COVID-19 VACCINES, PATENT BARRIERS AND LOCAL PRODUCTION IN DEVELOPING COUNTRIES

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THE PEOPLE'S VACCINE ASIA

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*Sudip Chaudhuri retired as a Professor of Economics from the Indian Institute of Management Calcutta after serving there for the last several decades. He also worked at the Centre for Development Studies, Thiruvananthapuram, for some time. His research interests include intellectual property rights regime and pharmaceutical industry, industrialization and economic development in developing countries, and the state's role in economic change.

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This publication carries a strong message – to the vaccine-hoarding wealthy countries, the ungenerous vaccine-manufacturing countries, the unsupportive international trade regime, and the ruthlessly profit-driven Big Pharmas – that there was indeed a different and more effective approach to dealing with the COVID-19 pandemic, had we worked collectively forgoing the self-serving interests and had we put lives first before profits. The efficacy of the COVID-19 vaccines indicates that a lot more lives could have been saved if the vaccines had more extensive coverage, especially across low-income countries. However, disregarding the lives that could have been saved, wealthy countries stockpiled vaccines. They did not provide their committed donation of vaccine doses to developing and low-income countries, while pharmaceutical companies were determined to protect their commercial interests through the use of the 'safeguarding intellectual property' argument, supported by the international trade regime. This shows that a more sustainable solution towards tackling COVID-19 and future pandemics would be the eventual establishment of vaccine manufacturing plants at regional and national levels to ensure a more efficient and cheaper supply of vaccines.

Amidst this harsh reality, SAAPE, as a member of the people's vaccine campaign, took the initiative to organise some research in South Asian countries to bring to the fore the issues related to vaccine manufacturing capacity, access to vaccines, and challenges against ensuring vaccine equity in the region. We are grateful to Prof Sudip Chaudhuri for agreeing to prepare this paper. His scholarly works on intellectual property rights regime and the pharmaceutical industry have educated the public on the bottlenecks in having a pro-poor health infrastructure in South Asia and beyond. We are also thankful to Sunita Sheel Bandewar and Kajal Bhardwaj of the Health, Ethics and Law Institute (HEaL Institute), India, for connecting us to Sudip, which helped us accomplish this research in a shorter period of time.

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We hope this publication helps further evidence to organise public campaigns to ensure people's vaccine for all.

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Contents

Abstract

Access to COVID-19 vaccines has been highly unequal. Compared to almost three-fourths of the people in high-income countries, less than one-fourth of people in low-income countries have been vaccinated with at least one dose. The developed countries have mainly relied on patent-protected vaccines marketed by Pfizer-BioNTech and Moderna and manufactured in their countries. These multinational corporations (MNCs) have refused to give voluntary licences and share technology for manufacturing in developing countries (except in a few cases lately). At the World Trade Organisation (WTO), developed countries have resisted attempts to eliminate patent barriers to facilitate manufacturing on a larger scale. The foremost lesson from the COVID-19 pandemic is that developing countries need to stop relying on MNCs and developed country governments and take proactive steps to be better prepared to deal with pandemics and public health emergencies. While the need to use flexibilities under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement has received wide attention, developing manufacturing capabilities and capacities in developing countries is also crucial. The COVID-19 pandemic has brought developing countries closer. Developing countries, particularly those with insufficient or no manufacturing capacities, have relied a lot on supplies from other developing countries. Again, the vaccines developed in developing countries are being manufactured in a number of countries through technology transfer and other arrangements. There are 92 manufacturers in 28 developing countries for 33 COVID-19 vaccines. The manufacturing and trade links between developing countries need to be further intensified and strengthened. An overall improvement in the manufacturing landscape is possible through appropriate national industrial and technology policies and collaboration among developing countries.

I Introduction

Within a year of the World Health Organization (WHO) declaring the coronavirus disease to be a pandemic on 11 March 2020, vaccines were developed for protection against the infection. Several other vaccines have been developed since then and are available for use. As on 26 September 2022, 12.71 billion doses of different vaccines have been administered globally, with two-thirds of the world population receiving at least one dose of a COVID-19 vaccine. But the distribution has been highly unequal, with less than a quarter of people in low-income countries receiving at least one dose[1]. This is a matter of serious concern. A research study published in The Lancet highlighted the importance of equitable access to vaccines to prevent COVID-19 deaths[2]. The mathematical modelling used in the study for 185 countries estimated that during the first year of the vaccination drive (between December 2020-December 2021), 19.8 million deaths were prevented. Many more lives would have been saved if the preliminary vaccination target of 40% in each country (by the end of December 2021) set by WHO had been met.

While the COVID-19 pandemic seems to be nearing its end, it is not yet over[3]. There is still a need for vaccination, particularly where even one dose has not yet been administered. There is also the issue of vaccination against possible new variants of the virus. And this may not be the last pandemic. Developing countries need to learn from the COVID-19 experience and take steps to be much better prepared to face current and future pandemics or public health emergencies. This will also help them to ensure better access to medical products in general. COVID-19 medical products include not only vaccines but also diagnostics, equipment and medicines. The focus of this paper will be on vaccines.

Section II provides the background to the study. We will discuss the progress in the development and manufacturing of COVID-19 vaccines and vaccination status in different countries – both developed and developing countries[4]. The developed countries have mainly used patent-protected vaccines marketed by Pfizer-BioNTech and Moderna and manufactured in their countries. These MNCs have refused to give voluntary licences and share technology for manufacturing in developing countries (except in a few cases lately). As a result, Developing countries have relied mainly on COVID-19 vaccines manufactured by multiple manufacturers in developing countries. Vaccination records have been better in countries with COVID-19 vaccine manufacturing capacities than those without such capacities.

Among developing countries, China and India have the largest manufacturing capacities. In Section III, we will review how India has responded to the pandemic. We will see that India has relied on local production for vaccinating the residents. We will briefly discuss the historical background that made it possible for India to develop and manufacture COVID-19 vaccines.

In view of poor access to COVID-19 vaccines in some parts of the world, the main task now, both nationally and internationally, is how to make it possible for people, particularly in low-income countries to access the effective vaccines that are available. The Indian case study demonstrates the importance of abolishing patent barriers and also developing capabilities and capacities to manufacture vaccines and improve vaccination.

The issue of patent-based monopolies attracted attention from the beginning of the COVID-19 pandemic. India and South Africa submitted a joint proposal to the TRIPS Council in October 2020 requesting a temporary waiver to eliminate patent (and other intellectual property) barriers to the manufacturing and marketing of COVID-19 medical products. In Section IV, we will discuss how despite the overwhelming support from developing countries, the decision taken at the WTO Ministerial Conference in June 2022 has been disappointing for developing countries, with no substantive changes envisaged for eliminating patent barriers. Hence it is important for developing countries to go beyond the June 2022 Decision. We will review some of the options that developing countries have to eliminate patent barriers in Section IV.

But as Section V discusses, what is also of critical importance is developing local capabilities and capacities so that developing countries can manufacture products which are not patented, or where patents have been waived or where compulsory or voluntary licences have been given. If such capacities are yet to be developed, then even in the absence of any patent barriers, the countries may not be able to manufacture the vaccines. Therefore, an industrial policy must be in place so that an environment free from patent restrictions can be used for the development of the industry.

