

Revisiting the Question of Local Production of Medical Products in Developing Countries in the light of COVID-19 Pandemic

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Abstract

Import-dependent developing countries suffered tremendously during the COVID-19 pandemic because of the inability to secure international supplies of vaccines. The importance of diversifying production is now acknowledged both nationally and internationally. The paper critically reviews the initiatives underway to develop the vaccine and pharmaceutical industries with special reference to African countries which have been among the worst affected during the pandemic.

Despite intense deliberations and negotiations in different international forums, attempts to remove intellectual property barriers to facilitate the manufacturing of medical products in developing countries have not yet succeeded. While these efforts need to continue, it is also essential for developing countries to take proactive steps for developing manufacturing capacities. The elimination of IP barriers does not automatically lead to the creation of such capacities. The abolition of product patent protection in India and Bangladesh, for example, has contributed to the development of pharmaceutical industries in these countries. In both the countries specific steps were taken before the abolition which empowered the local firms to take advantage of an environment free of patent restrictions.

Notable progress has been made in creating capacities for vaccine manufacturing in Africa. But despite a long history of vaccine and pharmaceutical manufacturing and in spite of some incentives that have been put in place to support the industry in several African countries, the overall impact has been disappointing in the past. But the post COVID-19 environment is quite different from the past. It is important to understand the constraints under which the African countries operate and also appreciate the changes in the environment that have emerged for sustainable development of the industry.

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A major reason for the less-than-satisfactory performance has been pessimism and negativism about the prospects for sustainable local production. Citing unfavourable circumstances, doubts are expressed about the ability of these countries to manufacture quality drugs at competitive prices. What is highlighted is the contradiction between local production and access to medicines. Rather than the more difficult task of developing their own industry, the African countries found it convenient to buy medical products from cheaper sources such as China and India or to rely on donated products sourced from such countries. Despite the talk about promoting local production, policies remained piecemeal and an effective strategy to overcome initial difficulties has been absent. Influential international organizations such as the World Bank highlighted the inefficiencies associated with government intervention and advised a strategy of relying on market forces, de-regulation and import liberalization. But this too did not improve the situation.

In all the countries where modern industries have developed, the government has played a coordinating and leading role in developing the industry. In Africa too governments need to intervene actively recognising the complementariness between government intervention and market forces and the private sector.

The environment is much more congenial for the development of the industry. There is greater political will and international support for the development of the industry. A number of initiatives have been taken for technology transfer and technology development. Financial commitments have also been made.

However, the difficulty local manufacturers face in competing against imports is also a critical constraint in Africa. Even when technology and funds are available, private firms are unlikely to undertake the nature and scale of investments necessary investments without the assurance of the market. But the problem has not received the attention it deserves.

All late industrializing countries which have developed new industries have invariably protected local firms in some form or the other against import competition. However, foreign firms practically face a free trade regime in Africa in medical products. Protection is opposed on the grounds that prices will be higher due to higher costs of production (and supplies may be deficient.) These are legitimate concerns, but they are not insurmountable. The problem is overemphasized. Some market studies including some simulation and modelling studies suggest that protection does not necessarily lead to higher prices.

Protection eliminates international competition but not internal competition. The objective of protection is not to create inefficient industries. It is supposed to give local firms the time and the opportunity to upgrade their knowledge to be competitive and to withstand foreign competition in the future. The presumption should not be that local production is necessarily not viable. A strategy of providing necessary technological and financial support to local firms, generating a degree of competition in the local industry together with some protective measures to assure the required market can create the environment necessary for the development of the local industry.

But if even temporary higher prices that may happen in some cases are not acceptable, if protection is opposed apprehending that prices will be higher, then given the uncertain market prospects, the necessary investments may not take place and hence import dependence may continue. Higher prices may not be desirable. But is the situation witnessed during the COVID-19 pandemic when Africa was unable to get supplies from international sources any better?

