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Ethical Issues Relating to India's COVID-19 Vaccine Policy: An Idealistic vis-à-vis Realistic Perspective

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Abstract *The socio-economic challenge emanating from the COVID-19 pandemic can be effectively arrested by inoculating the people all over the world. Tiding over the pandemic warrants vaccine solidarity by ensuring equity in the vaccine distribution among the countries around the globe. However, the Vaccine Nationalism (VN) attitude of many countries, especially the countries from the global north, is threatening the global fight against the pandemic. VN refers to the problem of the rich or vaccine-developing countries securing a majority of the supplies of vaccines initially to inoculate their own population. In this backdrop, the article highlights the case of the vaccine diplomacy of India, the domestic problem of vaccine shortages, and future directions. The vaccine diplomacy strategy adopted by India can be viewed as a humanitarian approach in the spirit of considering the world as one family from the idealistic viewpoint, whereas such steps can be seen as a strategic measure to counter China's dominance in South Asia and also to reposition its global image. Such initiatives are also in line with South-South Cooperation and South-South and Triangular Cooperation. However, trading-off between domestic vaccine requirements and foreign vaccine requirements is extremely important for India, considering its huge population. Scaling up vaccine production by ensuring voluntary licensing for Indian origin vaccines, tackling vaccine hesitancy, and eventually, promoting vaccine solidarity will remain at the centre of the vaccine policy decision in the near future.*

Keywords *COVID-19 Vaccines, Vaccine Solidarity, Vaccine Nationalism, Vaccine Diplomacy, South-South Cooperation, South-South and Triangular Cooperation*

INTRODUCTION

The world is facing an unprecedented challenge due to the emergence of the COVID-19 pandemic. A crisis which initially started as a health crisis soon became a socio-economic humanitarian crisis. Vaccination may be the only feasible solution to tide over the health vis-à-vis the socio-economic crisis. Controlling this pandemic requires concerted actions from all the countries around the globe to ensure that the vaccines are equitably distributed. However, the effectiveness of the vaccination drive is very much dependent on ensuring equal access to the vaccines at a faster pace throughout the globe. Thus, on the one hand, the production of the vaccines requires scaling up, and on the other hand, there is an acute need to reach the vaccines to the people of different countries around the globe equitably. Vaccine solidarity (or 'vaccine cosmopolitanism') among the nations is critical in combating the pandemic, as the pandemic is not going to taper off unless all have equal access to the vaccine at the global level (Ferguson & Caplan, 2020).

However, it is prudent that the supply of vaccines in the short run will be insufficient to meet the global demand and there lies the risk associated with 'my nation first' or the Vaccine Nationalism (VN) approach. VN refers to the problem of the rich or vaccine-developing countries securing a majority of the supplies of vaccines initially to inoculate their own population first, thereby resulting in an insufficient supply of vaccines to the needy poor countries of the world. VN is a myopic attitude of the high-income and vaccine-developing countries which ignores the view that there should be equitable distribution of the COVID-19 vaccines and drugs to make the fight against the virus effective (Kretchmer, 2020). Advance purchase of the available vaccines through bilateral agreements with the vaccine-developing pharmaceutical and biotechnology companies, hoarding more than the actual requirement of vaccines (what Canada and the US have done by acquiring vaccines for ten times its population), and restricting the export of essential ingredients for the vaccines adversely affect the prices of such vaccines, which further makes it difficult for the low-income poor countries in financing vaccination drives. Bilateral supply agreements with the pharmaceutical companies for prioritising the orders to a specific country

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is made possible by offering a higher price or by entering into a contract with advance purchase at the pre-approval stage (Gruszczynski & WU, 2021). This has resulted in a notable variation of the prices of the vaccines which ranged between $2.19 and $40 per dose; often, the pharmaceutical companies overcharge developing countries for the vaccines in comparison to the advanced countries (Ghosh, 2021).[1]

The short supply of the vaccines due to patent rights[2] is at the core of VN. However, patent is not the sole problem as COVID-19 vaccine development involves a really complex process which necessarily requires the use of other patented technologies, equipment, and processes. Therefore, the waiver of patent rights by a vaccine manufacturer will not be sufficient, as there still will remain the requirement of the waiver on many other aspects of vaccine manufacturing. The solution to this problem lies in the waiver of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreements of World Trade Organization. Although the interpretive statement of the Doha Declaration issued in 2001 clearly suggested that TRIPS must not hinder the governments of different countries to go for compulsory licensing[3] in case of public health emergencies, surprisingly, most of the developed countries oppose it. In October 2020, India and South Africa, along with 57 other WTO members, advocated for ad-hoc waiver of certain provisions of the TRIPS in scaling up the production of the vaccines across the world (Lee & Holt, 2021). The proposal received support from more than 100 developing countries around the globe and from WHO. However, developed countries[4] blocked this proposal in the TRIPS Council, which is most unfortunate in the prelude of this global pandemic, and especially when this is going to benefit the whole world (So, 2021).