II Development and Manufacturing of COVID-19 Vaccines and Vaccination Status

Vaccine Inequality

As on 28 September 2022, 47 COVID-19 vaccines have been approved for use in at least one country. Currently, there are 201 countries with vaccines approved by their national regulatory agencies. The common ones approved in a number of countries include: Oxford/ AstraZeneca's Vaxzevria (149 countries) and Covishield (49 countries); Pfizer-BioNTech's Comirnaty (149 countries); Janssen's (Johnson & Johnson) Jcovden (113 countries); Sinopharm (Beijing)'s Covilo (93 countries); Moderna's Spikevax (88 countries); Gamaleya's Sputnik V (74 countries); Sinovac's Coronovac (58 countries); Novavax's Nuvaxovid (40 countries) Valneva's VLA 2002 (33 countries) and Bharat Biotech's Covaxin (14 countries)[5].

Despite the development of such a large number of vaccines, access has been very limited in many parts of the world. WHO set the target in 2021 for 70% global vaccination by mid-2022[6]. But only 58 of WHO's 194 member states achieved the target by June 2022. Even the interim target of 40% vaccination coverage was not achieved by 69 countries[7].

Since then, vaccination has improved, but glaring inequities continue to exist. As on 28 September 2022, whereas 72.54% of the people in high-income countries have been vaccinated with at least one dose, the corresponding proportion for people in low-income countries on the whole is only 24.27%[8]. In 25 countries, it is even worse. Less than 10% of people in eight countries, including Senegal, Madagascar, Yemen, and Papua New Guinea, have received at least one dose of vaccine. In another 17 countries, including Nigeria, Namibia, Algeria, Sudan, and Malawi, the corresponding proportion is more than 10% but less than 24%[9].

The problem is not only with low vaccination coverage in low-income countries but also with delayed vaccination, making it more difficult for them to deal with and recover from the pandemic. While vaccination has improved lately, in early September 2021, i.e., about one year and a half into the pandemic, the vaccination coverage in low-income countries was only 1% of the population compared to 53% in high-income countries[10].

Another critical issue is booster doses. Whereas a large number of people in many developing countries are yet to get even one dose, some countries have administered booster doses to a significant proportion of their population. Booster doses administered per 100 people is 58.4 in September 2022 in high-income countries, 48.3 in upper-middle-income countries, and 16.9 in lower-middle-income countries, compared to only 1.4 in low-income countries[11].

Manufacturing of Vaccines in Developed Countries

As the Table below shows, the developed countries have mainly relied on the two vaccines marketed by the multinational corporations (MNCs) – Pfizer-BioNTech and Moderna. European Union countries and Canada have also used, to some extent, the vaccine developed by Oxford/AstraZeneca. Vaccines marketed by another MNC - Johnson & Johnson, have also been used on a much smaller scale in the EU and the US.

These vaccines are patented and hence cannot be manufactured by others without the consent of the patent holders or unless compulsory licences are given, or the patents are waived. The COVID-19 Technology Access Pool (C-TAP) was launched in May 2020 by WHO and others to provide a platform to voluntarily pool knowledge, intellectual property and data so that COVID-19 medical products are accessible to all. But despite the endorsement by 45 WHO members countries and the backing of international organisations such as UNDP and UNITAID and despite the appeals from different civil society organisations, Pfizer-BioNTech and Moderna refused to share their technologies to facilitate production in developing countries for faster and better access to the vaccines.

COVID-19 Vaccine doses administered in developed countries, September 2022

Entity	Pfizer-BioNTech (%)	Moderna (%)	Oxford/ Astra-Zeneca (%)	Johnson & Johnson (%)	Total (Million doses)
European Union	72.2	17.4	7.7	2.1	874.87
United States	59.3	37.7	0.0	3.1	615.48
Japan	75.7	24.2	0.0	0.0	323.13

Source: https://ourworldindata.org/covid-vaccinations, accessed on 28 September 2022.

Pfizer-BioNTech has manufactured its vaccine in developed countries – the US, Germany, Italy, UK, Ireland, France, Germany, Switzerland, Austria and Belgium. However, only recently, after the requirements of vaccines have been largely met in developed countries, some technology transfer deals have been announced for manufacturing in developing countries – South Africa, Brazil, China, Rwanda and Senegal[12].

Similarly, Moderna concentrated its manufacturing operations in developed countries - the US, France, Switzerland, Netherlands, Canada, Spain and Australia. While Moderna announced that it will not exercise its patent rights in developing countries, it did not volunteer to share its technology. It was only in March 2022 that Moderna announced a memorandum of

understanding with the government of Kenya to establish its manufacturing plant there. In May 2022, another manufacturing deal was announced with a South Korean firm. Johnson and Johnson too exclusively manufacturers its vaccine in developed countries except for a technology transfer deal that it announced with Biological E in India.

The only major exception in this regard is Oxford/AstraZeneca. Apart from manufacturing its vaccine in developed countries, it has transferred technology to organisations in a number of developing countries – Argentina, Brazil, China, India, Mexico, South Korea and Thailand[13]. This contributed to the vaccination drive in developing countries. The Oxford/AstraZeneca's vaccine manufactured by the Serum Institute of India is not only the leading vaccine used in India but is also exported to a large number of countries.

COVAX

In an effort to ensure that people in the world will get access to COVID-19 vaccines once they are available, regardless of their wealth, the COVAX (COVID-19 Vaccines Global Access Initiative) facility was established bringing together governments, global health organisations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to the COVID-19 vaccines.

The low-income countries were supposed to benefit from donations from high-income countries under the COVAX initiative. But the performance has lagged far behind the targets. The COVAX initiative has succeeded in procuring and delivering half of the two billion doses planned for 2021[14]. A major reason for supplies behind schedule and in smaller quantities has been the vaccine grab by developed countries, particularly in the initial stages of the pandemic. These countries directly negotiated with vaccine manufacturers and procured or reserved for themselves vaccine supplies. Developing countries which were unable to manufacture vaccines or to purchase from manufacturers abroad suffered the most.

Donations under COVAX have improved in 2022. But as Table 1 shows, only smaller countries - Austria and Greece – have fulfilled their commitments. Australia is yet to donate any quantity. The largest commitments have been made by the US, the EU and UK. But the proportion of the quantities committed but not yet donated by each of these countries are 43%, 25% and 41%, respectively.

Manufacturing of Vaccines in Developing Countries

The developing countries have relied mainly on COVID-19 vaccines manufactured in developing countries and developed by Oxford/AstraZeneca, Sinovac (China), Gamaleya (Russian Federation), Sinopharm (China), CanSino (China) and Bharat Biotech (India)[15]. The distinctive feature is that these are manufactured by multiple manufacturers in several developing countries.

But manufacturing capacities and actual manufacturing have varied a lot among developing countries. Vaccination status differs not only between developed and developing countries but also within developing countries. Vaccination depends not only on vaccines manufactured in the country but also on other factors such as vaccination infrastructure and the ability and opportunity to import vaccines through donations or otherwise. Some countries, for example, Nepal and Bhutan, with single-dose vaccination coverage of more than 90% of the population did not manufacture any vaccines. But as Table 2 shows, in general, developing countries with manufacturing capacities have much better vaccination records than those which do not manufacture vaccines.

