ICS WEDNESDAY WEBINAR

Global vaccine supply chain and its distribution: India and China

23 JUNE 2021

REPORT

The Chair, **Rama V. BARU** began by noting the importance of COVID-19 vaccine as a global project and stated the elements that guide it. As some of the major vaccine producers for COVID-19, China, Russia, India and the EU have to balance their domestic needs with their export commitments. Although the US and the EU have only exported only 1% and 28% of their vaccines respectively, China has continued to export 48% of its vaccine production. Highlighting the Indian export of 65%, she argues that China has been effective in maintaining the balance between its domestic needs and export, while also maintaining its position as one of the top vaccine producers. Therefore, there are two concepts at work — that of vaccine nationalism which is being visibly followed by the US and EU, and the limited ability of the COVAX network in achieving vaccine equity. Concluding her introductory statements, the Chair opened the session with a key question on what should be the ideal balancing framework to help achieve both national obligation and international commitments.

SPEAKERS:

Biswajit Dhar began by thanking the chair for her introductory remarks on where the world stood, acknowledging the WHO's call for vaccinating everyone to help recover from the pandemic. He expressed that among the countries that have been very effective in inoculating their citizens, only 70 of them have been able to provide one dose of vaccine to more than 20% of the population. Most of these countries were developed with the US having successfully administered 50% of their population with at least one dose of the vaccine. However, in the rest of the world only 5% of their population have been vaccinated. These countries have mostly been low-income countries located in Africa and Asia and the speaker reiterated the world's expectations from the G7's pledge to provide a billion COVID-19 vaccines to such lower income countries. However, WHO expressed that this was far below the need of almost 11 billion for such countries, and developed countries have been pulling back on vaccine distribution. While the US reported an excess surplus of COVID-19 vaccine in some states, the rest of the world was still struggling to get access and inoculate its citizens. India and South Africa had proposed to the WTO in October that for free access to technology for producing vaccines, there had to be some waiver of intellectual property rights. This very proposal is now being co-sponsored by 61 countries that are mostly less developed countries with support from almost two thirds of WTO members. It was not only vaccine nationalism that was the cause of such large inequity but also the process of augmenting vaccines for national purposes by having production supplies across a large number of countries. Further, with such countries being home to major pharmaceutical companies, there had always been

hesitancy in sharing private technology with other countries. Thus, with room for only detailed negotiations for vaccine accessibility, there was high probability for text based negotiations in the multilateral forum. While sharing his experience over how tough such negotiations are, the speaker gave the example of how it took the WHO more than two years to work on the issue of AIDS. However, with China and Russia's decision to support the waiver of intellectual property rights over vaccines, it could be a major shift in the supply chain in the near future as both countries have been contributing greatly to vaccine availability in developing nations. An early conclusion to the negotiations that are likely to end towards the third week of July, would help stop the pandemic before it is too late. Looking back at the Doha Declaration in 2001, the flexibility of using compulsory licensing was a major victory for the public health sector. Amidst such a public health emergency, it was necessary for the global community to use this flexibility that was achieved long back especially for a country like India that had the capability of mass production of vaccines. It would not only help in achieving a vaccine commitment balance that India was striving for but also inspire emerging pharmaceutical sectors such as Bangladesh to use such a move in order to work towards vaccine equity. In conclusion, Prof. Dhar expressed that although there was a long road ahead for technological availability, it is necessary for the global community to be cautiously optimistic.

Sujatha Rao began by giving a broad overview of India's manufacturing capability for all vaccines. She shared that India has the capacity to manufacture up to 2 billion doses of vaccines a year with over a billion doses of such childhood vaccines used domestically and almost 700 million doses exported. India had 18 state-of-the-art manufacturing companies which makes it a very competitive environment with low manufacturing costs. While this was just one of its strengths, India had the ability to do clinical trials at a much lower cost and the skilled manpower made it an attractive destination for vaccine manufacturing. India's contribution to UNICEF and GAVI along with global companies like Sanofi, GSK and BB amount to almost 60% of children's vaccines. While countries such as the US, Canada and Japan looked to corner almost all the produced vaccines through their agreements with global producers, India's strive for an indigenous COVID-19 vaccine production framework dates back to July 2020 when the ICMR got into an active relation Bharat Biotech with phase 3 clinical trials sites and additional funding provided by the Government. The Serum Institute of India, the world's largest vaccine manufacturer, also had an agreement to manufacture AstraZeneca vaccines under the company's license. This gave India two vaccines that could be produced and distributed domestically. However it was only when Pfizer had applied in India for emergency authorisation after completing all phase trials and already receiving authorisation in UK and US, both the Bharat Biotech and Serum Institute of India also insisted on receiving emergency authorisation. While the indigenous companies were given the nod, the DCGI had asked Pfizer to conduct a bridging study on the Indian population before receiving the approval for emergency use. She shared that this had been a long traditional rule for any foreign company willing to sell vaccines in India, it was always a requirement to conduct bridging study. Although the sample study was of 500 people before, recent amendments have expanded it to 1600. She reiterated that this was a necessity because the Indian genetic composition