I: Vaccine Inequity and Global Vaccine Manufacturing Capacity

Vaccine Inequity

On 30 January, 2020, the World Health Organization declared the outbreak of COVID-19 as a Public Health Emergency of International Concern and confirmed its pandemic status on 11 March. Within a year, in December 2020, the first COVID-19 vaccine for protection against the infection was approved and vaccination efforts started. Since then, several other vaccines have been developed and are available for use. As of 14 October, 2023, 50 COVID-19 vaccines have been approved for use in at least one country - there are 201 countries with vaccines approved by their national regulatory agencies.¹

Vaccination is one of the most effective measures against the virus. It reduces the disease burden and the spread of infection. It is a global problem and requires access to vaccines in sufficient quantities for people all over the world. But despite the development of such a large number of vaccines, access has been very limited in many parts of the world even three years into the pandemic. As of 14 October, 2023, 13.51 billion doses of different vaccines have been administered globally with 70.5% of the world population receiving at least one dose of a COVID-19 vaccine. Nevertheless, the distribution has been highly unequal with only 32.6% of people in low-income countries receiving at least one dose.² It is even worse in 28 countries. Less than 10% of people in five countries – Madagascar, Haiti, Yemen, Papua New Guinea and Burundi have received at least one dose of vaccine. In another 23 countries including Congo, Gabon, Mali, Namibia and Malawi, the corresponding proportion is more than 10% but less than 32.6%.³ Sub-Saharan African countries have been among the worst sufferers. As of September, 2023, half of the top 50 countries in terms of unvaccinated population are from this region.⁴

Public health experts stress the importance of achieving global herd immunity through widespread vaccination. In 2021, the WHO set a target of reaching 70% global vaccination by mid-2022. However, by April 2023, only 67 out of the WHO's 194 member states had achieved this goal. Even the interim target of 40% vaccination coverage was not met by 56 countries by that date.⁵

Another critical issue is that of booster doses. While a large number of people in many developing countries⁶ are yet to receive their first dose, some countries have already administered booster doses to a significant proportion of their population. Booster doses administered per 100 people was 66.4 on October 12, 2023 in high-income countries, 50.1 in upper-middle-income countries, 19.6 in lower-middle-income countries, compared to only 4.0 in low-income countries.⁷

It is important to note that the situation was far worse in the initial stages than what the above figures indicate. Vaccination started very late in many countries, with significantly lower vaccination rates, particularly in low-income countries.

High-income countries were able to fully vaccinate a third of their population by early July 2021. The corresponding proportion was less than 1 % in low-income and less than 5% in lower and upper-middle income countries. In another year's time, i.e., by early July, 2022, the high-income and upper-middle income countries were able to vaccinate nearly three-fourths of the population and lower-middle income more than half the population. But the proportion was only 13.3% in low-income countries. The progress of vaccination has been extremely tardy with the proportion of fully vaccinated population in low-income countries remaining below one-fourth by early 2023.⁸

What caused immense suffering including deaths was not only the late start of vaccination but also poor access to vaccines. Several studies have highlighted the importance of equitable access to vaccines to prevent deaths. The mathematical modelling used in a study of 185 countries estimated that during the first year of the vaccination drive (between December 2020 and December 2021), 19.8 million deaths were prevented due to vaccines. 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 the WHO had been met (Watson 2022). A study of 152 countries found that greater vaccine sharing would have prevented 295.8 million infections and 1.3 million deaths by the end of 2021 (Moore et. al 2022). A study on 20 lower-middle and low-income countries estimated that more than 50% of deaths (min-max range: 54-94%) could have been averted if, during the crucial initial months in 2021, the rate of vaccination in these countries were the same as the per capita daily vaccination reported in selected high-income countries (Gozzi 2023).

Concentration of Global Vaccine Manufacturing Capacity

Manufacturing of Vaccines in Developed Countries

The developed countries have primarily relied on the patented vaccines marketed by multinational corporations (MNCs) – Pfizer, BioNTech and Moderna. Pfizer-BioNTech and Moderna vaccines accounted for 97% of the vaccine doses administered in the United States and 89.6% in the European Union as of September 2022.⁹ Among the other vaccines used in developed countries, the most prominent has been the vaccine developed by Oxford/AstraZeneca.

Oxford/AstraZeneca has transferred technology for manufacturing not only in developed countries but also to organizations in many developing countries – Argentina, Brazil, China, India, Mexico and Thailand.¹⁰

However, Pfizer, BioNTech and Moderna have manufactured their mRNA vaccines in developed countries and refused to share technologies for organizations in developing countries

to manufacture the vaccine. Lately, they have taken some initiatives to manufacture vaccines in developing countries.¹¹ But as we will discuss below, delayed announcements and slow implementation have had little impact on the supply of mRNA vaccines.

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).¹²

Under the COVID-19 Vaccines Global Access Initiative (COVAX), developing countries, particularly low-income countries were expected to benefit from donations from high-income countries. However, due to factors such as vaccine grabs by developed countries, supplies to developing countries lagged far behind targets.

