was to the tune of Rs. 35,000 crore [113] while the country imported 386 million kgs of total pharmaceuticals worth Rs. 40,139 crore with a 14.68% increase over the previous year in 2019-20. Of the total value, Drug Formulations & Biologicals formed 39.78% of the total exports

[111] https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf
[112] https://www.makeinindia.com/sector/pharmaceuticals
[113] https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf

while Bulk Drugs & Drug Intermediates formed 60.22% in 2019-20. India imports pharmaceuticals primarily from China, USA, Italy, Singapore, Spain, Switzerland, USA, Belgium and Germany. **(Exhibit 26)**

In April 2020, India exported pharmaceutical products worth Rs. 11,758 crore while in May 2020, this increased to Rs. 14,959 crore. The industry in May registered a growth over the same time last year at 27.12%. Collectively, total exports in the months of April and May in 2020 totalled Rs. 26,631 crore as compared to Rs. 22361 crore for the same months in 2019. Collectively, a total growth of 19.10% was registered over the same period last year. [114]

India's overall exports in April-May 2020-21 are estimated to be $ 61.57 billion, exhibiting a negative growth of - 33.66 % over 2019-2020. Overall imports in April-May 2020-21 are estimated to be $ 57.19 billion, exhibiting a negative growth of - 48.31 % over 2019-2020. [115] FDI up to 100% in the pharmaceutical sector is permissible through automatic route for greenfield investment and up to 74% for brownfield investment. Beyond 74%, FDI in pharmaceutical sector for Brownfield investment is permissible through Government approval route.[116]

What's Next for the Government and the Indian Pharmaceutical and Medical Device Industry in India?

K.G. Ananthakrishnan stressed the importance of keeping up the good work. "It is crucial that the good practices established during the lockdown continue in order to speed up progress on several fronts for the Indian Pharmaceutical Industry. The type of co-ordination that has happened over the lockdown period should become a norm." [117] For example, while the Uttar Pradesh government exempted the industry from labour laws for a period of three years on May 08, 2020, the subject of labour laws in India will need to be addressed on a larger scale if the Government of India wants to successfully build domestic API parks in the country. According to Dinesh Dua, "In order to make ease of doing business better, the Government must focus on acquiring land because it takes more than three years. Until one addresses the Labor Laws in this country, no one will approach us."[118] On the subject of price control, Satish Reddy and Daara Patel stressed the urgency to free the country from the shackles of price control. "Price control has been strangling us and needs to go. For every molecule, there are a number of manufacturers and hence, the competition will take care of itself. The government should ease out the controls and only focus only on monitoring." [119]Adding further to this, Satish Reddy said that, "India will need to move up the value chain and build a position in innovation space which accounts for 2/3 of global market."

Dr. V.G. Somani summed up the common goal for the industry. "Quality and organization should define India's image as the *Pharmacy to the World*." While it was clear that the industry had been able to maintain production and increase efforts between January 2020-May 2020 as compared to the same timeline in 2019 — both from the perspective of the top 20 firms and the top 20 brands across therapy

[114] Estimates for Selected Major Commodities (April-May, 2020); Ministry of Commerce
[115] India's Foreign Trade, May 2020; F. No. K-12011/3/2020-EPL-1, Government of India, Ministry of Commerce & Industry, Department of Commerce, Economic Division
[116] https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf
[117] Interview with K.G. Ananthakrishnan; Director General, Organisation of Pharmaceutical Producers in India (OPPI); Prof. Arvind Sahay, IIMA; July 03, 2020; Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020
[118] Interview with Dinesh Dua; Chairperson, Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) & CEO, Nectar Lifesciences Limited; Prof. Arvind Sahay, IIMA; June 17, 2020
[119] Interview with Satish Reddy; Chairman of Dr. Reddy's Laboratories and President, Indian Pharmaceutical Alliance (IPA); Prof. Arvind Sahay, IIMA; June 25, 2020; Interview with Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA); Prof. Arvind Sahay IIMA; July 06, 2020

areas (**Exhibits 22-24**) — going forward required key decisions and robust implementation on an API policy, on R&D, on testing and clinical trial protocols and on price controls. How would the industry-government cooperation continue with a mechanism that enabled the growth momentum to truly make India the *Pharmacy to the World?*

APPENDIX

(A) Government Bodies

The Indian Pharmaceutical Market is broadly governed by the Ministry of Health & Family Welfare and the Ministry of Chemicals & Fertilisers. In addition, the Ministry of Science & Technology, Ministry of Commerce & Industry and the Ministry of Environment & Forests regulate aspects of the Indian Pharmaceutical Market.

1. **Ministry of Health & Family Welfare:** The MoHFW represents the central government. The Director-General of Health Services (DGHS) oversees the regulatory functions of the Ministry of Health & Family Welfare.

    a. **Central Drugs Standard Control Organisation:** Under the DGHS, the CDSCO holds the final delegation of regulatory responsibility. The CDSCO is not a statutory body and hence is not independent of the Ministry of Health & Family Welfare. It prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country. It also regulates the market authorization of new drugs and clinical trials standards, supervises drug imports and approves licenses. While the head office is located in New Delhi, the regulatory body has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories. The government body has 121 regular officers including the Drugs Controller General India (DGCI), 09 deputy drugs controllers, 25 assistant drugs controllers and over 65 drug inspectors.

2. **Ministry of Chemicals & Petrochemicals**: Under the Ministry of Chemicals & Petrochemicals, falls the National Pharmaceutical Pricing Authority (NPPA), the Department of Chemicals & Petrochemicals (DCP) and the Department of Pharmaceuticals (DOP).

    a. **National Pharmaceutical Pricing Authority:** The NPPA is responsible for fixing the prices of bulk and formulation of drugs within the National List of Essential Medicines (NLEM). It was instituted in 1997 under the Department of Chemicals and Petrochemicals, which fixes or revises the prices of decontrolled bulk drugs and formulations at judicious intervals. It periodically updates the list under price control through inclusion and exclusion of drugs in accordance with established guidelines. It also maintains data on production, exports and imports and market share of pharmaceutical firms and enforces and monitors the availability of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.

b. **Department of Pharmaceuticals:** The DoP was formed on July 01, 2008 under the Ministry of Chemicals & Fertilizers with the objective to throw focus on the development of pharmaceutical sector in India and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research and development, protection of intellectual property rights and international commitments related to pharmaceutical sector which required integration of work with other ministries. Upon the recommendation of the NPPA, the Ministry of Chemicals & Fertilizers fixes a ceiling price of Active Pharmaceutical Ingredients (APIs) and issues notifications in respect of drugs which are scheduled drugs and formulations.

3. **Ministry of Science & Technology:** Under the Ministry of Science & Technology falls the Indian Council of Medical Research (ICMR), Bhabha Atomic Research Centre (BARC) and Council of Scientific and Industrial Research (CSIR).

   a. **Indian Council for Medical Research:** In 1911, the Government of India set up the Indian Research Fund Association (IRFA) with the specific objective of sponsoring and coordinating medical research in the country. After independence, several important changes were made in the organization and the activities of the IRFA. It was re-designated the Indian Council of Medical Research (ICMR) in 1949, with considerably expanded scope of functions. ICMR, the apex body in India for formulation, coordination and promotion of biomedical research is one of the oldest medical research bodies in the world.

4. **Ministry of Commece & Industry:** Under the Ministry of Commerce & Industry falls the Patent Office, Department of Commerce & the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL), Directorate General of Foreign Trade (DGFT) and the Controller General of Patents.

a. **Pharmaceuticals Export Promotion Council of India (PHARMEXCIL):** PHARMEXCIL is the authorized agency of the Indian government for the promotion of pharmaceutical exports from India. It was set up under the provisions of Foreign Trade Policy by the Ministry of Commerce and Industry in May 2004. Various pharmaceutical products, namely, bulk drugs, formulations, biotech products, Indian systems of medicines, herbal products, diagnostics, clinical research, etc. are covered under its purview. The organization takes up several external trade promotion activities by organizing trade delegations outside India, arranging buyer-seller meetings, international seminars, etc.