VN is not new; rather, it re-emerges whenever some novel drug or vaccine is developed in response to a novel health crisis. For example, VN was very much evident with respect to the H1N1 influenza vaccine in 2009[5] and small pox, and so on. Drawing a lesson from the past, the realistic perspective (in contrast to the normative idealist perspective[6]) stresses the need to protect national interests (i.e., 'ultimately for its own survival') over international morals. By criticising the universal moralism of the idealist's stand, realists believe in moral relativism[7]. Guided by an ethics of responsibility, realists uphold the spirit of national interest, and therefore, prioritised the statesman's duty to their own nations (Lekon, 2003).

While many of the large and so-called developed economies stuck to VN without bothering about the people of other countries, India encouraged the development of the vaccine at a faster pace in the country and responded to the needs of the people in its neighbouring and other economies of the world (Chatterjee et al., 2020; Manish, 2021). The Vaccine Maitri (vaccine friendship) programme has been undertaken by the Ministry of External Affairs of the Government of India to ensure the supply of vaccines produced in India to the neighbouring and other countries in the spirit of the philosophy of *'Vasudhaiva Kutumbakam'*, which is a Sanskrit phrase from the *Hitupanishad* signifying that the world is one family.

In this context, this paper unveils some of the ethical issues relating to the case of vaccine diplomacy (VD) in India, the domestic problem of vaccine shortages, and the expected future vaccine policies. The study contributes to the extant literature by illuminating the stand of India on VN and the way forward.

METHODOLOGY

This paper critically evaluated the policy stance of the Indian government on COVID-19 vaccine in the perspective of the idealism vis-a-vis realism debate in the international relations. Drawing a lesson from the past, the realist perspective (in contrast to the normative idealist perspective[8]) stresses the need to protect national interest

[1] For example, AstraZeneca charged $5.25 per dose to South Africa, whereas the price was merely $3.50 per dose in the EU.

[2] Patent rights allow companies to enjoy exclusive monopoly rights over the manufacturing of the patented items.

[3] It signifies the granting of permission by the government of any country to a third-party to use the patent, without the permission of the owner of the patent, in lieu of a royalty to the patent holder.

[4] The recent decision of the US Government to support the waiver of TRIPS is a welcome step in this direction. However, EU countries, the UK, Japan, and Australia are yet to support the waiver of TRIPS (So, 2021).

[5] Also, a similar experience of VN during 1996 with respect to the HIV medicines.

[6] Learning from the experience of World War I, the idealist view dominated in the literature on international relations in the 1920s and the early 1930s. However, in the wake of the Great Depression in the 1930s and the 1940s, the idealist doctrine was replaced by the realist one. Thereafter, the realist view was challenged by behaviouralism (Lekon, 2003).

[7] Moral relativism sets boundaries through its own particular code of morals within its borders. In the realist 'un-normative' objective analysis, the international arena is divorced from the domestic arena (Lekon, 2003).

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(i.e., 'ultimately for its own survival') over international morals. By criticising the universal moralism of the idealist's stand, realists believe in moral relativism[9] (Lekon, 2003). The policy of vaccine solidarity is rooted to the idealist perspective, which believes in internationalist morality over nationalist interests. Accordingly, the idealist perspective believes in fostering international cooperation and harmony across countries (Lekon, 2003). Vaccine nationalism, on the other hand, believes in the realist perspective, which upholds the spirit of national interest, and therefore, prioritised the statesman's duty to their own nations.

However, document analysis and systematic review of available resources in this study provides us an opportunity in identifying the gap between the desired effort and concrete practices undertaken by the countries in countering vaccine nationalism. Exploratory approach is broadly followed in presenting the facts and findings of this study.