The major manufacturers and exporters of COVID-19 vaccines in developing countries have been China, India, the Russian Federation and Cuba.¹³ Other manufacturers of COVID-19 vaccines in developing countries include Brazil, Vietnam, Iran, Egypt, Argentina, Turkey, South Africa, Thailand and Bangladesh.¹⁴

But it took time to initiate and scale up production in these countries and supplies were inadequate, particularly in the initial stages when the need for vaccines was critical.

The majority of developing countries did not manufacture vaccines at the time of the outbreak of the pandemic. Despite the rise in manufacturing after the COVID-19 pandemic, only Rwanda and Senegal in Africa and Myanmar and Bangladesh in Asia are among the 46 Least Developed Countries (LDCs) and only Rwanda among the 26 low-income countries currently manufacture COVID-19 vaccines or plans have been initiated to do so.¹⁵

Africa has been one of the worst affected regions due to the pandemic. A study on the vaccine industry in Africa published a few years before the pandemic, revealed that African countries depended on external sources for 99% of the vaccine requirements. Vaccines were manufactured on a modest scale only in four countries – Egypt, Tunisia, Senegal and South Africa. (UNIDO, AVMI and WHO 2017).

Vaccination depends not only on vaccines manufactured in the country but also on other factors such as vaccination infrastructure, funding, vaccine hesitancy and the ability and opportunity to import vaccines through donations or otherwise. Some countries, for example Nepal and Bhutan, achieved single-dose vaccination coverage of over 90% of their population, without manufacturing vaccines. But the inability to secure international supplies has been a critical factor during the pandemic when domestic production was inadequate or absent.

II: COVID-19 Pandemic and Removal of Barriers to Manufacturing in Developing Countries

The need for expanding global vaccine manufacturing capacities was realized right from the beginning of the COVID-19 pandemic. It was also apprehended that if new medical products are patented or protected by other intellectual property (IP) rights, then the patentees (or owners of other IP) will have the right to prevent others from manufacturing and entering the market. This may result in supply shortages and high prices. Thus, the elimination of IP barriers was deemed important to expand the manufacturing and supply of vaccines and other medical products. However, the elimination of such barriers alone does not provide the necessary technical know-how required to manufacture the products. Thus, making technology transfer equally critical.

To address these two important barriers – legal and technical – what evoked strong interest and optimism, especially in the initial phases of the pandemic are C-TAP and the TRIPS Waiver proposal. Currently, a pandemic agreement is being negotiated by WHO member countries which continues to deliberate on these important issues of IP and technology transfer.

In this section, we will critically review the progress and the impact of these international initiatives.

C-TAP

In response to the pandemic, the initial focus was on voluntary measures. Within a few months of WHO declaring COVID-19 to be a pandemic, WHO, in collaboration with the Government of Costa Rica and other partners launched the COVID-19 Technology Access Pool (C-TAP) in May 2020. A Solidarity Call was issued for the developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data with manufacturers through voluntary, non-exclusive and transparent licenses. C-TAP is currently endorsed by 45 WHO Member States.¹⁶ It includes some developed countries such as Belgium, Norway and the Netherlands. This however does not include other developed countries such as the US, the UK, France and Germany and developing countries such as China and India.

The Medicines Patent Pool (MPP) expanded its activities to include COVID-19 medical products and became the main implementing partner of C-TAP. Let us see under the auspices of C-TAP, what MPP has been able to do to arrange licensing. For COVID-19 medicines, MPP has signed three agreements for Ensitrelvir Fumaric Acid (with Shionogi of Japan), Molnupiravir (with Merck Sharp & Dohme) and Nirmatrelvir (with Pfizer).¹⁷ Even in these cases, many countries have been left out and the terms and conditions have not been transparent and reasonable.¹⁸

In the context of the pandemic, the main concern was eliminating IP and technology barriers for COVID-19 vaccines. But it was not before August, 2023, i.e., almost three years after the first COVID-19 vaccine was approved that MPP was able to licence an approved COVID-19 vaccine (with a Taiwanese firm, Medigen Vaccine Biologics).¹⁹ The 15 agreements that MPP has been able to arrange are mostly for diagnostic and research tools.²⁰ MPP could not arrange for licensing for expanding the manufacturing of widely used patent-protected vaccines such as mRNA in developing countries to save lives. The shortcomings of C-TAP have actually been acknowledged by senior WHO officials during the 2nd World Local Production Forum, The Hague, November, 2023.²¹

This is a limitation of the voluntary licensing model. It is not that voluntary initiatives are not necessary or desirable. When it works, it is a better option than mandatory measures. In the case of compulsory licensing, for example, the owners of IP will invariably not share the technologies needed to manufacture the products. In the case of voluntary licensing, the owners of IP may, in fact usually also provide technological assistance. When IP owners are willing to license out, MPP expertise can facilitate effective negotiations reducing transaction costs for both owners and users of technology.²²