(B) Industry Associations

There are few trade associations in the industry representing different groups of producers. These include the Indian Pharmaceutical Alliance (IPA), the Organisation of Pharmaceutical Producers of India (OPPI), Confederation of Indian Pharma Industry (CIPA), Bulk Drug Manufacturers Association (BDMA) and the Indian Drug Manufacturing Association (IDMA).

a. **Indian Pharmaceutical Alliance:** IPA companies account for 57% of the total Indian drug market in terms of domestic sales and at least 85% of the private sector investment in pharmaceutical research and development. The IPA members account for over 80% of the pharmaceutical exports from India and around 62% of price-controlled medicines. The

alliance's key aims and objectives include partnering with the GOI in the evolution of a patent regime that will, on the one hand, meet the TRIPs obligations and on the other serve national interest; engaging the Government in constructive dialogue to move to price management from price control regime; working with the Government in progressively upgrading regulatory regime to suit the country's requirements; assisting the Government agencies in carrying out a campaign against spurious drugs.

b. **The Organization of Pharmaceutical Products in India:** Established in 1965, the Organisation of Pharmaceutical Producers of India (OPPI) represents the research-based pharmaceutical companies in India. OPPI member companies invest in the research of new medicines. OPPI is focused on research and innovation driven pharmaceutical companies committed to addressing India's healthcare needs by facilitating greater access to quality healthcare solutions, encouraging research and innovation, disseminating knowledge and sharing best practices and by contributing meaningfully in policy dialogues.

c. **Indian Drug Manufacturing Association:** The Indian Drug Manufacturers' Association (IDMA) is a mix of micro, small and medium sized members. The association has over 800 manufacturing members of which approximately 200 are those who are associated with the ancillary industry. The head office operates in Mumbai while the liaison office operates in New Delhi. Of seven state boards including Bangalore, Hyderabad, Baddi Kolkata and New Delhi, Maharashtra has around 400 members based in Mumbai followed by Gujarat with 250 members in Ahmedabad and Chennai with 200 members.

EXHIBITS

Exhibit 1: Government Regulatory Bodies [120]

GOVERNMENT REGULATORY BODIES		
DIVISION	**HEAD**	**ABOUT**
Ministry of Health & Family Welfare (MoHFW)	Dr. Harshvardhan Goel	***Dr. Harshvardhan Goel*** *is an Indian otorhinolaryngologist and the incumbent Minister of Science and Technology, Minister of Health and Family Welfare and Minister of Earth Sciences in the BJP-led NDA government of Prime Minister Narendra Modi.*
Central Drugs Standard Control Organisation (CDSCO)	Dr. Venugopal G. Somani	***Dr. Venugopal G. Somani*** *became the Drug Controller General of India (DGCI) under the Central Drugs Standard Organization(CDSCO) in July 2019. Somani, who began his career as a drug inspector has worked for 22 years with CDSCO in various capacities.*
Ministry of Chemicals and Fertilisers (MoC&F)	D.V. Sadananda Gowda	***Devaragunda Venkappa Sadananda Gowda*** *is an Indian politician serving as the Minister of Chemicals and Fertilizers in the Government of India in the second terms of the NDA government representing the Bangalore North constituency. He had also served as the 20th Chief Minister of Karnataka.*
National Pharmaceutical Pricing Authority (NPPA)	Shubra Singh	***Shubra Singh*** *is a Rajasthan Cadre IAS Officer from the batch of 1989. She has been heading the NPPA since November 2018.*
Department of Chemicals & Petrochemicals (DCP)	Mansukh L. Mandaviya	***Mansukh Laxmanbhai Mandaviya*** *is the Union Minister of State for Shipping and Union Minister of State for Chemical and Fertilizers. He is also a Rajya Sabha member from Gujarat*
Department of Pharmaceuticals (DoP)	Dr. P.D. Vaghela	***Dr. P.D. Vaghela*** *is a Gujarat Cadre IAS Officer from the batch of 1986. He holds the position of Secretary, Department of Pharmaceuticals since August 2019.*
Ministry of Science & Technology	Dr. Harshvardhan Goel	***Dr. Harshvardhan Goel*** *is an Indian otorhinolaryngologist and the incumbent Minister of Science and Technology, Minister of Health and Family Welfare and Minister of Earth Sciences in the BJP-led NDA government of Prime Minister Narendra Modi.*
Indian Council for Medical Research (ICMR)	Dr. Balram Bhargava	***Balram Bhargava*** *is an Indian science administrator who became the Director-General at the Indian Council of Medical Research in 2018.*

Exhibit 2: Industry Leaders [121]

INDUSTRY LEADERS		
COMPANY	**FOUNDER/MD/CHAIRMAN**	**ABOUT**
Sun Pharmaceuticals	Dilip Shanghvi	*Dilip Shanghvi borrowed $200 from his father, a pharmaceuticals distributor to start Sun Pharma in 1983 to make psychiatric drugs. Today, Mr. Shanghvi, who ranks #253 on Forbes Billionaires 2020, has a net worth of $ 7.8 billion. Sun Pharmaceuticals is the world's fourth-largest speciality generics maker and India's most valuable pharma outfit. The head office is based in Mumbai.*

[120] Interviews & News Sources
[121] Interviews & News Sources

Zydus Cadila	Dr. Pankaj Patel	*Dr. Pankaj Patel is the Chairperson of Zydus Cadila, an Indian pharmaceutical company that began its journey in 1950 when it was setup by Ramanbhai Patel. Dr. Patel took over the Rs. 200 crore business in 1995 and witnessed the company become a Rs. 14,000 crore company by the end of 2019. Dr. Patel stepped down as Managing Director of the company in 2019 to make way for his son Sharvil P. Patel to take over.*
Dr. Reddy's Laboratories	Satish Reddy	*Dr. Reddy's Laboratories was setup in 1984 by Satish Reddy's father K. Anji Reddy in Hyderabad. Satish Reddy worked as Managing Director of the company from 2007 to 2014 after which he became Chairman of the company. Satish pursued his M.S. Degree in Medicinal Chemistry from Purdue University in the USA. Mr. Reddy has also twice headed the Indian Pharmaceutical Alliance (IPA) as Chairman from 2013 to 2015 and 2019 to present times.*
Torrent	Samir Mehta	*Samir Mehta has been the Chairman of Torrent Pharmaceuticals since 2014 after his brother, Sudhir Mehta moved on to becoming Chairman Emeritus of the company.*

Exhibit 3: Industry Association Heads [122]

INDUSTRY ASSOCIATIONS		
INDUSTRY ASSOCIATION	**HEAD**	**ABOUT**
The Indian Pharmaceutical Alliance (IPA)	Sudarshan Jain	***Sudarshan Jain*** *began his career with Lupin after graduating from IIMA in 1977. After a career spanning 40 years in the pharma industry is now the Secretary General of The Indian Pharmaceutical Alliance (IPA) that represents 24 research based national pharmaceutical companies. Collectively, IPA companies account for 57% of the total Indian drug market and at least 85% of the private sector investment in pharmaceutical research and development. The IPA members account for over 80% of the pharmaceutical exports from India.*
The Organization of Pharmaceutical Products in India (OPPI)	K.G. Ananthakrishnan	***K.G. Ananthakrishnan*** *who began his career with Novartis as a medical representative in 1976, had only just taken over as Director General of the Organisation of Pharmaceutical Producers of India (OPPI) in early 2020 when the pandemic struck. Previously, he held the position of Vice President and Managing Director at Merck Sharp and Dohme (MSD India) between 2010-2017.*
Indian Drug Manufacturing Association (IDMA)	Daara Patel	***Daara Patel*** *is the Secretary General of the IDMA. The Indian Drug Manufacturers' Association (IDMA) is a mix of micro, small and medium sized members. The association has over 800 manufacturing members of which approximately 200 are those who are associated with the ancillary industry. The head office operates in Mumbai while the liaison office operates in New Delhi. Of seven state boards including Bangalore, Hyderabad, Baddi Kokata and New Delhi, Maharashtra has around 400 members based in Mumbai followed by Gujarat with 250 members in Ahmedabad and Chennai with 200 members.*
Pharmaceuticals Export Promotion Council of India (PHARMEXCIL)	Dinesh Dua	***Dinesh Dua*** *graduated from the Indian Institute of Management, Ahmedabad in 1979. His vast experience includes work with several pharmaceutical companies, the paint industry and the polymer industry. Mr. Dua heads the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) as Chairperson since June 2018. He is also the CEO & Director of Nectar Lifesciences Limited since 2007.*

Exhibit 4: China Coronavirus Statistics [123]

Continent	Location	Date	Total Cases	Increase/Decrease (%)	Total Deaths	Increase/Decrease (%)
Asia	China	2019-12-31	27	0%	0	0%
Asia	China	2020-01-31	9714	99.72%	213	100.00%
Asia	China	2020-02-29	79355	87.76%	2837	92.49%
Asia	China	2020-03-31	82241	3.51%	3309	14.26%
Asia	China	2020-04-30	83944	2.03%	4637	28.64%
Asia	China	2020-05-31	84128	0.22%	4638	0.02%
Asia	China	2020-06-25	84673	0.64%	4640	0.04%
Source: *Our World in Data*						