China and India are the two largest manufacturers of COVID-19 vaccines among developing countries. China, with 20 manufacturers, has been able to vaccinate 88.86% of its population with at least one dose and India, with 18 manufacturers[16], 74.23%. The number of people vaccinated with at least one dose in the three most populous countries in the world is 1.30 billion in China, 1.02 billion in India and 268.37 million in the US[17].

Other developing countries with manufacturing capacities and better vaccination coverage include Brazil (86.37% vaccination with six manufacturers); Vietnam (92.21% vaccination with four manufacturers) Argentina (91.35% vaccination with three manufacturers). Even countries with some manufacturing have done much better than those with no manufacturing. All the countries with at least one manufacturer have achieved more than 50% vaccination coverage except four countries (South Africa, Kenya, Algeria and Senegal). On the other hand, vaccination coverage is less than 10% for seven developing countries with no COVID-19 vaccines manufactured. For the other 22 countries with no manufacturing, the vaccination rate varies between 10% and 29% for Mali (11%), Gabon (14%), Sudan (15%), Algeria (18%), Nigeria (21%), Namibia (23%), Somalia (26%), Jamaica (28%) (Table 2). Some developing countries with no manufacturing capacities have relied solely on vaccines manufactured and supplied from China and India, for example, Congo, Mali, Niger, Gambia, Nigeria and Chad[18].

Another important feature to note is that vaccination started earlier in developing countries with manufacturing capacities and helped them cope with the pandemic much better. For example, vaccination started in China in July 2020. In countries such as Mexico and Argentina, it started in December 2020 and in countries such as India, Brazil, and Egypt in January 2021. In contrast, in countries with no manufacturing, vaccination started in Cameroon and Congo in April 2021, Madagascar in May 2021, Burkina Faso and Chad in June 2021 and Burundi in October 2021 (Table 2).

III India's Response to the COVID-19 Pandemic

COVID-19 Vaccines Approved and Manufactured in India

As on 28 September 2022, 12 COVID-19 vaccines have been approved in India (Table 3). What is distinctive about India and a few other developing countries such as China and Cuba is that these developing countries primarily relied on COVID-19 vaccines manufactured in their own countries.

Pfizer-BioNTech vaccine is not yet approved and is not available for use in India. Moderna and Janssen (Johnson & Johnson) vaccines are approved, but the vaccines which have been primarily used for the vaccination drive in India are the Covishield vaccine developed by Oxford/ AstraZeneca and manufactured in India by Serum Institute of India and Covaxin vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research and the government laboratory, the National Institute of Virology. The other locally produced vaccines which are listed and approved for use in different vaccination centres in India are Corbevax[19] and ZyCov-D[20] developed in India, and Sputnik V, developed by Gamaleya (Russian Federation). However, the list of vaccines currently available for vaccination in different centres across the country shows that Covishield and Covaxin continue to be the most widely used vaccines, followed to some extent by Corbevax[21].

Exports of COVID-19 Vaccines from India

As a part of the Vaccine Maitri (Vaccine Friendship) initiative, India started exporting COVID- 19 vaccines in January 2021, around the same time that vaccination started in the country. However, during the second wave of the pandemic, when there was a shortage of vaccines for India itself, the Government of India stopped the export, which was resumed later in October 2021[22]. India's exports accounted for only 6% of domestic supplies (as on 31 May 2022)[23]. But 254.42 million doses of vaccines have been exported to 99 countries (and to UN health workers and peacekeepers) as on 25 August 2022 (Table 4).

Out of 254.42 million doses exported, 6% were grants, 74% were commercial sales and 20% were the contributions to COVAX[24]. Grants of 14.85 million doses of vaccines have gone mainly to five countries – Myanmar, Bangladesh, Nepal, Iran and Afghanistan, each receiving more than one million doses. As part of the COVAX arrangement, the Serum Institute of India has exported 50.44 million doses to 48 countries. However, ten countries - Bangladesh, Nigeria, Nepal, Ethiopia, Ghana, Sudan, DR Congo, Syria, Mozambique and Kenya received 79% of the total COVAX exports. COVID-19 vaccines of 189.12 million doses were exported on a commercial basis to 38 countries. Five developed countries - Netherlands. Australia, New Zealand, the USA and Canada got 61% of the commercially exported volume. The exports to these developed countries are for the Novovax vaccine developed abroad and manufactured in India by the Serum Institute of India under licence and in the brand name - Covovax[25]. The Oxford/AstraZeneca vaccine manufactured by Serum Institute of India is the other vaccine exported commercially to the UK and developing countries such as Bangladesh, Brazil, Nepal and South Africa. Limited quantities of Covaxin have been exported to countries such as Myanmar, Mauritius, Cambodia, Botswana, Iran and Paraguay.

How Manufacturing Capacities Developed in India

It has been possible to manufacture and develop vaccines in India because of the long history. Capabilities and capacities have been built over the years[26]. Currently, there are 21 firms manufacturing a range of vaccines with an annual installed capacity of nearly 5 billion doses. India is a major manufacturer and exporter of vaccines in the world. Serum Institute of India, the manufacturer of Covishield, is the largest vaccine manufacturer in the world in terms of volume.

The foundation of the vaccine industry was laid during British rule more than a century back. The government set up the Central Research Institute, Kasauli, in 1905, the Pasteur Institute of India, Coonoor, in 1907 and the Haffkine Institute in 1899 (set up by the provincial government in Bombay). After independence in 1947, the government set up the BCG Vaccine Laboratory, Guindy, in 1948 and three public sector undertakings later. Private firms, too, started manufacturing vaccines. The major private firms in terms of sales turnover are Biological E (set up in 1953), Serum Institute of India (1966), Panacea Biotec (1984) and Bharat Biotech (1996).

India was able to produce much of the older and non-patented vaccines such as tetanus, tuberculosis, diphtheria, rabies and so on. But neither the vaccine nor the pharmaceutical manufacturers could manufacture the new patented products that started entering the market since the second world war.

The MNCs had the necessary technological and financial resources and held the product patent rights for the drugs patented in the India. India adopted the policy of inviting the MNCs in the 1950s to come and invest in the country to develop the pharmaceutical industry. But MNCs at that time were not very keen to invest in

manufacturing operations in the country.

It was the lack of response from the MNCs which basically prompted the government to take the initiative to develop the industry from basic stages through public investments in manufacturing and R&D. The setting up of the public sector plants under Hindustan Antibiotics Ltd (HAL) in 1954 and Indian Drugs and Pharmaceuticals Ltd (IDPL) in 1961 to produce antibiotics, and synthetic drugs were important landmarks in the development of the industry. Though both of them are now ailing, they gave a tremendous boost to indigenous efforts in the private sector and contributed to its success. The founders of many private firms got the initial training working in these public sector units.

Another important step was the setting up of a number of government laboratories. These laboratories, too, helped the development of the technological skills necessary for manufacturing medical products. There are 49 government institutions engaged in pharmaceutical R&D - 13 under the Council of Scientific and Industrial Research (for example, Central Drug Research Institute and Indian Institute of Chemical Technology), 11 under the Department of Biotechnology (for example, National Institute of Immunology and Bharat Immunologicals and Biologicals Corporation) and 25 under the Department of Health Research/Indian Council of Medical Research (for example, National Institute of Virology and National Institute of Malaria Research)[27]. A distinctive feature of the pharmaceutical industry in India has been the close collaboration between government laboratories and the private sector.