The problem with voluntary licensing, however is that it is voluntary – owners of IP may not be willing to license out their technologies. In cases where they refuse, there is little that MPP can do as seen with patented mRNA technologies. It is important to note that when C-TAP was launched, MNCs such as Pfizer with significant control over COVID-19 vaccine IP and technology, condemned the move and chose not to participate.²³

TRIPS Waiver Proposal and the Decision

If the owners of IP had shared technologies and IP, if C-TAP had the desired impact, mandatory measures may not have been necessary. With the disappointing progress with the C-TAP initiative launched in May, 2020, a TRIPS Waiver proposal was submitted in October, 2020.

India and South Africa submitted the joint proposal to the TRIPS Council 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 deliberated on the waiver proposal in several meetings. The vast majority of more than two-thirds of the WTO members supported the call for the waiver but a handful of developed countries opposed it. 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 (though it provides for negotiations to extend the coverage to include COVID-19 diagnostics and therapeutics), waives

only certain provisions related to the use of patented products/processes and does not apply to all the countries. These make the Decision practically ineffective.²⁴

The most significant aspect of the Decision is that it facilitates the grant of a compulsory license by an eligible member of WTO by waiving certain requirements under TRIPS. Compulsory licensing will be simpler, faster and wider in scope for five years during which the waivers are applicable.

However, the main constraint is that developing countries with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. The developing countries with no capacity to manufacture are the potential beneficiaries of the Decision. This includes several LDCs that are entitled under the TRIPS agreement not to recognize product patent protection in pharmaceutical products. For them the 17 June Decision is redundant. They can outright abolish product patent protection and need not be dependent on any compulsory licensing procedure.

The 17 June 2022 Decision of course makes it easier for developing countries that are not LDCs and which currently do not have the capacity to manufacture vaccines to use compulsory licensing. However, if these countries do not have manufacturing capacities, the question of compulsory licensing for manufacturing or exporting does not arise.

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

A more basic issue was raised during the debate concerning the TRIPS Waiver. Will the elimination of IP barriers help if the owners of IP do not share the technology involved in manufacturing the products? This was raised in the context of the argument that the main constraint is not IP - even if the waiver is granted, most developing countries will not be able to take advantage of it because they lack the capacities and capabilities to manufacture the products.

It is true that the elimination of IP barriers does not automatically empower others to manufacture the product. In fact, in a pandemic when the speed at which products are available is critical, technology transfer from patentees may appear to be more important than removing IP barriers because it takes time to develop technologies (Shadlen 2023). But the problem is that the outcome depends entirely on what owners of IP decide to do. When patentees are keen neither to transfer technologies to others nor to manufacture the products themselves in developing countries, as has happened in the case of mRNA vaccines, removal of IP barriers becomes critical. If IP barriers are not eliminated even an attempt to manufacture the product can be problematic. The mRNA technology used by Moderna and others is protected by hundreds of patents including pending applications (Correa 2021). Therefore, any of these patentees can file a suit alleging infringement against any non-patentee attempting to manufacture the vaccine. An environment where there are no patent barriers or where there is

no threat of litigation, is more conducive for experimentation and development of products as WHO's mRNA hub discussed below demonstrates.

Pandemic Agreement

During a Special Session of the World Health Assembly in December 2021, WHO's Member States decided to establish an intergovernmental negotiating body (INB) tasked with drafting an international agreement to prevent, respond to, and prepare for future pandemics (also referred to as a Pandemic Treaty). The *Proposal for Negotiating Text of the WHO Pandemic Agreement* was circulated on 30 October, 2023 (WHO 2023a). This followed the circulation of the Zero Draft in February 2023 (WHO 2023b)) and another draft in May 2023.

The Negotiating Text addresses a wide range of issues, including public health surveillance, readiness and resilience, access and benefit sharing, global supply chain and logistics and communication. We focus here on the clauses relating to research and development, sustainable production and transfer of technology and know-how.

The Negotiating Text reiterates concerns that have been deliberated upon ever since the outbreak of the pandemic, viz., the use of TRIPS flexibilities, the question of time-bound waivers of IP, promotion of voluntary licensing and transfer of technology. What is important is not only what is finally agreed upon but whether the clauses can be or will be implemented without qualifications and restrictions and uncertainty.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has opposed the negotiating text, claiming that it would have a “chilling effect on the innovation pipeline for medical countermeasures.”²⁵ IFPMA used similar words to oppose the TRIPS Waiver proposal in 2020: it “would jeopardize future medical innovation, making us more vulnerable to other diseases.”²⁶ The consistent and persistent opposition²⁶ of the MNCs backed by the developed country governments acts as the main deterrent to implementation of any effective IP waiver proposal.