[122] Interviews & News Sources
[123] Our World in Data

Exhibit 5: India Coronavirus Statistics [124]

Continent	Location	Date	Total Cases	Increase/Decrease (%)	Total Deaths	Increase/Decrease (%)
Asia	India	2019-12-31	0	0%	0	0%
Asia	India	2020-01-31	1	100.00%	0	0%
Asia	India	2020-02-29	3	66.67%	0	0%
Asia	India	2020-03-31	1251	99.76%	32	100.00%
Asia	India	2020-04-30	33050	96.21%	1074	97.02%
Asia	India	2020-05-31	182143	81.85%	5164	79.20%
Asia	India	2020-06-25	473105	61.50%	14894	65.33%

Source: *Our World in Data*

Exhibit 6: A Brief Timeline of the Pandemic [125]

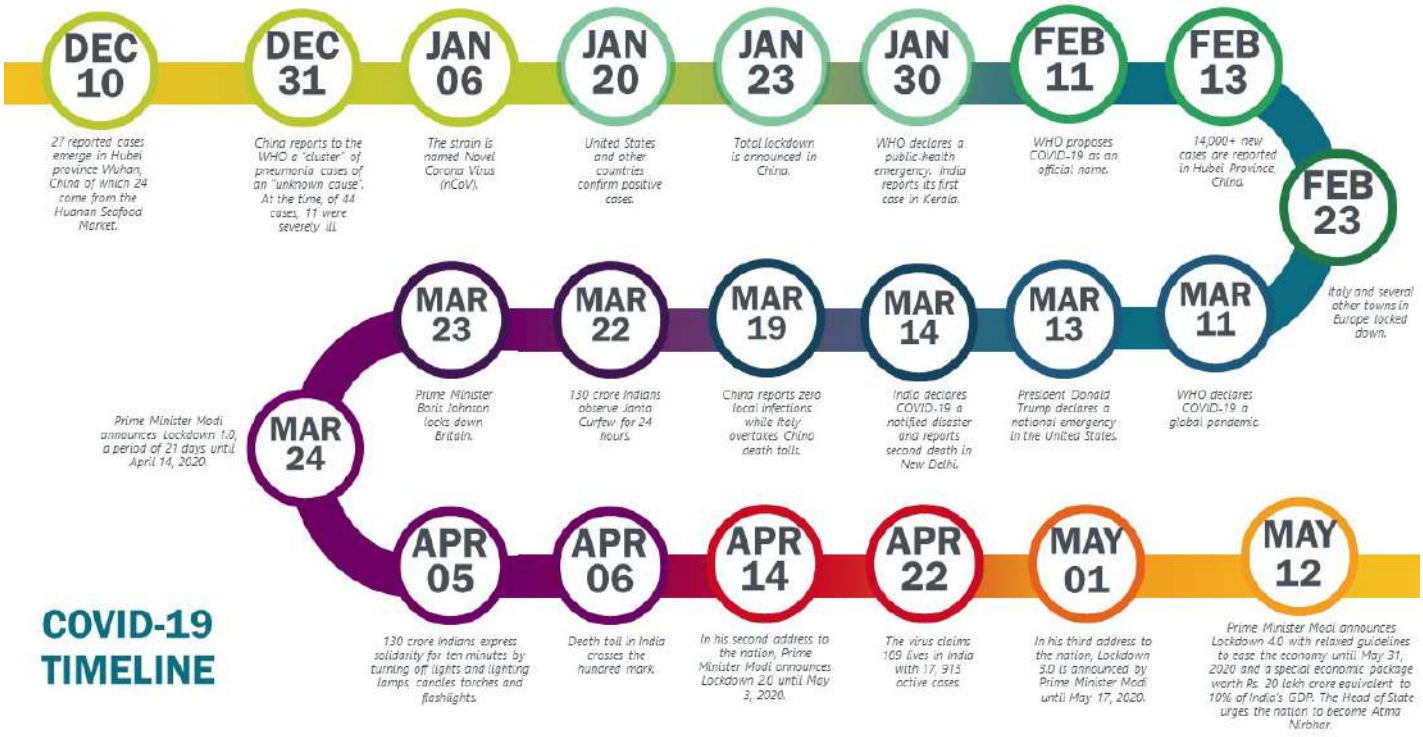


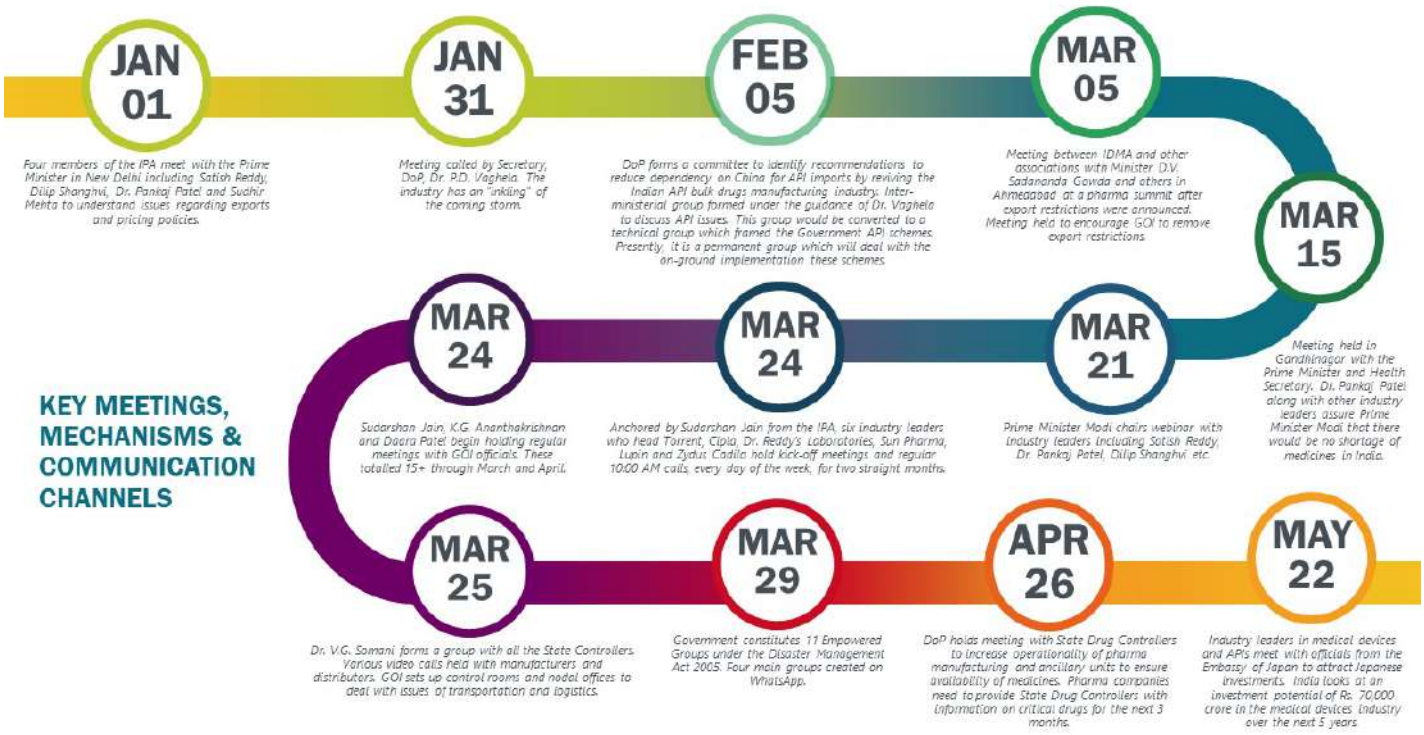
Exhibit 7: Phases of the Inter-Ministerial Group[126]

INTER-MINISTERIAL GROUP

[124] Our World in Data
[125] News Sources
[126] Interview with Dr. P.D. Vaghela, Secretary, Department of Pharmaceuticals (DoP); Prof. Arvind Sahay, IIMA; July 04, 2020

Phase I (Pre-Lockdown)	The group's initial focus was on the potential trouble of the unavailability of APIs/KSMs if the lockdown were to continue in China. This would be followed by large-scale unemployment, a severe health crisis and troubles in export. The group mentioned in one of the several meetings that there are 13 KPIs that are manufactured in China's Wuhan province which had been under lockdown since January. Hence, it was required that export restrictions be placed. But luckily, Wuhan came out of lockdown in the beginning of April and restrictions could be lifted. Had Wuhan remained under lockdown for a long period of time, India would suffer consequences.
Phase II (Lockdown)	In a second phase, the group worked on the nuances that would go into providing a 20% incentive on the sale value of an API that is manufactured in India. In fermentation based APIs, the difference in the cost of production between China and India used to be 15-23% while the difference in the cost of production for chemical based APIs was 5-11%. Several factors contributed to this difference including the cost of electricity, income tax, environmental costs, land costs etc. The group clubbed all these costs together and arrived at a single figure.
Phase III (Post Lockdown)	The group has become a permanent technical group which is focused on the implementation of these schemes, a long-term action plan which could take over two years to implement.