RESULTS AND DISCUSSION

Under the Vaccine Maitri initiative, India supplied more than 66 million doses of vaccine to 95 countries during January-April, 2021. In the wake of the second wave of the pandemic, foreign supply was suspended due to shortage of vaccine in meeting domestic demands (Gettleman et al., 2021). However, the government announced resumption of Vaccine Maitri in September 2021. Till 24 December 2021, India exported approximately 101.5 million doses of vaccines to 97 countries around the world.[10] Out of the total, nearly 33.21 million doses were supplied as part of its commitment under the COVAX initiative, 13.27 million as a grant/gift, and the rest were supplied as per the commercial contract (55.03 million) with different countries.

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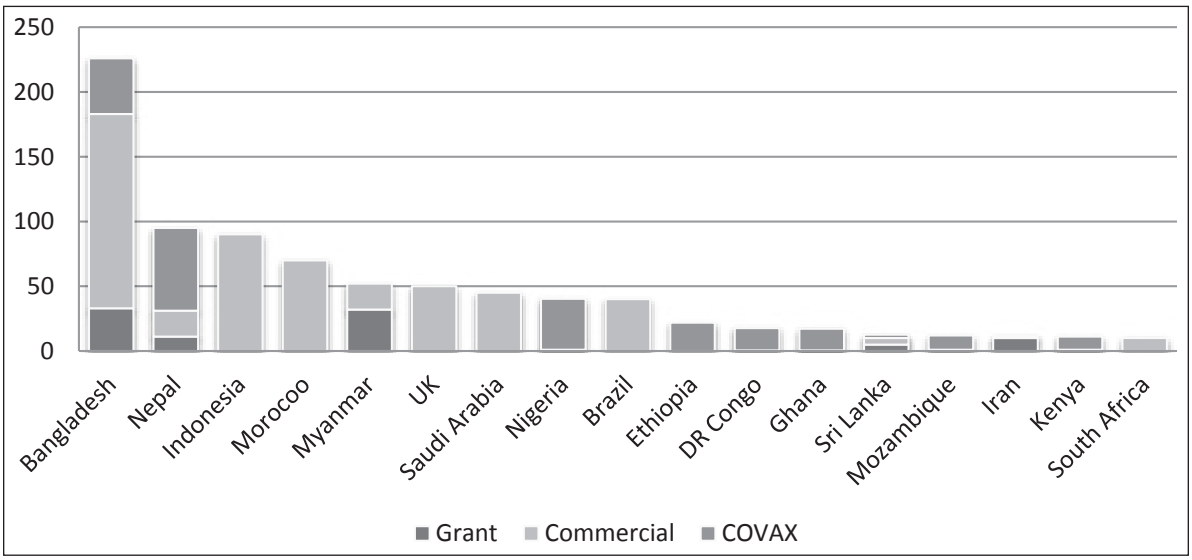
[10] https://www.mea.gov.in/vaccine-supply.htm



Source: Author's own compilation from the data provided by the Ministry of External Affairs, GoI (https://www.mea.gov.in/vaccine-supply.htm).

Fig. 1: Export of Make-in-India COVID-19 Vaccine Supplies (in Lakhs)

In its 'neighbourhood first' policy, neighbouring countries such as Bangladesh, Myanmar, Nepal, and Bhutan received maximum number of vaccines so far. As a part of vaccine diplomacy (VD), India has also extended its cooperation to a number of countries in South-East Asia, Africa, and the Middle East. Further, to fight against the pandemic among the SARRC countries, a COVID-19 Emergency Fund based on voluntary contributions was created, as per the proposal of the Prime Minister of India. India contributed USD10 million,[11] which also shows India's commitment and intent towards working together to stop the spread of the pandemic in the region and the world. India is truly upholding the