Article 9 of the Zero Draft included the clause: “establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies.” This generated huge optimism. Much of the R&D done by MNCs including by Moderna and others for developing technologies for mRNA vaccine were publicly funded (Abbott 2023, Table 1, p. 29). Hence any conditions imposed on the use of the outcome of such R&D would go a long way in removing IP and technology barriers to expansion of production. However, in the negotiating text of 30 October, 2023, there is no mention of imposing any such conditions. It only refers to requirements to publish the terms of government-funded research and development agreements without any commitment to ensure affordable, equitable and timely access to pandemic-related products.

The other clauses on the use of publicly funded research that have been incorporated in the latest draft include the following recommendations:

- encourage particularly those that receive significant public financing, to grant non-exclusive, royalty-free licenses to any manufacturers, particularly from developing countries, to use their intellectual property and other protected technology and know-how.
- encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to waive or manage, for a limited duration, royalties on the use of their technology for the production of pandemic-related products;
- encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers

The main shortcoming of these clauses, as highlighted in the written submissions on the negotiating text by several organizations such as Médecins Sans Frontières (MSF), Oxfam and Health Action International is the absence of any binding commitments.²⁷ In the absence of any explicit obligations, the implementation of these recommendations will depend on the discretion of IP owners and developed country governments funding R&D, with limited room for involvement from developing countries, who are meant to be the main beneficiaries.

Similar declarations and recommendations expressing concern about the disproportionate impact of COVID-19 pandemic in developing countries, stressing the need for geographically diversifying manufacturing capacity and support for technology transfer, use of TRIPS flexibilities, waiver on intellectual property, etc. have been made in several other international meetings for example in the United Nations General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response in September 2023.²⁸

Again, if the recommendations are implemented without qualifications and restrictions, it can help to eliminate IP barriers and to facilitate the transfer of technology. But as the Statement issued by the South Centre on the UN High Level Meeting has said these declarations are not backed by strong and concrete commitments and guidance for effective Pandemic Prevention, Preparedness and Response.²⁹

III: Vaccine Manufacturing Initiatives in Africa

While the C-TAP initiative and the TRIPS Waiver proposal did not proceed as envisaged, notable progress has been made in creating capacities for vaccine manufacturing and technology transfer and development, especially in Africa. This is the result of a conscious and determined attempt to stimulate manufacturing. Both the urge and political support to develop local production and partnerships and assistance from international organizations and foreign

vaccine developers and manufacturers have contributed to a surge in the manufacturing of vaccines in Africa. We discuss in this section the nature of the initiatives and the progress.

In response to the limited access to COVID-19 vaccines in Africa and the widespread public outcry over the devastation that the pandemic caused, the African Union, African Ministers of Health and Africa Centres for Disease Control and Prevention (Africa CDC) convened a series of meetings to address the unprecedented situation.³⁰ Following a summit meeting of African Union Heads of State on Expanding Africa's Vaccine Manufacturing for Health Security in April 2021, the Partnerships for African Vaccine Manufacturing (PAVM) was launched to scale-up vaccine manufacturing in Africa. The latter prepared a Framework for Action (FFA) under the supervision of the Africa CDC with the long-term vision to enable “the African vaccine manufacturing industry to develop, produce, and supply over 60 percent of the total vaccine doses required on the continent by 2040, up from less than 1 percent today (with interim goals of 10 percent by 2025 and 30 percent by 2030)” (African Union Africa CDC 2022, p. 8). The African Development Bank (AfDB) has set up the African Pharmaceutical Technology Foundation in June 2022 to enhance Africa's access to technologies to manufacture medicines, vaccines, and other pharmaceutical products. The Foundation will act as a mediator between the African pharmaceutical industry and global and southern companies to facilitate the sharing of IP-protected technologies, know-how and patented processes. It will operate independently of AfDB and raise funds from various sources including governments, development finance institutions, and philanthropic organizations, among others.³¹