But it was not before India abolished product patent protection in medical products in 1972 that the industry actually started developing. The MNCs used their patent rights earlier to prevent Indian companies from manufacturing though they themselves were not interested in manufacturing the new products in the country. With the abolition of product patents in pharmaceutical products in 1972, Indian firms were no longer prevented from producing and marketing new drugs. Particularly in pharmaceuticals, the technologically proficient Indian firms started manufacturing and marketing the latest drugs leading to a remarkable development of the industry. The abolition of product patents also permitted experimentation for the development and manufacturing of vaccines. It attracted the entry of new biotechnology firms. For example, the country's first Recombinant Hepatitis B vaccine was developed by an Indian firm, Shantha Biotechnics, working in close association with the government laboratory, the Centre for Cellular and Molecular Biology and other Indian research institutes. This was a major achievement in a field dominated by MNCs with high technology. The success of Shantha Biotechnics prompted an MNC, Sanofi, to take it over. Another more recent and notable example is the COVID-19 vaccine developed by another Indian firm, Bharat Biotech, in collaboration with government institutes, as mentioned above.

The private sector also benefitted from public investments in R&D and manufacturing through informal channels. Consider the Serum Institute of India (SII), the largest vaccine manufacturer in the world. SII demonstrated its ability not only to absorb the technology transferred by Oxford/AstraZeneca but to manufacture the vaccine – Covishield – on a large scale not only for the Indian market but also for exporting to a large number of countries. The founders of SII had no background in vaccine manufacturing and naturally lacked the technological knowledge to set up and run a vaccine plant. It was with the help of technical staff recruited from the public sector, Haffkine Institute, that they started manufacturing vaccines. It is to the credit of SSI that it has been able to develop in-house capability over the years to emerge as such a major player in this technology-intensive sector. The government vaccine manufacturing units contributed to the development of other private firms as well by supplying technical manpower, for example, to Bharat Biotech, the manufacturer of Covaxin.

The government aided the growth of the vaccine industry in India, but as the private sector developed, the government started neglecting public-sector manufacturing. In fact, the rise and growth of the private sector have been associated with the decline of public-sector manufacturing[28]. During the second wave of the pandemic, with vaccine shortages and desperate attempts to increase production, India strongly felt the absence of state-run vaccine manufacturers. A country with a long tradition of public sector vaccine manufacturing had to rely on two private firms – Serum Institute of India and Bharat Biotech - to supply COVID-19 vaccines. While the private sector stepped up to increase the availability of vaccines, attempts were made to get a few public sector units involved in manufacturing Covaxin as a panic reaction[29]. The pandemic has shown the need for better planning and a robust public sector to minimise the uncertainty associated with private investments, production, and pricing and to ensure uninterrupted supplies of vaccines at affordable prices.

The growth of the private sector need not be and should not be at the cost of the public sector. The tremendous technological resources in the public sector can be used for revitalising public sector manufacturing. With proper investments and support and a reorientation of official policies and attitudes, it is possible to revive and make the public sector a significant player.

IV Eliminating Patent Barriers for Manufacturing COVID-19-related Medical Products

As mentioned above, the three widely used vaccines marketed by Pfizer-BioNTech, Moderna and Oxford/ AstraZeneca are patent protected. The latter gave licences and transferred technology to selected countries, but Pfizer-BioNTech and Moderna refused to do so.

TRIPS Waiver Proposal and the Decision

Right from the beginning of the COVID-19 pandemic, it was apprehended that if new medical products developed are patented, then non-patentees can be prevented from manufacturing and marketing the products, and as a result, supplies can be adversely affected. India and South Africa submitted a joint proposal to the TRIPS Council on 2 October 2020 (and a revised one on 21 May 2021) requesting a temporary waiver so that WTO member countries are not required to implement, apply and enforce patents (and other intellectual property - copyright, industrial designs and protection of undisclosed information) relating to health products and technologies for the prevention, treatment or containment of COVID-19. Since October 2020, the TRIPS Council has deliberated on the waiver proposal in several meetings. From December 2020, patent-protected vaccines began to be approved for use for COVID-19. The vast majority of more than two-thirds of the WTO members supported the call for the waiver, but a handful of developed countries - the EU, the UK, the US, Japan and others continued to oppose it[30]. Finally, on 17 June 2022, i.e., more than one and a half years after the request for a waiver was made, a decision was taken at the WTO Ministerial Conference. These developed countries not only succeeded in delaying the decision but also influenced an outcome not favourable to developing countries. In contrast to the original TRIPS Waiver proposal, the Decision is related to only vaccines and not to other COVID-19 medical products[31], waives only certain provisions related to use of patented products/processes and is not applicable to all the countries. These make the Decision practically ineffective.

The most significant part of the Decision is that an eligible member of WTO is permitted to grant a compulsory licence through any executive orders, emergency decrees, judicial or administrative orders, whether or not the member has a compulsory license regime in place. Further, the Decision waives the requirements under Article 31(b) (to make efforts to obtain a voluntary licence) and under Article 31(f) (predominantly to supply its domestic markets). The licensees can not only manufacture for the domestic market but also for exports. (Re-exports are, however, permitted only in exceptional circumstances)[32]. Thus, compulsory licensing will be simpler, faster and wider in scope for five years the provisions are applicable.

Footnote 1 clarifies that all developing countries are eligible to use the Decision but also points out that: "Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022." The background is that China as a major manufacturer and exporter of COVID-19 vaccines objected to the use of the criterion of export share to determine eligibility and voluntarily announced in the General Council meeting on 10 May 2022 not to use the flexibility if the concern is addressed[33].

What about other developing countries with manufacturing capacities? Through voluntary licensing arrangements, India manufactured Oxford/AstraZeneca's vaccine both for the Indian market and for exports and, as mentioned above, significantly contributed to the vaccination drive. A basic purpose of the TRIPS waiver proposal was to facilitate the manufacturing of other patented medical products such as Pfizer-BioNTech's or Moderna's vaccines. But this will not happen if, in the light of the footnote, India or other countries which have manufacturing capacities are expected to and make a binding commitment not to use the proposed compulsory licensing procedure.

The developing countries with no capacity to manufacture are the potential beneficiaries of the Decision. Out of the 29 developing countries listed in Table 2, which do not manufacture COVID-19 vaccines, 17 countries are Least Developed Countries (LDCs) (for example, Burundi, Chad, Gambia, Madagascar, Niger) and the remaining 12 countries are not LDCs (for example, Congo, Gabon, Jamaica, Namibia, Nigeria).

LDCs are entitled under the TRIPS agreement not to recognise product patent protection in pharmaceutical products. For them, the 17 June Decision is redundant. LDCs, which currently recognise product patent protection, can outright abolish it and need not be dependent on any compulsory licensing procedure. In line with the Decision of 17 June 2022, this can be done through simple executive or administrative or

similar orders. Countries do not require permission from the WTO to do so. There is precedence – as an LDC, Bangladesh abolished product patent protection in 2008 in pharmaceuticals through a simple notification.