Exhibit 8: Key Meetings, Mechanisms & Communication Channels [127]



[127] Interviews

Exhibit 9: Structure of the WhatsApp Groups [128]

WHATSAPP GROUPS		
NAME	**MEMBERS**	**PURPOSE**
MANUFACTURERS GROUP	21	This was the first general group formed by the three pillars of the Indian Pharmaceutical Market: government bodies, industry players and members of industry associations.
INDIA MOVES PHARMA	82	This group was created to facilitate the movement of domestic and international cargo of APIs, intermediates, medical devices, testing kits, ventilators etc. The group's members included representatives from the Ministry of Civil Aviation, Federation of Freight Forwarders Association, North India Shippers Association, Air Cargo Agents Association of India and members of major airlines including Air India Spice Jet, Go Air, Vistara, Indigo, Alliance Air, Air Asia and Blue Dart. This group also helped in the movement of medicines, medical devices and ventilators to various destinations in the country. Airlines rendered all help in facilitation.
PHARMA POSTAL RAILWAYS GROUP	29	This group co-ordinated on logistic issues with the Postal Department and Indian Railways. The main aim was to ensure the supply of life saving medicines throughout the country including the red zones. Senior officials from the postal department collaborated with IDMA and started services in Gujarat followed by UP and across India. Complaints of delays were attended to by the officials with all alacrity. The BBC did a story on out-of-the-box thinking by postal departments in delivering medicines, testing kits , devices and ventilators. The Postal Department provided the cold chain arrangements to deliver medicines and went an extra mile to collect medicines and also arranged for door deliveries.
BADDI GROUP FOR HIMACHAL REGION		This group was specifically created to handle issues in Himachal, Punjab and Haryana.
Source: *Note by IPA*		

[128] Interviews

Exhibit 10: A Timeline of IPA's & OPPI's Efforts over the Lockdown[129]

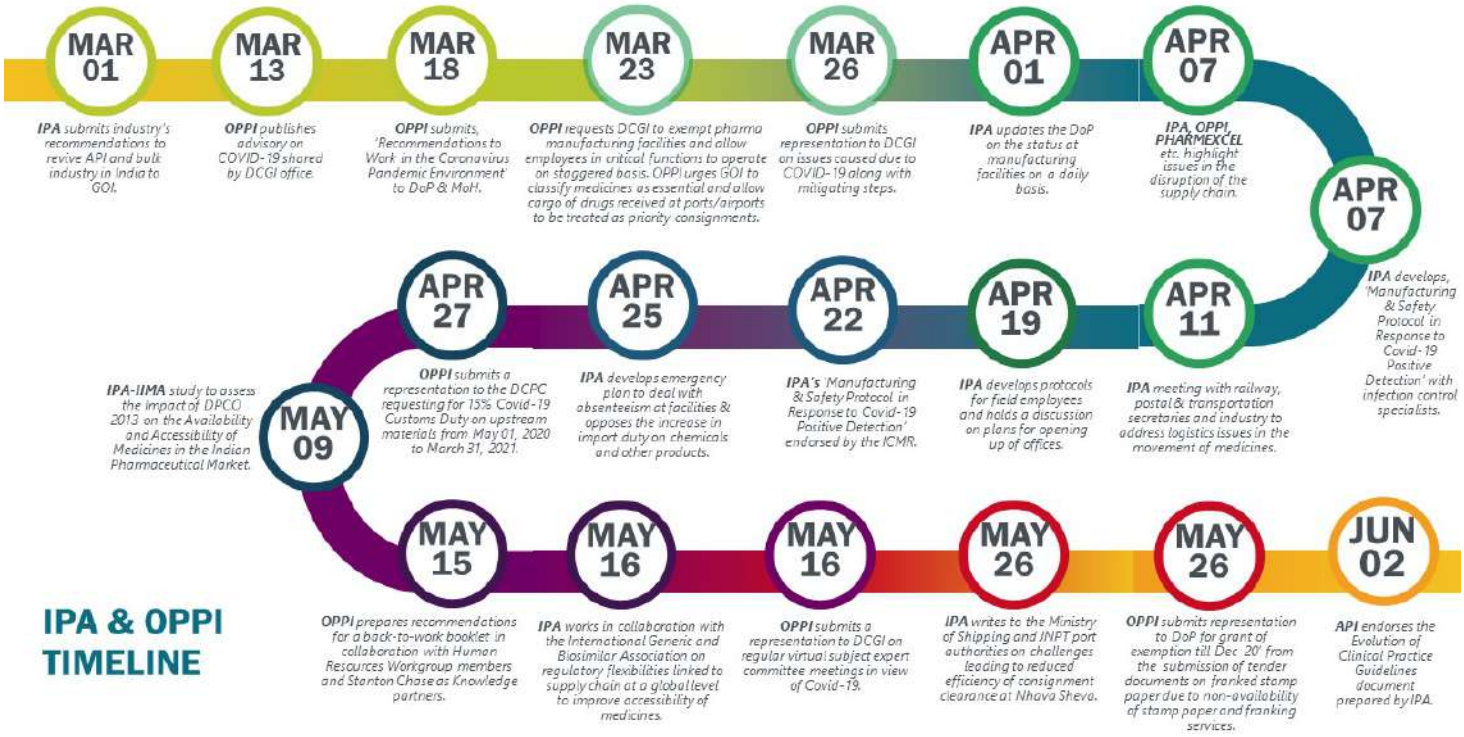


Exhibit 11: Future of Work Safety Guidelines, Lockdown 3.0 [130]

[129] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

[130] https://www.business-standard.com/article/companies/ppes-work-life-balance-the-new-normal-as-pharma-salesforce-hits-the-field-120050900898_1.html

EMPLOYEE SAFETY KIT	SOME OF THE GUIDELINES
Surgical Masks	Internal e-courses
Sanitizers	Webinars for employees' families
Gloves	Counselling for family members
Face Protection Shield	Fewer visits to doctors, chemists and stockists
Transparent Tablet Pouch	Emphasis on lunch discipline when on-field

Exhibit 12: PHARMEXCEL's & IDMA's Efforts during the Lockdown[131]

PHARMEXCEL's EFFORTS DURING THE LOCKDOWN
The organization ensured a uniform interpretation of notifications and facilitation.
The organization ensured the Minister of Civil Aviation and the Minister of State for Commerce & Industry, Hardip Puri to permit passenger airlines to be utilized as cargo airlines.
PHARMEXCEL digitally worked very closely with the Counsel General of 24 EU nations in Delhi to sort out their issues and discuss long term sustainability.
The organization worked intensively with diagnostic and medical devices industries to work with the Government to ensure that like Lifesciences these two sectors also become vibrant footprints domestically as well in exports.
IDMA's EFFORTS DURINGS THE LOCKDOWN
The IDMA communicated the problems of micro, small and medium sized companies to government and state officials.
The organization provided support and relief to these MSMEs in times of crisis.
IDMA played a huge role in collating data from the grassroot levels and provided government and state officials with an accurate perspective of ground realities.
The organization sorted several problems faced by the MSMEs on a personal level.