These African initiatives have been followed by international announcements of support for example during the EU-AU Summit (2022); Germany's G7 summit (2022), Japan's G7 summit (2023) and individually by countries such as the US, UK, Canada, Italy for strengthening local pharmaceutical systems and manufacturing. Announcements offering financial assistance followed including by the European Union, Japan International Cooperation Agency (JICA), International Finance Corporation (IFC), Bill and Melinda Gates Foundation (Momeni 2023, slide 3). AfDB through its lending arm, the African Development Fund approved in November 2022 a grant to the Common Market for Eastern and Southern Africa (COMESA) to build regulatory, quality control and R&D capacities for the pharmaceutical sector. COMESA is a regional economic community comprising of 21 countries including Burundi, Djibouti, Egypt, Ethiopia, Kenya, Rwanda, Tunisia and Zimbabwe.³²

Rise of COVID-19 Vaccine Manufacturing in Africa

Prior to the COVID-19 pandemic, only four countries - Egypt, Tunisia, Senegal and South Africa - manufactured vaccines in Africa. There has been an upsurge in creating COVID-19 vaccine manufacturing capacities in Africa in the last few years. Manufacturing of vaccines had started or announcements have been made for 30 projects in 14 African countries. This included the four existing vaccine manufacturers in Africa diversifying to manufacturing of COVID-19 vaccines and ten other countries initiating vaccine manufacturing (Algeria,

Morocco, Ghana, Nigeria, Botswana, Kenya, Rwanda, Tanzania, Ethiopia and Uganda).³³ Capacities have been installed in 14 of these projects (Momeni 2023, slide 3). African countries where substantial COVID-19 manufacturing progress has been made include Algeria, Egypt, Morocco and South Africa (Clinton Health Access Initiative 2022, slide 3).

The Russian institution (Gamaleya National Center of Epidemiology and Microbiology) and Chinese enterprises (Sinovac and Sinopharm) have been involved in not only exporting vaccines. They also took the initiative to provide technical and other assistance to set up manufacturing facilities in different developing countries including in Africa for the vaccines developed by them. These are government-owned organizations or supported by the government and the government funders in these countries have encouraged and supported technology transfer abroad (Abbott 2023, pp. 11; 36-7). The initial impetus to vaccine manufacturing in Africa was provided by enterprises from the Russian Federation and China – Gamaleya in Algeria, Sinopharm in Morocco and Sinovac in Algeria and Egypt.³⁴ While India manufactured and exported the Oxford/AstraZeneca vaccine to Africa, the vaccine developed in India (by Bharat Biotech) was mainly used in the country.

While country-wise data are not available with us on vaccines currently manufactured in Africa, there has been a substantial expansion of manufacturing capacities overall. A survey conducted by Africa CDC, CHAI, and PATH between December 2022 and March 2023 found that compared to the current average annual vaccine demand of 1.3 billion doses, Africa's current capacity to manufacture vaccines is around 2 billion doses. If all plans to further increase such capacities are realized, the capacity would be more than double the projected African vaccine demand in 2030.³⁵

The creation of capacities, however, has been mainly in the final stage of “fill and finish” rather than the more technologically challenging and capital-intensive production of active vaccine component (or, antigen). It is important not only to avoid overcapacity in fill and finish activities but also to plan for developing adequate capacities and capabilities in the production of active components in the next stage. This is crucial to reduce dependence on other countries, especially in pandemic-like situations.

mRNA vaccines have proved to be very effective against COVID-19. The technology is relatively easy to share and adapt to new variants. It can also be used for the development of vaccines for other infections and diseases.³⁶ But these vaccines could not be manufactured in Africa during the peak of the pandemic because Moderna, Pfizer and BioNTech refused to share the technology. They themselves started taking the initiatives to manufacture only recently. Moderna announced as late as in March 2023 plans to set up a manufacturing facility in partnership with the Government of Kenya to produce mRNA vaccines.³⁷ Pfizer and BioNTech announced plans in 2021 to manufacture mRNA vaccines in Africa and signed some agreements.³⁸ But it was not before June 2022 that the construction of the factory started in Rwanda. BioNTech has also announced plans to set up additional factories in Senegal and South Africa in coordination with partners in respective countries.³⁹

Apart from Moderna, Pfizer and BioNTech, the other major player in COVID-19 vaccine manufacturing from developed countries is Oxford/AstraZeneca. Unlike the former, it has transferred technology for manufacturing its vaccine but only to countries with more developed vaccine manufacturing capacities for example Brazil, China and India, not to Africa.⁴⁰

To be better prepared for pandemics, it is important for Africa (and other developing countries) to take steps to develop technological and manufacturing capacities and capabilities. In this connection, perhaps the most significant initiative has been the setting up of the mRNA technology hub.