[11] http://covid19-sdmc.org/covid19-emergency-fund

spirit of global solidarity in enabling the other countries (especially in the Global South) in inoculating the people who are at high risk. VD by the way of voluntary gifting of the COVID-19 vaccines to other countries in the global south by India can be seen as a precedence of South-South Cooperation (SSC),[12] whereas such efforts under the COVAX programme can be seen as an example of South-South and Triangular Cooperation (SSTC).[13] In fact, the principle of solidarity and standing together to overcome the COVID-19-induced socio-economic crisis is in line with Goal 17 of the Sustainable Development Goals, i.e., "strengthen the means of implementation and revitalise the global partnership for sustainable development". The UN has also emphasised the catalytic role of global solidarity as a moral imperative to tide over this pandemic in everyone's interests. Further, India always wanted to strengthen the strategic diplomatic ties with the neighbouring countries, considering the dominance of China in the South-Asian region (Chatterjee et al., 2020). Many argue that there are idealistic and realistic explanations to the VN strategy adopted by India (Prabhu, 2021). The idealistic view suggest that the VD of India is primarily driven by the ethical values deep-rooted in the Indian cultural system, whereas realistic justification would be the interest of India to obtain a geopolitical edge over China which already has strong economic influence in the region (Chandra, 2021). VD will enable India to strengthen its global image. China is also actively engaged in VD in the Global South. However, lack of transparency surrounding the efficacy and the delay in supply of the Chinese vaccines (Sinovac and Sinopharm) helped India to overtake China in this race of VD, at least in the first quarter of 2021 (Chatterjee et al., 2020).

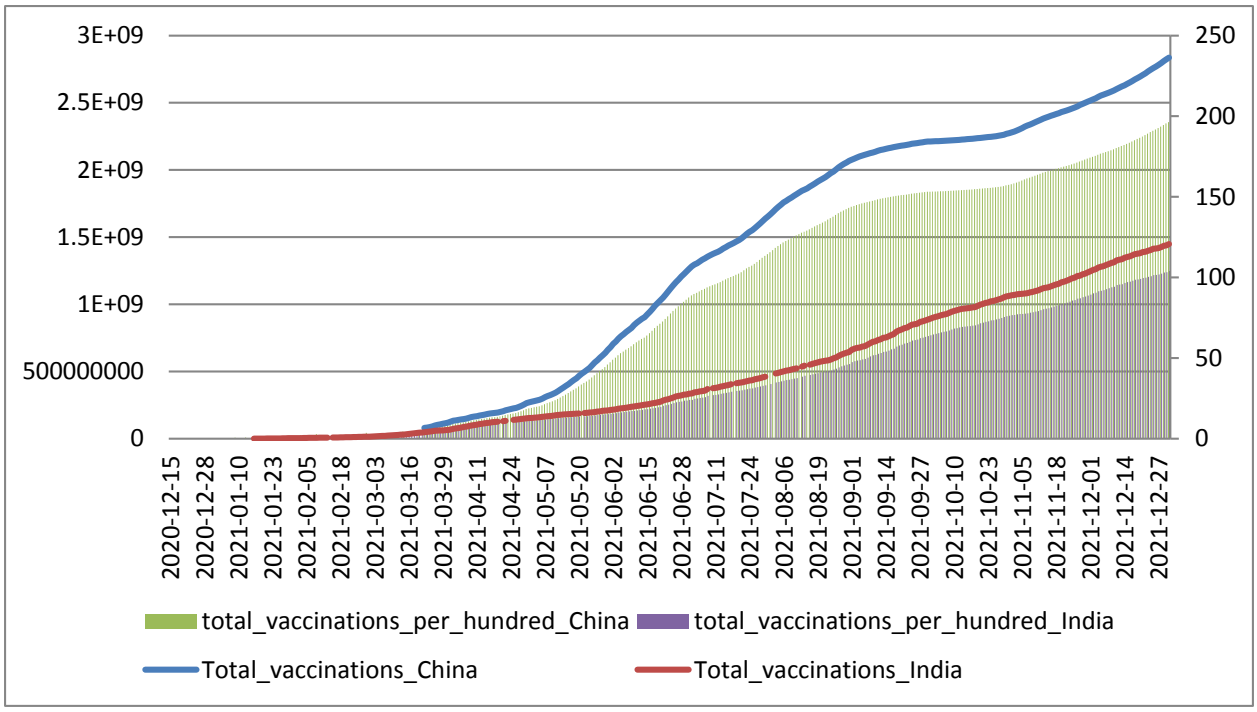
However, there is a socio-economic and political cost of the VD adopted by the Indian government. The move towards benefiting humanity by making the vaccine available to the neighbouring and other countries came under serious criticism from all corners within the country. Although India is considered to be the largest producer of the vaccines in the world, it is literally struggling to cope with the huge domestic demand, coupled with the additional demand on the grounds of VD. Exporting the vaccine under commercial contracts, as gifts, and under the COVAX obligation received heavy condemnation from the opposition parties and the public at large. Such sentiments are natural considering the failure of the system in satisfying the burgeoning domestic demand on account of the landfall of the second wave of the COVID-19 pandemic, and especially when the vaccine is considered as the only saviour. While India, along with some of the South Asian nations remained less affected by the first wave of COVID-19, the effect of the second wave was disastrous, which was reflected in the total number of cases and morbidities, especially in India. The inadequate healthcare infrastructure soon succumbed to the second wave of the COVID-19 pandemic, as evidenced by the dearth of beds in hospitals, patients dying due to lack of oxygen and essential COVID-19 medicines, and so on (Pandey, 2021). The only option (apart from lockdown which has serious socio-economic ramifications) is to inoculate its own population with the available vaccines (Covishield, Covaxin, Sputnik-V) in India. Inoculating a large chunk of the total population in India required scaling up of vaccine production by the Serum Institute of India (the world's largest vaccine manufacturer) and Bharat Biotech. However, the production was much less than the actual demand, which resulted in a huge rush at the vaccination centres. Such a vaccine crunch emerged mainly because of the inadequate production by the manufacturers and VD at the beginning. It really led to a huge hue and cry around the country and many mainstream media houses heavily criticised the Government of India for not being able to arrange the supply of vaccines in the desired numbers and also for sending vaccines to foreign countries. As a matter of fact, people in various parts in India, including mainstream political parties, conducted protests against such VD (Dwarakanath, 2021; Hindustan Times, 2021; Mid-Day, 2021). Shielding itself from the heavy criticism within the country, and most importantly, in response to the rising number of cases, the Government of India put restrictions on the export of the vaccines temporarily.