The 17 June 2022 Decision makes it easier for developing countries that are not LDCs and currently do not have the capacity to manufacture vaccines to use compulsory licensing to manufacture or export vaccines. But if these countries do not have manufacturing capacities, the question of compulsory licensing for manufacturing or exporting does not arise. If other countries with manufacturing capacities cannot export to these countries, then they will, of course, enjoy natural protection against imports. But the availability of demand alone will not lead to more production. They need to develop technological capabilities and manufacturing capacities to manufacture, which cannot be done overnight. The Decision is silent on the possible use of compulsory licensing for imports. But in any case, this will be extremely difficult if countries such as India, which have manufacturing capacities, cannot use compulsory licensing to export to them. A possible option is to rely on LDCs such as Bangladesh, where product patent protection in medical products is not in force. Bangladesh has made remarkable progress in the pharmaceutical industry and has also diversified into vaccine manufacturing. But so far as COVID-19 vaccines are concerned, the country is dependent on imports. Moreover, Bangladesh is scheduled to graduate from LDC status in November 2026 and, after that, will be required to re-introduce product patent protection in medical products in line with the TRIPS agreement.

If countries with no manufacturing capacities cannot use the simpler compulsory licensing procedure and those with manufacturing capacities, such as India, are expected not to use it, then the Decision arrived after more than one and a half years of intense negotiations will be devoid of any practical significance.

The phrase "existing capacity to manufacture" is not defined in the Decision. Hence it is not even clear which are the developing countries eligible and which are not. As the Table below indicates, manufacturing capacities vary a lot among developing countries. While there are a number of countries with a number of manufacturers, for example, China, India and Brazil, there are 16 countries with only one manufacturer and three countries with only two manufacturers[34]. Will the countries with limited quantities of vaccines produced by, say, one manufacturer be considered as having manufacturing capacities and expected not to use the simpler compulsory licensing procedures? In a pandemic, time is of fundamental importance. It is more than four months since the Decision has been taken on 17 June, 2022. But still there is no clarity about how the Decision is supposed to be implemented. This raises doubts about the basic purpose of the Decision.

COVID-19 vaccines manufactured in developing countries

No. of COVID-19 vaccine manufacturers	Developing countries
> 17	China (20); India (18)
9	Russian Federation
6	Brazil
4	Egypt, Iran, Vietnam
3	Mexico, Argentina
2	Thailand, Malaysia, Pakistan
1	Senegal, Algeria, Kenya, South Africa, Myanmar, Morocco, Belarus, Philippines, Rwanda, Indonesia, Venezuela, Bangladesh, Sri Lanka, Colombia, Peru, Nicaragua

Source and Notes: See Table 2.

Use of TRIPS Flexibilities by Developing Countries

To summarise, the response of MNCs such as Pfizer and Moderna and developed country governments to the COVID-19 pandemic has been as follows, subject to some exceptions mentioned above with respect to Oxford/AstraZeneca vaccine:

- Patented vaccines have been manufactured in developed countries
- Technologies have not been shared to facilitate production in developing countries
- Vaccines donations promised by high-income countries to low-income countries have lagged far behind targets.
- Efforts to eliminate patent barriers for production by non-patentees have been effectively resisted.

Hence rather than passively relying on MNCs and developed country governments, developing countries need to take proactive steps. The developing countries now need to go beyond the 17 June decision and use the flexibilities they enjoy under the TRIPS agreement to eliminate patent barriers where a patent indeed is a binding constraint. They also need to take steps to develop manufacturing capacities so that they are able to produce more in an environment free from patent and other IP restrictions. This will make them better prepared to deal with pandemics and situations of public health emergencies. We will discuss the question of manufacturing capacity in Section V.

Different options that developing countries have to prevent patent barriers are being widely discussed. The target must be to take simple and effective steps. Three steps that can be initiated are related to compulsory licensing in conformity with Article 31 of the TRIPS Agreement, exceptions to exclusive patent rights under Article 30 and Security Exception under Article 73[35].

Compulsory licensing is one of the most important flexibilities under the TRIPS agreement. Certain conditions, as listed in Article 31, need to be satisfied. But as several commentators have pointed out, it is not difficult to simplify licensing procedures and make the system easy to use. Moreover, in the case of compulsory licensing in a national emergency or other circumstances of extreme urgency, TRIPS permits waiving certain conditions, such as prior negotiation for voluntary licences. The Doha Declaration on the TRIPS agreement and public health affirms that WTO members have the right to determine what constitutes a national emergency or other circumstances of extreme urgency and have the freedom to determine the grounds for compulsory licences. There is no reason developing countries cannot take special and urgent measures in the extraordinary situation arising from the COVID-19 pandemic. Of course, there are political and economic pressures from developed countries. But basically, it is a question of political will and priority.

The developing countries also need to pursue other options, particularly the security exception. Under Article 73 (Security Exceptions) of TRIPS, any WTO member is permitted to take any action "for the protection of its essential security interests" in an "emergency of international relations." The COVID-19 pandemic can be considered to constitute an emergency in international relations, and suspension of IPRs may be considered necessary to protect essential security interests[36]. The effect is similar to patent waiver – patent rights can be suspended. And this can be done without going through the elaborate process of amending patent acts in different countries. Like what Bangladesh did while abolishing product patent protection in pharmaceuticals, patent rights can be suspended by a notification. The developed countries may oppose it and take the matter to the WTO dispute settlement body. But the developing countries will have the opportunity to defend their action. The onus will be on developed countries to argue for the rejection of security exception, unlike in the case of the TRIPS waiver, where the onus was on the developing countries to argue for its approval.

V Developing and Expanding Manufacturing Capacities in Developing Countries

Where necessary capabilities are absent, developing countries will not be able to manufacture patented products even if patent barriers are eliminated. To ensure universal access to COVID-19 medical products, it is important not only to eliminate patent barriers but also to take steps to enhance manufacturing capabilities and capacities.

Feasibility and Possibility of Promoting Local Production in Developing Countries

Issues related to the elimination of patent barriers have received wide attention in the last few years in the context of the outbreak of the pandemic. Similar attention and support are required for developing manufacturing capacities in developing countries.

As we have discussed above, developing countries with some manufacturing capacities have done better in general in terms of access to vaccines than those with no such capacities. COVID-19 pandemic has been a threat. But it is also an opportunity for developing countries to further develop manufacturing capacities and reduce dependence on others.

Doubts are often expressed about the extent to which import-dependent developing countries will be able to develop manufacturing capacities. But already, COVID-19 vaccines are being manufactured on a substantial scale in developing countries. There are 92 manufacturers in 28 developing countries listed in Table 2 for 33 vaccines[37].

Of course, capabilities and capacities vary a lot among these firms and countries. On the one hand, there are countries such as China and India with substantial manufacturing and innovative capabilities and capacities, and on the other hand, there are several developing countries with only one or few manufacturers of COVID-19 vaccines (Table 2).

It is not possible to drastically change the manufacturing landscape in the short run. It is a question of giving it some priority and putting in place medium-term and long-term strategies to initiate manufacturing where there are no capacities at present and scale up capacities where there are some capacities. Countries such as Bangladesh have manufacturing capacities in pharmaceutical products and vaccines. For these countries, the task is to strengthen these capacities. There are also countries such as Tanzania and Ghana, which have some pharmaceutical manufacturing capacities. These countries need to further expand these capacities and diversify to vaccine manufacturing. Developing innovative capabilities for manufacturing vaccines involving new technologies is also important. Countries with more developed vaccine industries, such as China, Cuba and India, can take the lead in this regard.