Exhibit 13: Status of Operations Across Pharma Supply Chain[132]

[131] Interviews with Dinesh Dua & Daara Patel
[132] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

Table 2: Status of operations across pharmaceutical supply chain in % (100% assumes normal operations)

S.No.	Date	Manufacturing	Ancillary Services	Transportation	Distribution	Import/Export
1	27 March	<20%	<20%	<20%	<20%	<20%
2	03 April	20 – 25%	<20%	20 – 25%	<20%	<20%
3	10 April	25 – 35%	20 – 25%	25 – 30%	20 – 25%	20 – 25%
4	17 April	40 – 50%	30 – 35%	30 – 35%	25 – 30%	25 – 30%
5	24 April	50 – 60%	30 – 40%	35 – 40%	25 – 30%	25 – 30%
6	01 May	60 – 70%	40 – 50%	40 – 50%	30 – 40%	25 – 35%
7	08 May	70 – 80%	40 – 50%	50 – 60%	40 – 50%	30 – 40%
8	15 May	70 – 80%	45 – 55%	60 – 70%	40 – 50%	30 – 40%
9	22 May	70 – 80%	45 – 55%	65 – 70%	50 – 55%	40 – 50%
10	29 May	>80%	55 – 60%	65 – 70%	50 – 55%	45 – 55%

Exhibit 14: A Timeline of Government Notifications in Reference to Restricted Movement of Workers & Goods[133]

[133] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

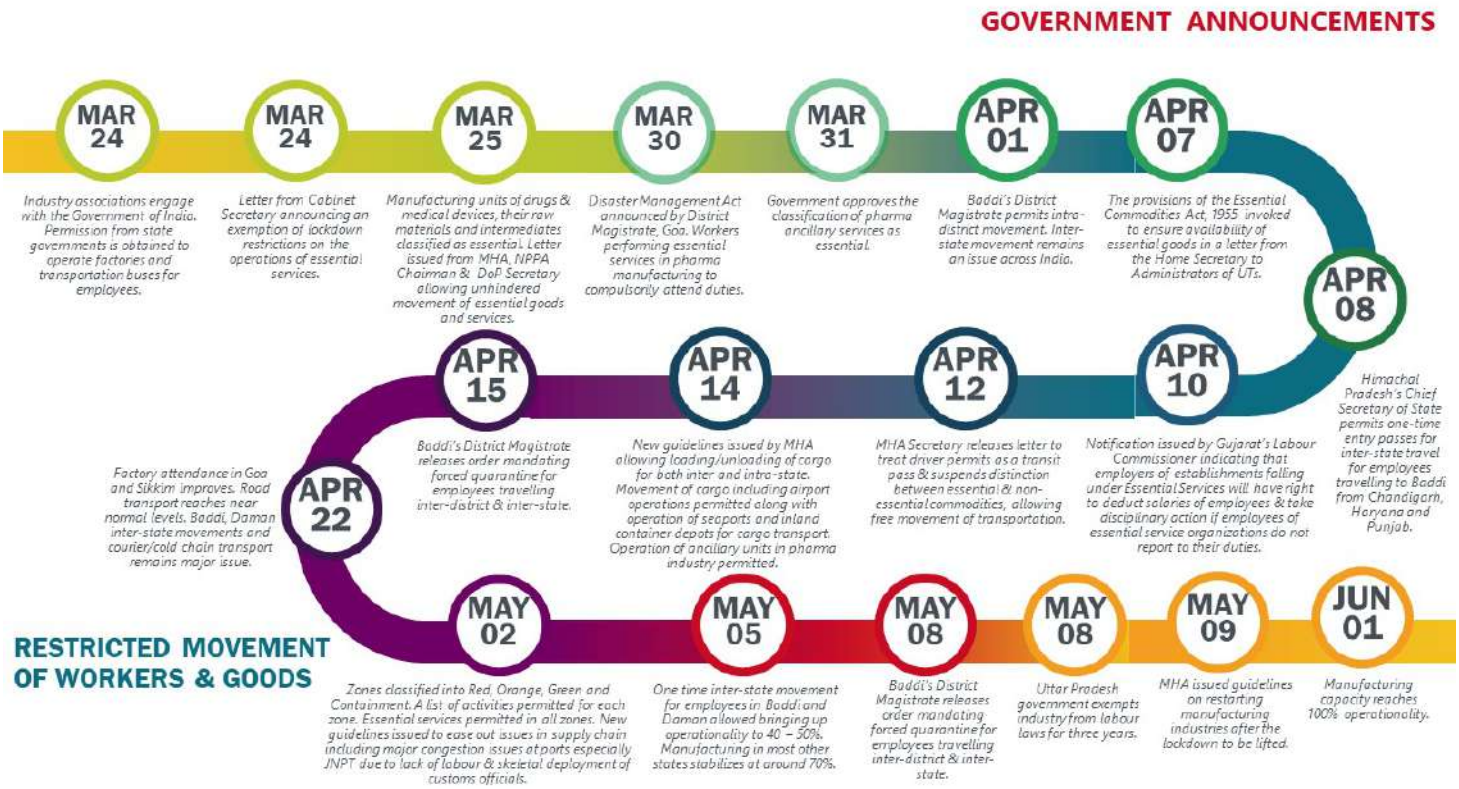


Exhibit 15: Status of Manufacturing at Pharma Hubs across States [134]

[134] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

S.No.	State	30 March	19 April	17 May	01 June
1	Andhra Pradesh	40%	52%	87%	87%
2	Assam	45%	71%	73%	83%
3	Baddi, Himachal Pradesh	<20%%	32%	62%	73%
4	Dadra and Nagar Haveli	<20%	<20%	52%	62%
5	Daman and Diu	<20%	35%	62%	66%
6	Goa	25%	62%	75%	77%
7	Gujarat	50%	65%	68%	73%
8	Madhya Pradesh	40%	45%	67%	78%
9	Maharashtra	45%	58%	71%	77%
10	Others (Uttar Pradesh, Karnataka, Rajasthan etc.)	40%	69%	71%	78%
11	Paonta Sahib	35%	60%	63%	71%
12	Sikkim	60%	82%	85%	88%
13	Telangana	40%	48%	70%	74%

Exhibit 16: China's Advantage over India [135]

CHINA'S ADVANTAGES OVER INDIA
Lower capex requirements due to large Special Economic Zones which are 10–15x the size of Indian SEZs.
Lower borrowing costs at 5–7% vs. 11–14% in India
Lower logistics costs at 1% of total costs in China vs. 3% for India
Lower conversion costs as labour and electricity costs in China are relatively cheaper (average ~11 US cents/kwh vs. 19 US cents/kwh in India)
Source: *Reviving the Domestic API Industry in Context of the Recent Corona Outbreak; February 2020; IPA-PwC Collaboration*

Exhibit 17: Top APIs Imported from China[136]

[135] Reviving the Domestic API Industry in Context of the Recent Corona Outbreak; February 2020; IPA-PwC Collaboration
[136] Reviving the Domestic API Industry in Context of the Recent Corona Outbreak; February 2020; IPA-PwC Collaboration

Top APIs imported from China

- Imports from China comprise approximately 45% of the total quantity and more than 95% of the total imported quantity
- For 8 out of 68 APIs, India relies solely on imports from China. They are penicillin G, levodopa, streptomycin, meropenem, carbidopa, vancomycin, gentamycin and progesterone.

Name of API	Quantity imported from China (in lakh kg)	Quantity imported from other countries (in lakh kg)	Total quantity (in lakh kg)	Total percentage imported from China	Stock in hand (in lakh kg)
Penicillin G	28.8	-	28.8	100%	2.4
Potassium Clavulanate	1.6	0.5	2.3	69%	0.4
Azithromycin	1.3	<0.1	2.1	62%	0.3
Tetracycline	0.9	-	1.2	77%	0.1
Metronidazole	0.8	<0.1	1.3	60%	0.6
Paracetamol	0.5	<0.1	16.6	3%	4.0
Acyclovir	0.2	-	0.3	66%	0.3
Amoxicillin	0.2	<0.1	6.6	3%	1.2
Levofloxacin	0.1	-	0.9	15%	0.1
Levodopa	0.1	-	0.1	100%	0.1
Others	0.5	<0.1	19	3%	6.7
	35	0.6	79	45%	16.2

Note: Data is for the period of April 2019–January 2020
Source: IPA member companies

Exhibit 18: A Timeline of Notifications in Reference to Active Pharmaceutical Ingredients[137]