Although the Government of India never accepted the restrictions on the export of vaccines, the delay in the promised vaccine consignments to countries like Nepal, the UK, Morocco, Brazil, and Saudi Arabia since March 2021 proves the slowing down of the vaccine exports from India (Gettleman et al., 2021). India has so far been able to administer more than 144 crore doses till December 2021. India is lagging far behind China (a comparable country in terms of population), where approximately 283 crore doses of vaccines was administered in the last year. China has exported 80 million doses to about 60 countries, but only after it managed its own internal COVID-19 crisis.[14]

[12] South-South Cooperation is the idea of sharing and exchanging knowledge, technology, resources, and so on between and for the mutual benefits of the countries in the global south.

[13] When South-South Cooperation receives support from the developed countries or multilateral organisations, then such initiatives become South-South and Triangular cooperation.

[14] The European Union (EU) has exported 113.5 million doses to 43 countries, but the EU is made up of 27 countries (Haider, 2021).



Source: Authors' own presentation based on our world in data (https://ourworldindata.org/covid-vaccinations).

Fig. 2: Trend of Vaccination in India and China

Many argue that vaccine scarcity in India was mainly because of improper planning by the Government of India in placing procurement orders on a timely basis. In fact, the Indian government ordered very small quantities of the vaccines from the Serum Institute of India and Bharat Biotech at irregular intervals, without any strong assurance of bulk purchase orders in the near future (Roy Chowdhury, 2021). That stopped the two vaccine manufacturers from ramping up the production line in the desired manner. On the contrary, the alertness of the US and the EU was at the highest level, which is highlighted by the fact that during November 2020 these countries pre-booked nearly 700 million doses of the jab (an instance of VN). However, the act of flawed planning of vaccine purchase not only made the Indian population vulnerable to the second wave of the pandemic, but also hurt other countries, especially the neighbouring countries, as there was a pressure on the vaccine producers from the Government of India for ensuring adequate supply to India first for its domestic use. Neighbouring countries such as Bangladesh, Sri Lanka, Maldives, and Nepal are in deep trouble as there is a serious dearth of the second dose of Covishield vaccine, which is short in supply from India. A big brother kind of image that was created by India using the 'Vaccine Maitri' initiative soon lost its shine and it also created enough space for China to come to the rescue by supplying state-owned Shinopharm vaccines to those countries running out of the doses (Chandra, 2021). The positive attitude of international cooperation and rising above VN is good as a humanitarian approach to fighting the pandemic. However, India must not overlook its own huge demand of vaccines, especially after being hit hard by the second wave.