The government in the United States intervened in various ways on a war footing to support the development of the mRNA vaccines there[38]. Similarly, the technology gap with developed countries can be reduced through appropriate national industrial and technology policies and collaboration among developing countries.

It is important to mention that the public sector plants under the Indian Drugs and Pharmaceuticals Ltd, which played such a crucial role in the development of the pharmaceutical industry in India, were set up with technical help from the USSR at a time when the MNCs were not very enthusiastic about setting up basic manufacturing facilities themselves, did not want to provide technology to others and the Indian private sector was not matured enough to undertake production from basic stages.

Similar collaboration among developing countries is crucial to reduce dependence on developed countries. The COVID-19 pandemic has brought developing countries closer, and it is a question of further building on it. Developing countries, particularly those with insufficient or no manufacturing capacities, have relied a lot on supplies from other developing countries. India, for example, has exported COVID-19 vaccines to 99 countries (Table 4). If we consider just the 57 developing countries listed in Table 2, we find from the table below that developing countries have relied a lot on vaccines developed in China, India and the Russian Federation and the vaccine developed by Oxford/AstraZeneca and manufactured in India by Serum Institute of India.

Use of COVID-19 vaccines developed/ manufactured in developing countries

Vaccines	No. of developing countries which used	Examples
Sinovac (China)	26	Egypt, Iran, Thailand
Gamaleya (Russian Federation)	44	Vietnam, Argentina, Malaysia
Sinopharm (China)	42	Pakistan, Senegal, Algeria
Covishield (Oxford/ AstraZeneca/Serum Institute of India)	36	Kenya, Myanmar, Morocco
Bharat Biotech (India)	13	Egypt, Iran, Vietnam
CanSino (China)	15	Malaysia, Pakistan, Morocco

Source: see Table 2.

Again, these vaccines developed in China and the Russian Federation are being manufactured in a number of developing countries through technology transfer and other arrangements as the table shows below:

Manufacturing of COVID-19 vaccines in developing countries

Vaccines	No. of developing countries where manufactured	Examples
CanSino	6	Brazil, Malaysia, Pakistan
Gamaleya	17	Algeria, Brazil, India
Sinopharm	6	Bangladesh, Morocco, Myanmar
Sinovac	8	Columbia, Egypt, Indonesia

Source: see Table 2.

The links among developing countries need to be further intensified and strengthened. What is required is not only collaboration between private firms. Some countries, for example, India, have many technological resources in the public sector. Attempts to pool such resources in India and other developing countries will be a good step forward in trying to develop more sophisticated and advanced products which these countries may not be able to manufacture currently.

Support from international organisations and supportive organisations in developed countries can facilitate and hasten the process of development of capabilities and capacities. A good example in this regard is the setting up of the technology transfer hub in South Africa to build capacity in low- and middle-income countries to produce mRNA vaccines. It is supported by WHO, Medicines Patent Pool and Act-Accelerator/COVAX. The international partners will provide financial and training support to develop technologies. Already 15 firms in 15 developing countries have been chosen for technological transfer and collaboration[39].

However, international collaboration, cooperation and initiatives are not substitutes for industrial and technological policies individual countries need to design and implement at the national levels. It may not be feasible for all developing countries to initiate the manufacturing of medical products. In such cases, it will remain a part of the international obligation to ensure essential supplies to these countries. But a number of developing countries, such as Tanzania and Ghana have some manufacturing infrastructure already. There are private pharmaceutical firms operating there for a long time. With appropriate support from the government, a conducive environment can be created for the development of manufacturing capabilities and capacities[40]. It is a question of political will and priority.

VI Recapitulation

Several vaccines have been developed and are available for use for protection against the COVID-19 pandemic. But the access to these vaccines has been highly uneven. Compared to almost three-fourths of the people in high-income countries, less than one-fourth of people in low-income countries have been vaccinated with at least one dose. The proportion is much lower in many developing countries.

The developed countries have mainly used vaccines marketed by Pfizer-BioNTech and Moderna:

- Pfizer-BioNTech's and Moderna's vaccines are patent protected and have been manufactured in developed countries
- Technologies for these patented vaccines have not been shared to facilitate production in developing countries
- Vaccine donations promised by high-income countries to low-income countries have lagged far behind targets.
- The proposal in the TRIPS Council to eliminate patent (and other IP) barriers for production by non-patentees has been opposed by the developed countries, and the delayed decision taken at the WTO Ministerial Conference on 17 June 2022 is devoid of any practical significance.

The developing countries have relied mainly on COVID-19 vaccines manufactured in developing countries and developed by Oxford/AstraZeneca, and a few vaccines developed in China, India and the Russian Federation. In general, developing countries with manufacturing capacities have much better vaccination records than those which do not manufacture vaccines.

The foremost lesson from the COVID-19 pandemic is that developing countries need to take proactive steps to improve vaccination rather than passively relying on MNCs and developed country governments. The developing countries need to go beyond the 17 June 2022 decision and use the flexibilities they enjoy under the TRIPS agreement to eliminate patent barriers.

They also need to take steps to develop manufacturing capabilities and capacities so that they are actually able to produce more in an environment free from patent and other IP restrictions. The COVID-19 pandemic has brought developing countries closer, and it is a question of further building on it. Capabilities and capacities vary a lot among developing countries. An overall improvement in the manufacturing landscape is possible through appropriate national industrial and technology policies and collaboration among developing countries.

Table 1: Donations under COVAX by Selected Developed Countries, 2022

	(in a million doses)				
Entity	**Shipped by COVAX to recipient country**	**Donated to COVAX**	**Announced by not yet donated**	**Total**	**Announced as % of Total**
Australia	0	0	60	60	100
Austria	1.2	2	0	3.2	0
Belgium	8.2	4.4	2.4	15	16
Canada	14.2	15.2	21.6	51	42
Denmark	7.3	0	0.7	8	9
European Union	286.3	109	131.3	526.6	25
Finland	2.8	0.3	0.9	4	23
France	61.3	16.1	42.6	120	36
Germany	92.1	33.4	49.5	175	28
Greece	4.3	0	0	4.3	0
Ireland	1.6	2.1	0.3	4	8
Italy	42	21.1	8.9	72	12
Japan	18.1	26.2	15.7	60	26
Netherlands	14.2	3.3	9.5	27	35
New Zealand	1.2	6.5	1.3	9	14
Norway	3.5	2.5	1	7	14
Portugal	2.9	0.9	1.2	5	24
Spain	39.6	20.1	14.3	74	19
Sweden	6.6	4	0.4	11	4
Switzerland	1.8	0	6.2	8	78
United Kingdom	29.7	29.3	41	100	41
United States	237.6	276.1	386.3	900	43
TOTAL	879.6	585.5	839.1	2304.2	36

Source: https://ourworldindata.org/covid-vaccinations, accessed on 28 September, 2022.