was very different from people in the West. However, she expressed that while SII was still in the process of conducting bridging study at the time of clearance, Bharat Biotech was given a nod even when the phase 3 trial reports had not been published. She argued that this not only created a controversy over its efficacy, but also that it contributed a lot to the vaccine hesitancy among the general population. Although the leniency over COVID appropriate behaviour contributed a lot to the devastating second wave, India's trust over only two companies with any affordable alternative was a bad strategic choice. While Sputnik was put on hold for a long time, India chose to neither place advance purchase order from foreign companies nor its indigenous companies before granting emergency authorisation. India had shifted from its longer goal of inoculating its large population to the more current strategy of vaccinating the front line workers. With its first order of just 110 million doses, India parted with 66 million doses in the effort of beating China from vaccine diplomacy. While she agreed that this was a good move for smaller countries like Bhutan who did not have the capacity to produce vaccines, the need for closely studying the equation between supply and demand of vaccines in the country was missed out on. As India continued to expand its eligibility criteria gradually, neither Bharat Biotech nor the SII had the manufacturing capability to balance India's international commitments and domestic obligations. Thus, by the time cases surged and there was an unexpected huge demand for vaccines, India was already too late to take control of the situation. However, as the government opened vaccines for all above 18, it changed its ongoing policy by shifting the vaccine procurement responsibility to the states. As per the new policy, while the central government would procure only 50% of the total doses, the state would now have to compete in the market with the private sector. Although the central government argued that the States had the flexibility of procuring vaccines and even call for global tenders, this was unsustainable from the very start. She expressed that while states did call for global tenders, no bids were received for vaccine procurement. She shared that the states demanded for the decentralisation of the immunisation programmes which had been a traditional long standing practice. For the last few decades India had continued the practice of shared responsibility where the centre procured vaccines at low rates and the states conducted the immunisation programmes. The reason for this shared responsibility is because India always ordered for batch of almost 1 billion doses which made it easy to procure at a very low rate which was then put through a mandatory quality control check under the centre's supervision before supplying it to the states. The States in turn were given guidelines for the vaccine which were then followed and implemented. Taking example of the pulse polio programme, Ms Rao expressed that the centre should have taken a closer look at the historical success of India's vaccine policy. The centre changed its policy on June 7 where 75% of the doses were to be procured by the centre and the rest were to be left to the private sector — the government had two clear objectives for the move. Firstly, the government felt that this move was to prevent further losses by the companies because it was already procuring vaccines for ₹ 150 per dose and secondly, it felt that it was time for the private sector to also take responsibility. However, there was neither clarity about the quantity of vaccine to be produced nor about how private sectors would continue to sustain vaccine distribution amidst the current low market prices. Further, the centre's move to set a quota for

private procurement in the states would also become very difficult considering the vastness of the country. Ms. Rao concluded that the centre should make enough stock for the country to freely inoculate its citizens without the concern over shortage of vials. As to the debate over vaccine nationalism over vaccine equity, she expressed that given the poverty, health care system and huge population of the country, India should first address demands of its citizens, than follow a balance with its international commitments. However, if the country does become successfully self-reliant and is not completely dependent on vaccine material import from the US, it would then be imperative for India to contribute to the COVAX network in its effort to fight the pandemic globally.

E. Kumar Sharma began by expressing that anything related to India vs China has always been an emotive issue. While acknowledging their perfectly balanced vaccine policy and the presence of Chinese vaccines from COVAX to individuals, he pointed out the opaqueness when it came to data, the conspiracy over lab leaks and the efficacy of the vaccines distributed. He shared that countries that administered Chinese vaccines were now facing a surge in cases, China has continued to argue that these are consequences of untimely unlocks in countries that are registering high cases. Expressing that the Chinese have always been much disciplined because of the state culture, he pointed out that the Chinese colour coding system of vaccine tracking was highly innovative and was a key example of the government's long thought policy. Despite its history over vaccine quality and questions over Covid-19 vaccine efficacy, China has been successful in inoculating almost 40% of the population while India is still struggling to do so. With no clarity over vaccine procurement and distribution, India had a long way to go in terms of competing with China over vaccines. He also expressed that India's inability to not depend upon international actors over vaccine manufacturing and accessibility has contributed much to the country's slow vaccination pace. While China's state centred model has induced public sector units towards mass production of vaccine doses, India's move to let go of that opportunity is also a reason for its recent struggle. India had an impressive cadre of frontline workers — ASHAs and Anganwadi workers who have been effective for child immunisation, but it still lacks the functioning manpower to inoculate the entire population. India should invest more on educating people for following COVID appropriate behaviour and eliminate the existing mass vaccine hesitancy. Further, instead of exporting vaccines and choosing to administer only 2.4 million doses a day at the start which was less than daily average vaccines produced, India should have had a more clear bifurcation of its priorities. Arguing from the perspective of the media, Mr. Sharma expressed that it was very tough to access and interpret the data. To conclude, he opined that a larger part of this problem came from the issue of the government not focussing on a long-term thought strategy and instead undertaking last minute decisions when the issue became a crisis.

Prof. BARU concluded the discussion with key insights: a) There needed to be a better understanding of role that global regimes play; b) vaccine nationalism continued to affect inoculation capacity at the global spectrum; c) the policy paralysis through delays in decisions; d) the lack of coordination in the vaccination programmes and; e) the Chinese are still a long way ahead because of their balanced policy with market presence mainly in Southeast Asia, West Asia, Latin America and Africa.

In the Q&A session, questions were raised on the need for India to export vaccines and if India could match the capacity in terms of technology and capital for mass production of vaccines. The SII promised to export doses as one of the largest producers and the utilising the available vaccines that were not in complete use because of less vaccine eligibility and more vaccine hesitancy, was argued to be one of the reasons for such an export. In terms of capacity, although India had been utilising older science of vaccine production, the speakers felt that India in the near future will have the capacity to manufacture vaccines made of advanced medical sciences. Concerns were also raised on why Covaxin was not available for public manufacturing to which the speakers acknowledged that although it is true that investments were made from taxpayers money, the Government also had the responsibility to look after the business interests as well. The speakers expressed that a perfect strategy would have been if India could have paid a small royalty that would be based on how the company had invested and taken the technology to share it with other licensed manufacturers within the country by invoking compulsory licensing. However, they also shared that if that had happened, foreign companies would not have wished to share technology with India which would have in turn been detrimental to the vaccination process.

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