The whole world is now heading towards the third wave, as predicted by the health experts, due to the emergence of a new variant, Omicron, in South Africa. This new variant is already been traced in most of the countries across the world. The emergence of the COVID-19 in its new form can be explained by the uneven distribution of vaccines, particularly across the countries in the Global South. It permitted the virus to accelerate the process of mutation, sustaining the pandemic in the years to come. The rise of another variant like Omicron or Delmicron can be safely explained by the lack of global coverage in immunising the world's population. The experience of the rise in Alphas and delta variants also suggests recurrence of the situation. It is more prominent in Africa as nearly 7% of the population is still vaccinated. In South Africa, the vaccination rate is merely 35 per cent. However, it is observed to be higher in comparison to other African countries. As per WHO estimate, only 0.6 per cent of the population in low-income groups have received vaccines (Smith, 2021). A ray of hope on the COVAX initiative is now looming dim as it

abandoned its earlier mission of distributing two million doses. It can be safely postulated that variants shall continue to appear if a large portion of the world's population remains unvaccinated. Richer nations, including India, are now considering booster doses for its health workers and elderly population. Though vaccine booster dose is recommended for long-term immunity, it is 'essentially a dose that is not going to someone who's never even gotten their first shot'.[15]

A proper balancing is therefore required to meet the domestic as well as international demands. Therefore, the solution lies in a synthesis of optimistic views of liberalism and the pessimistic views of realism. In this direction, a tepid form of VN,[16] which propagates prioritising domestic needs without compromising the needs of other countries may be supported (Ferguson & Caplan, 2020). A similar policy of 'convergence of idealism and realism in strategic decision making' is proposed by other researchers (Pant, 2021; Kliem, 2021; Prabhu, 2021). In fact, it is also imperative for India to safeguard its own population by trying to save the world. However, this can only be possible by ramping up the production of the vaccines by making heavy investments in no time, speeding up the domestic inoculation process, and allowing more number of pharmaceutical companies to go for clinical trials so that other vaccines can be approved and manufactured for use in India.

A WAY FORWARD FOR INDIA

Through the lens of the realist-cum-idealist approach, some of the following emerging issues need to be prioritised.

Enhancing Production: The only viable option that is available to India is to elevate the production of the vaccines by providing incentives in its production. Now, when the Government of India has promised that vaccines are to be distributed to the states by the Centre directly, the right forecasting and planning are required for estimating the exact demand for the vaccines (domestic and international), so that orders for the jabs can be made at the right time. Advance contracts to the companies by the government can also be of great help for the vaccine manufacturers in financing the expansion of production lines. In this direction, the Government of India has already provided advances of Rs. 1,500 crores to Bharat Biotech and Rs. 3,000 crores to the Serum Institute of India to enlarge their existing facilities. Moreover, the grant of an additional Rs. 65 crores was also provided by the Government of India to Bharat Biotech to divert one of their existing production facilities to manufacture 'Covaxin' (Abrol & Franco, 2021). Dr. Reddy's Lab has also entered into an agreement to produce the Russian vaccine Sputnik V in India.

Voluntary Licensing: Although compulsory licensing is advocated for by many experts, it has its own limitations. Compulsory licensing does not necessarily create any legal obligation for the patent holder to ensure the transfer of the technology, which is a serious limitation considering the complex technological process in manufacturing the vaccine. The idea of compulsory licensing also seems opaque without the TRIPS waiver at the global level. Moreover, introduction of compulsory licensing of a foreign vaccine may hurt India by inviting sanctions by the other economies of the world, especially when a country is largely dependent on the supply of raw materials for producing the vaccines, lifesaving medicines, and other essential medical supplies. On the contrary, voluntary licensing is a much better option in case of an indigenously developed vaccine, and especially when the government is the co-inventor of that vaccine. It suits perfectly for India's own indigenously developed vaccine, Covaxin, developed by Bharat Biotech along with the Indian Council of Medical Research and the National Institute of Virology. The Government of India can allow other companies in India and abroad to manufacture Covaxin. Earlier, there was hesitancy among the manufacturers to produce Covaxin, as its phase three clinical trial results were not declared. However, with the phase three clinical trial results of around 77.8% efficacy (Koshi, 2021), it will only be a matter of time before the vaccine gets approval from the international medical agencies, including WHO. Therefore, it would be in the best interest of India to go for issuing voluntary licensing to other pharmaceutical companies who are capable of vaccine development, by making a complete transfer of technology. As a matter of fact, the Government of India has selected three public sector undertakings (Haffkine Corporation, Indian Immunologicals Ltd., and Bharat Immunologicals and Biologicals) that are capable of manufacturing Covaxin to start the production lines to meet the demand for the vaccine. However, this is not sufficient to inoculate almost 1.3 billion people, which would require approximately 3.1 billon doses (including 15% process loss). Therefore, it is equally important to invite and join hands with other private sector players to ramp up the production in India (Abrol & Franco, 2021). The negotiations between Bharat Biotech and Indian private sector enterprises such as Biological E. Limited and Hyderabad and Panacea Biotech can be seen as a welcome development in this direction.