Table 2: Vaccination and Manufacturing in Selected Developing Countries

Country	LDC status as on 21 November 2021	No of COVID-19 vaccine manufacturers*	Persons vaccinated with at least one dose per 100 (as on 26-09-2022)	First Vaccination date
Afghanistan	LDC	0	27.93	22-02-2021
Algeria	Not LDC	1	17.88	30-01-2021
Argentina	Not LDC	3	91.35	29-12-2020
Bangladesh	LDC	1	79.91	27-01-2021
Belarus	Not LDC	1	68.78	03-02-2021
Bosnia and Herzegovina	Not LDC	0	28.75	NA
Brazil	Not LDC	6	86.37	17-01-2021
Burkina Faso	LDC	0	12.81	02-06-2021
Burundi	LDC	0	0.163	18-10-2021
Cameroon	Not LDC	0	6.05	12-04-2021
Chad	LDC	0	22.76	04-06-2021
China	Not LDC	20	88.86	22-07-2020
Colombia	Not LDC	1	83.79	17-02-2021
Congo (Democratic Republic)	LDC	0	4.898	19-04-2021
Congo	Not LDC	0	12.61	23-03-2021
Djibouti	LDC	0	23.55	15-03-2021
Egypt	Not LDC	4	51.49	24-01-2021
Equatorial Guinea	Not LDC	0	19.25	12-02-2021
Gabon	Not LDC	0	13.93	23-03-2021
Gambia	LDC	0	18.72	10-03-2021
Haiti	LDC	0	3.168	NA
India	Not LDC	18	74.23	16-01-2021
Indonesia	Not LDC	1	74.57	13-01-2021
Iran	Not LDC	4	77.42	09-02-2021
Iraq	Not LDC	0	27.64	02-03-2021
Jamaica	Not LDC	0	28.06	10-03-2021
Kenya	Not LDC	1	25.03	05-03-2021
Madagascar	LDC	0	5.49	10-05-2021
Malawi	LDC	0	15.89	11-03-2021
Malaysia	Not LDC	2	86.81	24-02-2021
Mali	LDC	0	10.87	31-03-2021
Mexico	Not LDC	3	75.25	24-12-2020
Morocco	Not LDC	1	67.73	28-01-2021
Myanmar	LDC	1	63.92	27-01-2021
Namibia	Not LDC	0	23.11	19-03-2021
Nicaragua	Not LDC	1	91.49	03-03-2021
Niger	LDC	0	15.45	29-03-2021
Nigeria	Not LDC	0	21.25	05-03-2021
Pakistan	Not LDC	2	69.53	03-02-2021
Papua New Guinea	Not LDC	0	3.899	30-03-2021
Peru	Not LDC	1	90.54	09-02-2021
Philippines	Not LDC	1	70.62	01-03-2021
Republic of Moldova	Not LDC	0	27.26	03-03-2021
Russian Federation	Not LDC	9	57.54	NA
Rwanda	LDC	1	70.75	05-03-2021
Senegal	LDC	1	8.84	23-02-2021

Somalia	LDC	0	25.5	16-03-2021
South Africa	Not LDC	1	38.88	17-02-2021
South Sudan	LDC	0	17.34	06-04-2021
Sri Lanka	Not LDC	1	79.99	29-01-2021
Sudan	LDC	0	15.16	09-03-2021
Syrian Arab Republic	Not LDC	0	17.04	01-04-2021
Thailand	Not LDC	2	81.64	28-02-2021
Togo	LDC	0	26.15	10-03-2021
Venezuela	Not LDC	1	77.92	22-02-2021
Vietnam	Not LDC	4	92.21	08-03-2021
Yemen	LDC	0	2.44	20-04-2021

Sources (1) For vaccination status and first vaccination date: https://covid19.who.int/who-data/vaccination-data.csv, accessed on 26 September 2022; (2) For manufacturing status: "Production Locations", https://www.unicef.org/supply/covid-19-market-dashboard, accessed on 15 September 2022. Cuba with high vaccine coverage, is not included in the database; For LDC status as on 21 November, 20221, https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf.

Note: All countries other than high-income countries - as per World Bank classification - have been considered developing countries. The following countries have been included in the table: (1) all the developing countries where COVID-19 vaccines are manufactured or manufacturing has been announced and (2) all the developing countries with single-dose vaccination coverage of less than 30% of the population.

*: The number of manufacturers refers to not only manufacturers where actual production has started but also where agreements and deals to manufacture have been reported.

Table 3: COVID-19 Vaccines approved for use in India

Applicant	Vaccine approved (as on 28-09-2022)	Number of other countries where approved	Names of other countries where approved
Bharat Biotech	Covaxin	13	Developing countries - Botswana, Malaysia, Nepal, Paraguay, Vietnam, Zimbabwe etc)
Bharat Biotech	iNcovacc	0	
Biological E	Corbevax	1	Botswana
Gamaleya	Sputnik Light	25	Mainly developing countries
Gamaleya	Sputnik V	73	Mainly developing countries
Gennova Biopharmaceuticals	Gemcovac - 19	0	
Janssen (Johnson & Johnson)	Jcovden	112	Developed countries (USA, UK, EU countries etc.) and developing countries
Moderna	Spikevax	87	Developed countries (USA, UK, EU countries etc.) and developing countries
Oxford/AstraZeneca	Vaxzevria	148	Developed countries (USA, UK, EU countries etc.) and developing countries
Serum Institute of India	Covishield (Oxford/AstraZeneca formulation)	48	Mainly developing countries
Serum Institute of India	Covovax (Novavax formulation)	5	Bangladesh, Indonesia, Philippines, South Africa, Thailand
Zydus Cadila	ZyCov - D	0	

Source: https://covid19.trackvaccines.org/country/india/, accessed on 29 September 2022.

Table 4: India's Exports of COVID-19 vaccines, August 2022

Country	(in a million doses)			
	Grant	Commercial	COVAX	Total
Netherlands	0.00	93.60	0.00	93.60
Bangladesh	3.30	15.00	9.78	28.08
Myanmar	3.70	17.50	0.00	21.20
Australia	0.00	15.75	0.00	15.75
Nigeria	0.10	0.00	9.68	9.78
Nepal	1.11	2.00	6.39	9.50
Indonesia	0.00	9.01	0.00	9.01
Morocco	0.00	7.00	0.00	7.00
UK	0.00	5.00	0.00	5.00
Saudi Arabia	0.00	4.50	0.00	4.50
Ethiopia	0.00	0.00	4.20	4.20
Brazil	0.00	4.00	0.00	4.00
Canada	0.00	3.75	0.00	3.75
USA	0.00	3.24	0.00	3.24
Ghana	0.05	0.00	2.65	2.70
Mexico	0.00	2.03	0.00	2.03
Ivory Coast	0.05	1.20	0.61	1.86
Sudan	0.00	0.00	1.84	1.84
DR Congo	0.05	0.01	1.72	1.78
Afghanistan	1.00	0.00	0.47	1.47
Syria	0.00	0.00	1.36	1.36
Sri Lanka	0.50	0.50	0.26	1.26
Mozambique	0.10	0.00	1.10	1.20
Iran	1.00	0.13	0.00	1.13
Kenya	0.10	0.00	1.02	1.12
Total (including 74 other countries)	14.85	189.12	50.44	254.42

Source: Vaccine Supply Statement as of 25 August 2022 from the Ministry of External Affairs, Govt of India website, https://www.mea.gov.in/vaccine-supply.htm, accessed 29 September 2022).