WHO's mRNA Technology Hub

To help African - and other developing - countries to develop basic manufacturing technology capabilities for vaccines, the WHO has taken a major initiative. Soon after the launch of the vaccine manufacturing plan by the African Union, WHO announced in June 2021 the establishment of a technology transfer hub to build capacity in low and middle-income countries to manufacture mRNA vaccines. The initiative is supported by the Medicines Patent Pool and the Act-Accelerator/COVAX.

The mRNA hub aims to develop its own replica of Moderna's mRNA COVID-19 vaccine based on information in the public domain. Moderna refused to join WHO's mRNA hub in South Africa but also publicly stated that it would not enforce its patent rights during the pandemic.⁴¹ If Moderna had not done so, with its technology protected by hundreds of patents, the threat of litigation would have been a major deterrent as we have mentioned above. This signifies the importance of the TRIPS waiver proposal. An environment free of IP barriers is more conducive to technology development

A South African consortium comprising Afrigen Biologics, the South African Medical Research Council (SAMRC) and Biovac, a South African vaccine producer was selected to run the hub. The aim is to develop the technology and manufacture mRNA vaccines in the hub and then share technical know-how with a network of technology recipients in low and middle-income countries (LMICs). WHO and its partners will provide specialized technical training and financial support to develop human capital for production know-how and regulatory capacity.

The first batches of the vaccine have already been produced and 15 LMICs have been selected to receive the technology and produce the vaccine locally. The list includes six African countries – Egypt, Kenya, Nigeria, Senegal, Tunisia and South Africa. The other countries are Argentina, Brazil, Bangladesh, Indonesia, India, Pakistan, Serbia, Ukraine and Vietnam.⁴²

In light of the huge devastation that COVID-19 has caused in developing countries, when efforts to eliminate patent barriers and voluntary measures to transfer technologies to developing countries did not succeed, WHO's initiative to set up the mRNA hub is a big step

forward. It has the potential to greatly enhance technology development in developing countries, with mRNA technology applicable not only for COVID-19 but also for other infections and diseases

The mRNA hub goes beyond declarations of intent and promises. It demonstrates what international organizations can actually do to empower developing countries technologically.

CEPI

Another international organization involved in diversifying global production of COVID-19 vaccines is the Coalition for Epidemic Preparedness Innovations (CEPI). It was established in 2017 to develop and deploy vaccines against epidemic and pandemic threats. It has been actively working to establish a network of vaccine manufacturers in developing countries. CEPI signed funding agreements with South Africa's Aspen in December 2022 and with Senegal's Institut Pasteur de Dakar (IPD) in January 2023 to support their capabilities to manufacture routine and outbreak vaccines for Africa. The third member of CEPI's Global South manufacturing network is Bio Farma of Indonesia. A partnership agreement has been signed to support the establishment of mRNA and viral vector rapid response technologies to manufacture vaccines to combat new viral threats. Bio Farma is one of the technology recipients in WHO's mRNA technology transfer programme. CEPI's efforts complement that of WHO in promoting vaccine production in developing countries.⁴³

IV: Revitalizing Industrial Policy for Promoting Production of Medical Products in Africa

We focus on Africa. But many other developing countries in other regions too lack adequate local production facilities. Much of the discussion will be of relevance to these countries as well.

The expansion of vaccine manufacturing in Africa after the outbreak of COVID-19 pandemic is promising. But in the past attempts to develop the pharmaceutical and vaccine industry and to reduce import dependence have not always been successful. The recent efforts have been in response to extraordinary circumstances. Are these knee-jerk reactions to the pandemic and will these efforts subside over time? Will the experience be different from the past? Already doubts have been raised about the sustainability of the manufacturing initiatives – for example, that uncoordinated vaccine investments and production and competition in the same market may not generate adequate return on investments (Makenga et al 2022).

But the post-COVID-19 environment is quite different from the past. It is important to understand the constraints under which the African countries operated and why past efforts have been less than satisfactory. It is also important to appreciate the changes in the

environment that have emerged. African countries can exploit the more congenial and supportive environment and make them less import-dependent and self-reliant not only in vaccines but other medical products as well.

Past Efforts

The development of local production has been proclaimed as a priority in most of the African countries. The need for promoting local production has long been stressed not only by the African governments but also at the regional, continental and international levels. At the continental level, African Heads of States adopted the *Pharmaceutical Manufacturing Plan for Africa* in 2007. To expedite the implementation of the Plan, a *Business Plan* was prepared by the African Union Congress in partnership with the United Nations Industrial Development Organization in 2012. Regionally, the East African Community, for example, announced the 2nd *Regional Pharmaceutical Manufacturing Plan of Action (2017-2027)* (the first one being for the period 2012-16). In 2008 the World Health Assembly adopted the *Global Plan of Action and Strategy on Public Health*, which emphasized the role that local production of essential medicines can play in improving public health. As a part of its implementation, WHO sponsored several studies on local pharmaceutical production. Apart from UNIDO and WHO, other international organizations involved in actively promoting local production include UNDP, UNCTAD, UNAIDS and bilateral donors notably German and Japanese (West and Banda 2016).