Tackling Vaccine Hesitancy: Once the production of the vaccines is scaled up to match the demand, the next big challenge would be to tackle the vaccine hesitancy, especially among the people in rural India. Since the start

[15] Business Standard, November 30, 2021.

[16] A tepid form of nationalism can be realised by following limited national partiality in allocating vaccines as a component of justice rather than an obstacle in distributing vaccines to other nations (Ferguson & Caplan, 2020).

of the inoculation process in India in January 2021, vaccine hesitancy was observed even among a section of the frontline workers (Bhatia, 2021). The hesitancy among the frontline workers was mainly because of the lack of scientific data at the beginning of the inoculation process, considering the fact that both of the vaccines were allowed for restricted emergency use. For example, the third phase clinical trial outcomes for Covaxin only came out very recently, in July 2021. The questions regarding side effects, efficacy, and effectiveness resulted in vaccine hesitancy at the beginning of the mass inoculation. The situation has reversed with the passage of time, as a majority of the frontline workers have been vaccinated fully. With increasing awareness among the people about the vaccine, awareness drives adopted by the government, and the severity of the second wave of COVID-19 infections, people rushed to get inoculated. However, vaccine hesitancy is still very prominent in rural India, with two-thirds of the population hesitating because of misinformation, rumours, lack of knowledge, lack of trust, and so on.[17] Sharing of information, awareness programmes, and educating the rural people about the need for inoculation are the only ways to tackle vaccine hesitancy, which is of course not the sole responsibility of the government, but a collective responsibility of all the stakeholders in the society. Inoculating the rural population is very important, as around 48.5% of the total cases in the second wave, during May 2021, were from rural areas (SBI, 2021). Razai et al. (2021) suggested that the building of confidence and trust about the safety and efficacy of the vaccine; removing complacency by communicating the low risk associated with getting inoculated from trusted sources; ensuring convenience by way of arranging transportation for the people; eliminating any cost associated with vaccination; ease of booking slots and so on; stopping the spread of misinformation and rumours, especially through the social media; and consideration of contextual factors such as ethnicity, religion, occupation, and socioeconomic status are critical in handling vaccine hesitancy among the people.

SSC & SSTC: As mentioned, global solidarity is extremely important in making the vaccines available to all parts of the globe. In this vaccine race, 'we can either win together or lose together'.[18] In practice, there is a stark north-south divide in dealing with the COVID-19 crisis. While developed countries of the Global North have adequate financial resources to combat the crisis, the developing countries in the Global South are struggling on fiscal, monetary, and external payments fronts (UNCTAD, 2020). Collective actions and global solidarity, therefore, are the need of the hour. SSC & SSTC can be considered effective measures to ensure that the low-income developing countries can get equal access to the COVID-19 vaccines. India's efforts in this regard, through its vaccine diplomacy initiative of 'vaccine maitri', can be considered a major step towards global solidarity. The export of nearly 66.37 million doses of COVID-19 vaccines (mostly Oxford-AstraZeneca) to 95 countries (most of which are low-income developing countries from Asia, Africa, Caribbean, and Latin America) upholds the spirit of SSC. The distribution of vaccines under COVAX initiative to different countries of the globe is also an example of SSTC. Once the indigenously developed vaccine Covaxin gets the official nod from the WHO, and its production is scaled up through collaboration and voluntary licensing, India will be in a better position to address the need for the vaccines in the countries in the Global South, in the spirit of SSC and SSTC.

[17] It is more in the case of people belonging to tribal communities. Misconceptions and rumours, like the vaccination will cause impotency, serious side effects in the long run, affect female menstrual cycle, and even death are hindering rural people from getting inoculated, which is extremely unfortunate (Mint, 2021).

[18] Following a joint statement by UNICEF Executive Director Henrietta Fore and WHO Director-General Dr. Tedros.

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