Endnotes

1. https://ourworldindata.org/covid-vaccinations, accessed on 27 September, 2022.
2. Watson, O.J. 2022. "Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study", The Lancet Infectious Diseases, June 23 (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext).
3. According to WHO, the end of the Covid-19 pandemic is in sight though not yet over (https://news.un.org/en/story/2022/09/1126621), accessed on 6 October, 2022.
4. For the purpose of this paper, we will consider all countries other than the high-income countries - as per World Bank classification - as developing countries though there are significant differences among them.
5. https://covid19.trackvaccines.org/vaccines/approved/#vaccine-list, accessed on 29 September, 2022.
6. https://www.who.int/campaigns/vaccine-equity, accessed on 29 September, 2022.
7. Accelerating Covid-19 Vaccine Deployment: Removing Obstacles to Increase Coverage Levels and Protect Those at High Risk, April 2022 (https://www.who.int/publications/m/item/accelerating-covid-19-vaccine-deployment, accessed on 29 September, 2022).
8. https://data.undp.org/vaccine-equity/, accessed on 28 September, 2022.
9. https://covid19.who.int/who-data/vaccination-data.csv, accessed on 27 September, 2022.
10. See the chart, https://data.undp.org/vaccine-equity/, accessed on 28 September, 2022.
11. https://ourworldindata.org/covid-vaccinations, accessed on 28 September, 2022.
12. Information used for the discussion here on the manufacturing and technology transfer deals of Pfizer-BioNTech, Moderna and AstraZeneca have been obtained from: "UNICEF COVID-19 Vaccine Market Dashboard" (https://www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 15 September, 2022).
13. But some firms in some countries, for example in Bangladesh keen to manufacture vaccines under licences have been left out.
14. See, A de Bengy Puyvallée and K T Storeng. 2022. "COVAX, Vaccine Donations and The Politics of Global Vaccine Inequity", Globalization and Health, 2022 (https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00801-z).
15. https://covid19.who.int/who-data/vaccination-data.csv, accessed on 15 September, 2022; https://www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 15 September, 2022.
16. As mentioned in Notes to Table 2, the number of manufacturers refers to not only manufacturers where actual production has started but also where agreements and deals to manufacture have been reported.
17. https://covid19.who.int/who-data/vaccination-data.csv, accessed on 26 September, 2022.
18. Source: same as in Table 2.
19. Corbevax has been developed by Texas Children's Hospital and Baylor College of Medicine's Center for Vaccine Development and licensed to the Indian firm, Biological E (https://www.texaschildrens.org/texas-children%E2%80%99s-hospital-and-baylor-college-medicine-covid-19-vaccine-technology-secures-emergency) (accessed on 3 October, 2022).
20. ZyCov-D has been developed by the Indian firm, Zydus Cadila in partnership with the Department of Biotechnology and supported under the National Biopharma Mission for Preclinical Studies (https://pib.gov.in/PressReleasePage.aspx?PRID=1747669) (accessed on 3 October, 2022).
21. The Government of India website, https://www.mygov.in/covid-19, accessed on 29 September, 2022 provides vaccination centre-wise information on the vaccines available for vaccination.
22. https://www.ibef.org/blogs/india-resumes-vaccine-exports-as-domestic-stock-builds) (accessed on 29 September, 2022).
23. https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm, accessed on 29 September, 2022.
24. The discussion on country-wise exports of grants, commercial and COVAX is based on the same source as in Table 4.
25. https://www.seruminstitute.com/press_release_sii_281221.php (accessed on 29 September, 2022).
26. The discussion on India's pharmaceutical and vaccine industry is based on: Sudip Chaudhuri, The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS and Developing Countries (New Delhi: Oxford University Press, 2005) and Sudip Chaudhuri, "Decline of Public Sector Vaccine Manufacturing in India", March 2022 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4055411). These may be consulted for references to data cited in this section.
27. See the Report of the Working Group on Drug and Pharmaceuticals for 12th Plan, Annexure-I (pp. 141-42) cited in Sudip Chaudhuri, "India's Import Dependence on China in Pharmaceuticals: Status, Issues and Policy Options", RIS Discussion Paper Series # 268, July 2021 (https://www.ris.org.in/sites/default/files/Publication/DP%20268%20Prof%20Sudip%20Chaudhuri.pdf).
28. For a discussion of the decline of the public sector in vaccine manufacturing in India, see Chaudhuri, "Decline of Public Sector Vaccine Manufacturing in India", Note 26 above.
29. Under the agreement with Oxford/AstraZeneca, Covishield is manufactured only by SSI.
30. For a discussion on the patent barriers and the background of the India/South Africa TRIPS Waiver proposal, see Sudip Chaudhuri, "Patent Protection and Access to Covid-19 Medical Products in Developing Countries" August 2021 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3902314). Also published as a chapter in M Dutta, Z Husain and A K Sinha (eds.), The Impact of COVID-19 on India and the Global Order: A Multidisciplinary Approach, Springer, 2022.
31. However, within six months members can decide whether to extend the coverage to include COVID-19 diagnostics and therapeutics.
32. Draft Ministerial Decision On The Trips Agreement: Revision (WT/MIN(22)/W/15/Rev.2) (https://Docs.Wto.Org/Dol2fe/Pages/SS/Directdoc.Aspx?Filename=Q:/WT/MIN22/W15R2.Pdf&Open=True), accessed on 9 September, 2022.
33. See the Minutes of the General Council meeting, 9-10 May, 2022 (WT/GC/M/198, p. 36) (https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/M198.pdf&Open=True).
34. As mentioned in Notes to Table 2, the number of manufacturers refer to not only where actual manufacturing has started but where agreements and deals to manufacture have been reported.
35. Statement by South Centre on TRIPS Waiver: An Insufficient Multilateral Response. TRIPS-Consistent National Actions Are Called For, 21 June 2022 (https://www.southcentre.int/sc-statement-trips-waiver-21-june-2022/).
36. See Sudip Chaudhuri, "Patent Protection and Access to Covid-19 Medical Products", Note 30 above for details.
37. https://www.unicef.org/supply/covid-19-vaccine-market-dashboard, accessed on 15 September, 2022. The number of manufacturers refer to not only where actual manufacturing has started but where agreements and deals to manufacture have been reported. The latter indicates that manufacturing capacities already exist or are in the process of being built up.
38. Sunil Mani, "The Role of Industrial Policy in Market-Friendly Economies: Case of COVID-19 Vaccine R&D and its Manufacturing in India And The USA," Commentary on India's Economy and Society Series – 21, July 2021, Centre for Development Studies, Trivandrum (https://cds.edu/wp-content/uploads/21CommentarySeriesProfMani.pdf).
39. https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub, accessed on 4 October, 2022.
40. See for example, How Local Production of Pharmaceuticals Can Be Promoted in Africa: The Case of United Republic of Tanzania, 2016 (https://adphealth.org/upload/resource/Tanzania_Local_Production.pdf).

About SAAPE

South Asia Alliance for Poverty Eradication (SAAPE) is a regional platform of civil society organisations, social movements and people's networks fighting unitedly against the structural causes of poverty and social injustices in the region and beyond. It was conceived in 2001 against the backdrop of increasing anti-people globalisation marked by privatisation, deregulation, extractivism and capital accumulation. SAAPE's mission is to facilitate the process for establishing mechanisms to ensure people's genuine participation in the decision-making processes at all levels to contribute towards poverty eradication and sustainable development. SAAPE facilitates linkages among and between groups in the region, throughout the global South and with like-minded groups in the North.

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