[137] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

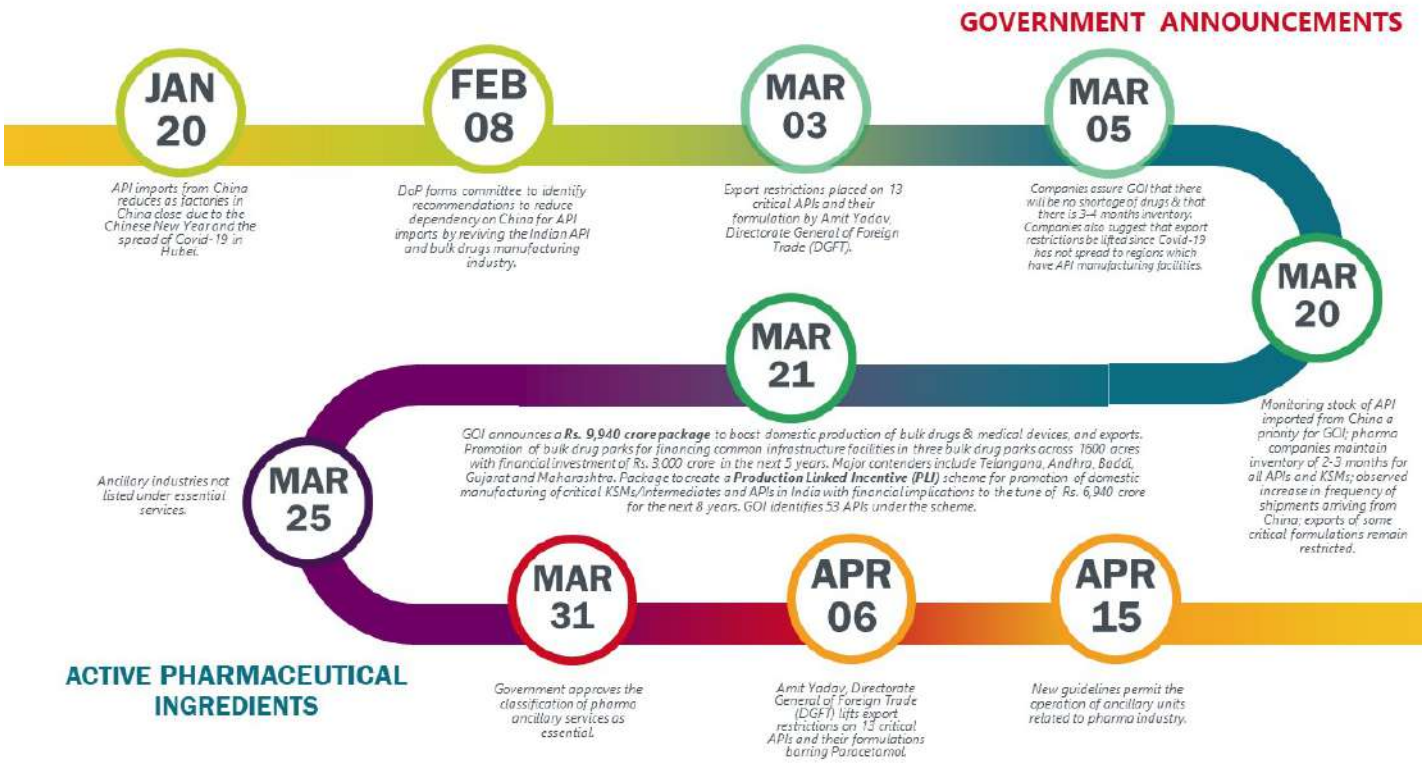
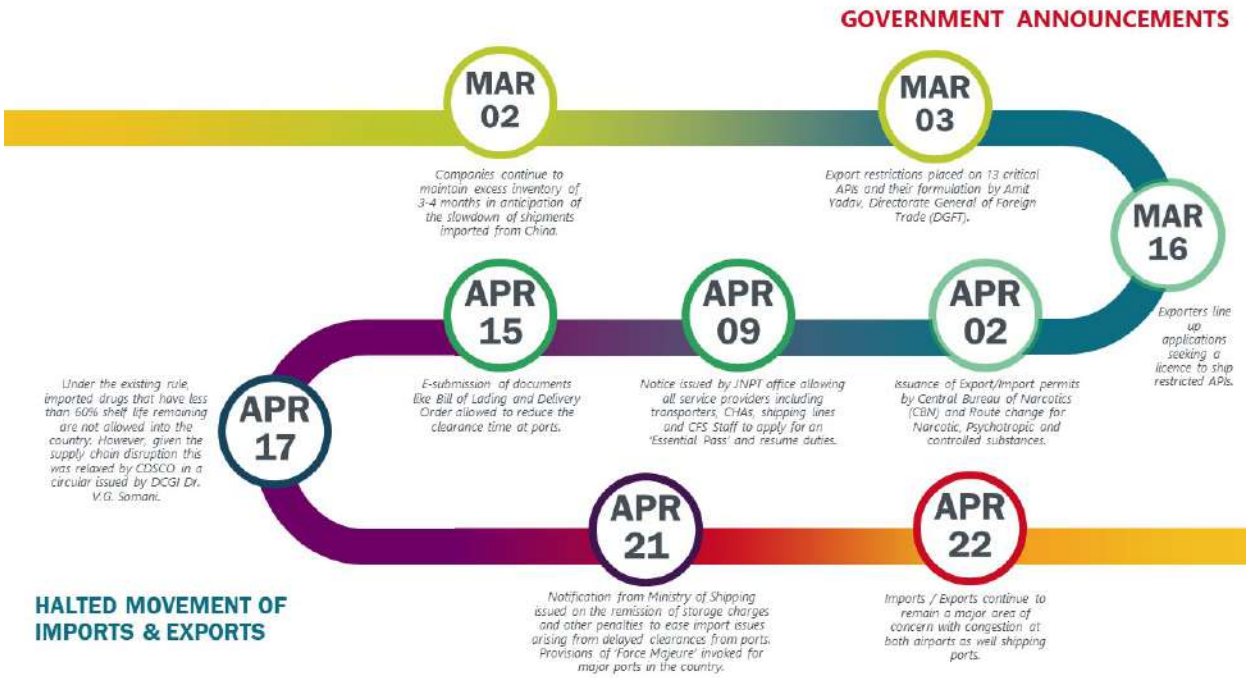


Exhibit 19: A Timeline of Notifications in Reference to Halted Movement of Exports & Imports[138]



[138] Timelines of Events & Government Notifications; Data sourced from the IPA & OPPI

Exhibit 20: Breakup of the Pharmaceutical Industry

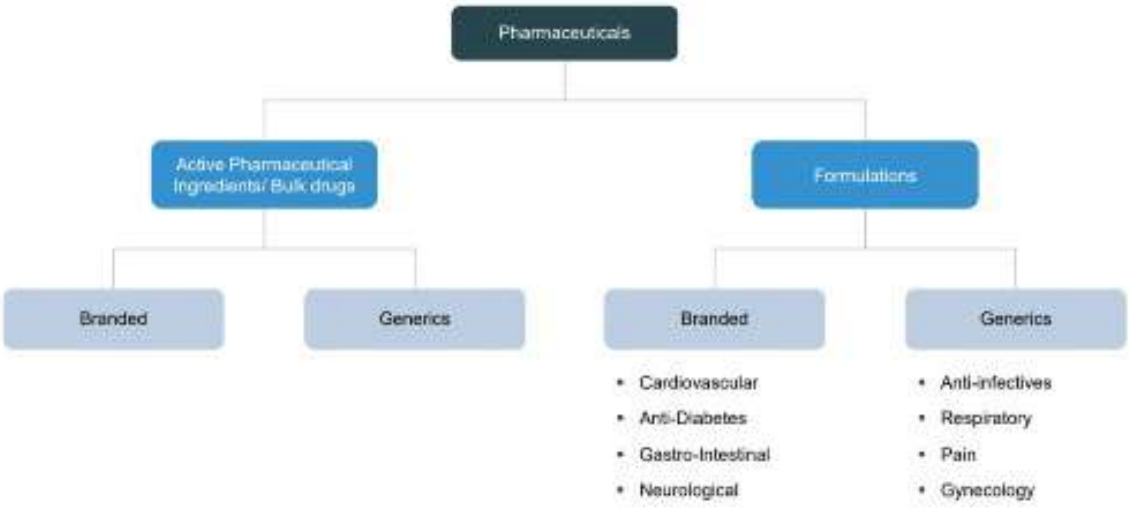


Exhibit 21 : Total Sales Audit & Secondary Sales Audit [139]

(Crore)

Month	TOTAL SALES AUDIT (TSA)								SECONDARY SALES AUDIT (SSA)							
	Moving Annual Total (MAT)				Monthly Turnover				Moving Annual Total (MAT)				Monthly Turnover			
	2020	2019	2018	2017	2020	2019	2018	2017	2020	2019	2018	2017	2020	2019	2018	2017
January	147,972	133,911	120,419	113,531	12,306	11,298	10,455	9,247	124,798	113,271	101,690	95,350	10,327	9,533	8,866	7,796
February	149,556	134,816	121,404	113,848	12,577	10,990	10,085	9,100	126,072	114,006	102,572	95,637	10,553	9,276	8,540	7,658
March	150,153	135,521	122,497	114,749	11,714	11,116	10,412	9,319	126,725	114,630	103,486	96,424	9,995	9,344	8,721	7,806
April	148,732	137,011	123,381	115,362	10,891	12,331	10,841	9,956	125,817	115,896	104,278	96,984	9,558	10,480	9,214	8,414
May	147,810	137,993	124,573	116,054	11,033	11,988	11,006	9,814	125,405	116,720	105,372	97,572	9,692	10,124	9,300	8,215

Source: *Market Reflections Report; IQVIA; January-May 2020*

[139] AIOCD Monthly Data; Indian Pharmaceutical Alliance (IPA)

Exhibit 22: India's Top 20 Industry Leaders [140]

(Crore)

MANUFACTURERS	FEBRUARY			MARCH			APRIL			MAY			MOVING ANNUAL TOTAL (MAT)			
	2019	2020	Growth (%)	2019	2020	Growth (%)	2019	2020	Growth (%)	2019	2020	Growth (%)	May-20	May-19	Market Share 2020 (%)	Growth (%)
SUN PHARMA	567	646	13.95%	565	666	17.72%	654	666	1.89%	606.1	568	-6.24%	7550	7002	5.5	7.82%
MANKIND	403	479	19.06%	402	471	17.21%	477	471	-1.31%	460.5	489	6.21%	6068	5402	4.7	12.34%
CIPLA	523	577	10.40%	521	636	22.10%	600	547	-8.79%	526.5	459	-12.88%	6568	6325	4.4	3.84%
ZYDUS CADILA	419	477	13.74%	428	323	-24.55%	339	307	-9.54%	437.3	407	-6.88%	5519	5019	3.9	9.95%
LUPIN LIMITED	411	466	13.37%	425	443	4.42%	444	420	-5.43%	438.1	402	-8.15%	5392	4987	3.9	8.11%
TORRENT PHARMA	311	366	17.35%	355	399	12.17%	402	406	0.90%	370.5	338	-8.80%	4417	4072	3.3	8.48%
INTAS	322	367	14.01%	320	366	14.59%	379	342	-9.82%	344.5	326	-5.42%	4285	3910	3.2	9.59%
ALKEM	328	371	13.17%	340	366	7.49%	392	331	-15.52%	348.9	302	-13.36%	4508	4200	2.9	7.35%
ABBOTT HEALTHCARE	319	340	6.71%	318	269	-15.32%	292	246	-16.03%	339.1	301	-11.35%	4167	3994	2.9	4.32%
RANBAXY	310	358	15.33%	308	156	-49.50%	169	142	-15.78%	314.5	286	-8.92%	4115	3811	2.8	7.98%
MACLEODS PHARMA	297	361	21.41%	289	383	32.80%	370	319	-13.86%	314.1	285	-9.35%	4076	3732	2.8	9.20%
GLAXOSMITHKLINE	309	334	7.85%	326	299	-8.24%	347	273	-21.16%	322.7	269	-16.54%	3934	3770	2.6	4.34%
ARISTO PHARMA	248	311	25.44%	258	277	7.57%	280	258	-7.92%	269.5	269	-0.31%	3742	3152	2.6	18.73%
ABBOTT	244	269	10.41%	241	360	49.22%	388	386	-0.50%	263.2	250	-5.09%	3205	2966	2.4	8.05%
PFIZER	248	283	14.01%	249	126	-49.50%	134	131	-2.19%	249.0	249	-0.05%	3361	3039	2.4	10.59%
SANOFI	259	285	9.97%	257	221	-14.22%	220	225	2.59%	263.4	242	-8.01%	3186	3048	2.3	4.54%
DR REDDYS LABS	249	302	21.42%	256	258	0.64%	258	237	-8.47%	258.6	233	-9.84%	3316	3016	2.3	9.94%
U S V	199	232	16.65%	202	236	16.69%	237	259	9.13%	221.0	230	3.92%	2874	2613	2.2	10.01%
GLENMARK PHARMA	249	287	15.59%	254	269	5.99%	264	255	-3.36%	241.4	226	-6.57%	3236	2990	2.2	8.23%
MICRO LABS	178	211	18.26%	206	187	-8.99%	183	167	-8.75%	196.1	179	-8.83%	2502	2325	1.7	7.64%
IPCA LABS	158	177	12.15%	153	207	34.69%	184	197	7.49%	150.0	161	7.10%	2103	1923	1.6	9.40%
ALEMBIC	140	149	6.15%	137	187	36.21%	184	160	-13.16%	127.0	109	-13.81%	1664	1660	1.1	0.23%
TOTAL TOP 20	**6,691**	**7,647**	**14.29%**	**6,811**	**7,105**	**4.31%**	**7,200**	**6,747**	**-6.29%**	**7,062**	**6,580**	**-6.83%**	**89,788**	**82,956**	**63.6**	**8.24%**
TOTAL IPM Market	**10,770**	**12,577**	**16.78%**	**10,876**	**11,714**	**7.71%**	**12,232**	**10,891**	**-10.96%**	**11,358**	**10,342**	**-8.94%**	**141,979**	**133,393**	**100.0**	**6.44%**

Source: *TSA Monthly Reports, Manufacturers, April 2019, March 2020 & April 2020, IPA Research; Industry Top 100 Companies, AIOCD AWACS Industry Mailer, March 2019, February 2020 & May 2020*

[140] AIOCD Monthly Data; Indian Pharmaceutical Alliance (IPA)

Exhibit 23: India's Top 20 Brands[141]

(Crore)

SR.NO	PRODUCTS	COMPANY	COMPOUNDS	THERAPY AREAS	JANUARY			APRIL		
					2020	2019	Growth (%)	2020	2019	Growth (%)
1	**Mixtard**	**Abbott**	Human Premix Insulin	**Anti-Diabetes**	64	56	13.60%	72	61	18.56%
2	**Lantus**	**Sanofi**	Glargine	**Anti-Diabetes**	48	40	20.48%	53	41	29.94%
3	**Glycomet-GP**	**USV Pvt .Ltd.**	Glimepiride + Metformin	**Anti-Diabetes**	44	42	5.10%	51	45	13.61%
4	**Dexorange**	**Franco**	Ferric Ammonium Citrate + Cyanocobalamine	**Vitamins**	22	23	-2.62%	39	35	11.90%
5	**Thyronorm**	**Abbott**	Levo-Thyroxine (Synthetic)	**Hormones**	36	29	23.29%	38	34	10.38%
6	**Novomix**	**Abbott**	Biphasic Aspart	**Anti-Diabetes**	37	34	8.23%	38	38	-0.95%
7	**Janumet**	**Merck Sharp & Dohme**	Sitagliptin + Metformin	**Anti-Diabetes**	36	37	-2.59%	37	41	-9.66%
8	**Foracort**	**Cipla**	Formoteral + Budesonide	**Cardiac**	38	33	14.35%	34	31	9.65%
9	**Augmentin**	**Glaxosmithkline**	Amoxycillin + Clavulanic Acid	**Anti-Infectives**	44	41	8.48%	33	36	-9.96%
10	**Liv-52**	**Himalaya**	Hepatic Protectors Including Ayurvedic	**Gastro Intestinal**	30	25	19.88%	32	37	-13.71%
11	**Becosules**	**Pfizer**	Vitamin B Complex With Vitamin C Only	**Vitamins**	22	21	6.87%	31	28	9.86%
12	**Pan**	**Alkem**	Pantoprazole	**Gastro Intestinal**	26	23	11.53%	31	27	12.52%
13	**Duphaston**	**Abbott**	Dydrogesterone	**Gynac**	32	30	7.44%	30	35	-13.33%
14	**Betadine**	**Win Medic**	Povidone-Iodine	**Derma**	33	30	11.51%	30	32	-6.24%
15	**Galvus Met**	**Novartis**	Vildagliptin + Metformin	**Diabetes**	20	29	-31.63%	30	30	-1.09%
16	**Clavam**	**Alkem**	Amoxycillin + Clavulanic Acid	**Anti-Infectives**	36	32	13.71%	30	32	-7.94%
17	**Monocef**	**Aristo Pharma**	Ceftriaxone	**Anti-Infectives**	25	21	18.42%	30	32	-7.60%
18	**Pan-D**	**Alkem**	Domperidone + Pantoprazole	**Gastro Intestinal**	22	23	-5.54%	27	26	3.48%
19	**Azithral**	**Alembic**	Azithromycin Monohydrate	**Anti-Infectives**	23	21	8.64%	24	21	12.84%
20	**Prevenar-13**	**Pfizer**	Pneumococcal Polysaccharides	**Anti-Infectives**	38	31	20.69%	20	32	-37.95%
	TOTAL TOP 20				**676**	**621**	**8.85%**	**708**	**696**	**1.84%**
	TOTAL IPM Market				**12,306**	**11,243**	**9.46%**	**10,891**	**12,232**	**-10.96%**

Source: *Market Reflections Report; IQVIA; January 2020 & 2019 and April 2020 &2019*

[141] AIOCD Monthly Data; Indian Pharmaceutical Alliance (IPA)

Exhibit 24: Top Therapy Areas[142]

(Crore)

		APRIL			JANUARY		
SR.NO.	**THERAPY AREAS**	**2020**	**2019**	**Growth (%)**	**2020**	**2019**	**Growth (%)**
1	Cardiac	1,690	1,494	13.12%	1,561	1,406	11.02%
2	Anti-Diabetic	1,331	1,205	10.46%	1,384	1,109	24.80%
3	Gastro Intestinal	1,128	1,335	-15.51%	1,170	1,105	5.88%
4	Anti-Infectives	945	1,351	-30.05%	1,384	1,281	8.04%
5	Respiratory	851	850	0.12%	1,142	1,033	10.55%
6	Vitamins/Minerals/Nutrients	848	1,006	-15.71%	898	834	7.67%
7	Pain/Analgesics	753	956	-21.23%	912	831	9.75%
8	Neuro/CNS	736	731	0.68%	743	677	9.75%
9	Derma	699	905	-22.76%	932	860	8.37%
10	Gynaec	484	643	-24.73%	605	559	8.23%
11	Urology	203	227	-10.57%	236	210	12.38%
12	Antineoplastic/Immunomodulator	188	188	0.00%	218	-	-
13	Hormones	177	196	-9.69%	195	178	9.55%
14	Ophthal/Otologicals	173	257	-32.68%	230	208	10.58%
15	Vaccines	135	233	-42.06%	256	219	16.89%
16	Oncology	-	-	-	-	168	-
	TOTAL IPM Market	10,891	12,232	-10.96%	12,306	11,243	9.45%

Source: *Market Reflections Report; IQVIA; January 2020 & 2019 and April 2020 &2019*

Exhibit 25: Number of Products[143]

		NUMBER OF PRODUCTS			
SR.NO.		**MANUFACTURERS**	**Apr-19**	**Apr-20**	**Growth (%)**
	1	SUN PHARMA	570	569	-0.18%
	2	MANKIND	674	675	0.15%
	3	CIPLA	968	1,000	3.31%
	4	ZYDUS CADILA	950	943	-0.74%
	5	LUPIN LIMITED	834	856	2.64%
	6	TORRENT PHARMA	798	794	-0.50%
	7	INTAS	987	1,009	2.23%
	8	ALKEM	691	679	-1.74%
	9	ABBOTT HEALTHCARE	703	677	-3.70%
	10	RANBAXY	439	419	-4.56%
	11	MACLEODS PHARMA	554	559	0.90%
	12	GLAXOSMITHKLINE	182	176	-3.30%
	13	ARISTO PHARMA	242	248	2.48%
	14	ABBOTT	176	178	1.14%
	15	PFIZER	107	106	-0.93%
	16	SANOFI	176	178	1.14%
	17	DR REDDYS LABS	378	381	0.79%
	18	U S V	179	179	0.00%
	19	GLENMARK PHARMA	382	392	2.62%
	20	MICRO LABS	634	620	-2.21%
	21	IPCA LABS	302	299	-0.99%
	22	ALEMBIC	415	403	-2.89%
		TOP 22 TOTAL	**11,341**	**11,340**	-0.01%
		TOTAL PRODUCTS IN IPM	30,690	31,307	2.01%

Source: *TSA Lead Tables, April 2019 & April 2020*

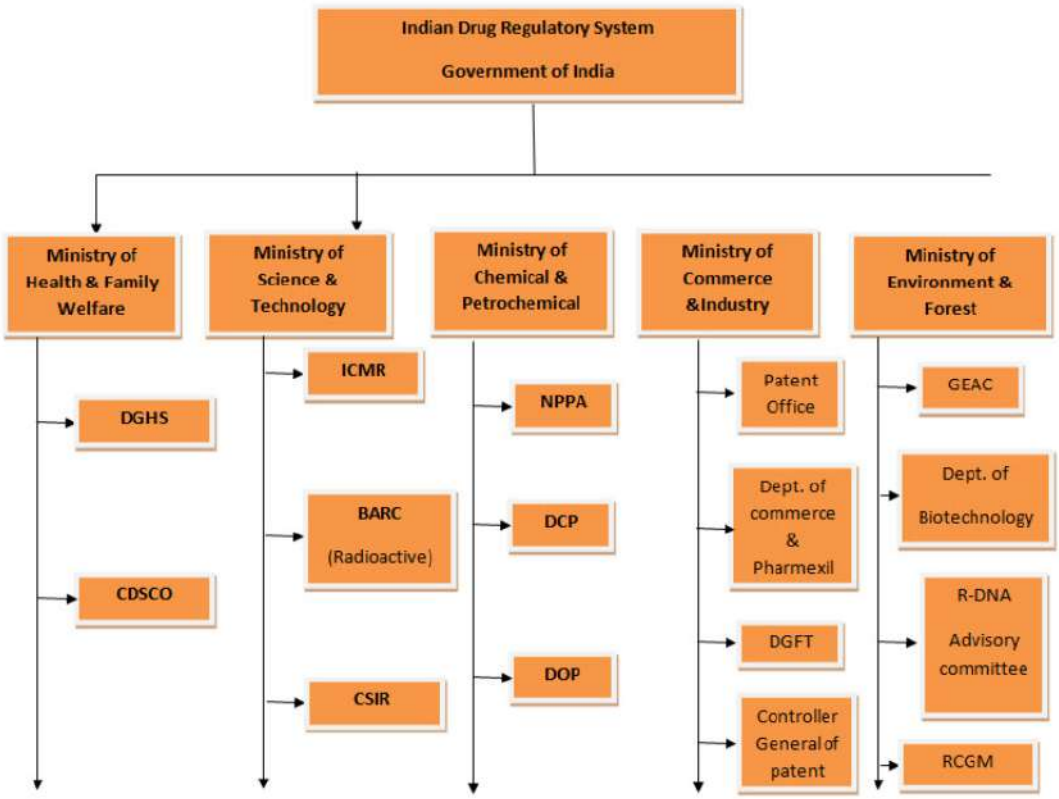
[142] AIOCD Monthly Data; Indian Pharmaceutical Alliance (IPA)
[143] AIOCD Monthly Data; Indian Pharmaceutical Alliance (IPA)

Exhibit 26: Exports & Imports[144]

APRIL 2019-MARCH 2020							
EXPORTS				IMPORTS			
Category/Country	**Total Quantity (Million, Kg)**	**Total Value (Crore, INR)**	**Total Value (Million, USD)**	**Category/Country**	**Total Quantity (Million, Kg)**	**Total Value (Crore, INR)**	**Total Value (Million, USD)**
Bulk Drugs, Drug Intermediates	**285.8**	**27,533**	**3,886**	**Bulk Drugs, Drug Intermediates**	**364.5**	**24,172**	**3,416**
USA	23.0	2,378	336	China	220.9	16,443	2,324
China	11.0	1,555	219	USA	8.4	851	120
Germany	8.4	1,233	174	Italy	3.9	727	103
Brazil	7.2	1,127	159	Singapore	28.3	697	98
Bangladesh	9.9	1,040	147	Spain	2.7	525	74
Drug Formulations & Biologicals	**263.2**	**113,002**	**15,940**	**Drug Formulations & Biologicals**	**21.9**	**15,967**	**2,255**
USA	57.6	44,339	6,256	Switzerland	0.7	2,198	310
South Africa	7.4	3,939	554	USA	0.9	2,161	305
UK	9.0	3,164	447	Belgium	1.2	2,049	290
Russia	5.9	3,060	432	Germany	1.0	1,309	185
Nigeria	12.7	2,741	386	China	1.7	1,164	165
Total	**549.1**	**140,535**	**19,826**	**Total**	**386.4**	**40,139**	**5,671**

[144]http://www.dgciskol.gov.in/TradeIndices_side_new.aspx

Exhibit 27: Organizational Structure [145]



[145] https://www.pharmatutor.org/articles/regulatory-canvas-of-indian-pharmaceutical-industry-challenges-and-future