Some incentives are in place to support the industry in several African countries but despite some successes in some countries, the overall impact has been disappointing. In fact, the share of local pharmaceutical production has been falling in many countries, for example in Tanzania (Tibandebage et. al 2016). The importance of local production for the security of vaccine supply is understood and appreciated. But a number of vaccine manufacturers in North Africa, Nigeria, Ethiopia and other places could not survive and stopped production in the last few decades (UNIDO, AVMI and WHO, pp. 12, 22). recognize

A major reason for the less than satisfactory performance has been pessimism and negativism about the prospects of sustainable local production in import-dependent developing countries. Citing the unfavourable circumstances, doubts are expressed about the ability of these countries to manufacture quality drugs at competitive prices. What is highlighted is the contradiction between local production and access to medicines. The availability of medical products at prices lower than those produced locally has been a major deterrent. Rather than developing their own industry, the African countries in fact found it convenient to buy medical products from cheaper sources such as China and India or to rely on donated products sourced from these countries.

But unfavourable circumstances and disadvantages and higher costs are nothing unusual in the initial stages. It is important to refer here to the historical experience of countries that tried to develop industries. All late industrializing countries faced initial difficulties including the

United States of America in the 19th century. This did not prevent the government in the US from intervening to support local production and create conditions for development (Chang 2002).

Not only the USA. Many other countries have succeeded in developing new industries for example South Korea (Amsden 1989) and Taiwan (Wade 1990), India in pharmaceuticals (Chaudhuri 2005, chapter 2); Brazil in aircraft manufacturing (Frischtak 1994); China in telecommunication equipment (Harwit 2008).

But perhaps what is relevant in the context of the discussion in this paper is that many other developing countries could not develop competitive industries despite initial attempts to do so. Developing countries in general adopted government-led strategies for industrialization in the 1950s and the 1960s. In a number of developing countries including in Africa, this did not yield the desired results and what is worse, many countries experienced economic crises. This led to the emergence of the Washington Consensus⁴⁴ which highlighted the inefficiencies associated with government intervention and advised a diametrically opposite strategy of relying on market forces, de-regulation and import liberalization.

Under the influence of the Washington Consensus, there has been opposition to protecting local firms against import competition. There has been a reluctance to fund R&D and technology development. Manufacturers found it difficult to access affordable funds but governments could not intervene the way required to enhance access to finance and take other measures of support which typically most countries which were able to develop industries did.

Washington consensus has been one of the major factors why despite the talk about promoting local production, policies remained piecemeal and a coordinated and effective strategy to overcome initial difficulties and develop the industry was absent.

But again, what is important is to highlight that the withdrawal of the government too did not lead to emergence of efficient industries in these countries. In fact, the situation worsened in the pharmaceutical sector in Africa as we have mentioned above.

It is increasingly being realized that it is not a question of Government vs Market. It is a matter of recognising the complementariness between government intervention and market forces and private sector and designing and implementing an industrial policy for promoting local production. The biggest change that COVID-19 pandemic has brought is the realization that this can no longer be ignored.

Context in the light of COVID-19 Pandemic

Promoting local production to take care of public health emergencies has always been a major argument. However, warnings that disruption of supplies from foreign countries of essential medical products can become a major health hazard have been ignored.

COVID-19 has exposed how disastrous such a strategy can be. Countries have been advised to rely on cheaper imports but during the pandemic when they needed it the most, international supplies were not available.

Many developing countries had to defer vaccination. MNCs such as Pfizer and BioNTech focussed on developed countries. Supplies from other developing countries were also not adequate. India stopped exporting Covid-19 vaccines – though temporarily - during the second wave of the pandemic, when there was a shortage in India. Promised donations under COVAX did not materialize on time and in the scale required.

Thus, the possibility that locally made medical products may be more expensive to start with should no longer be argued as a reason for not intervening in an effective way to develop local industry. A passive role of the government can no longer be justified. In view of the tremendous suffering during the pandemic, it is no longer an option but a compulsion to develop local production. As Egypt's minister for International Cooperation has said, health security is as important as food security.⁴⁵ The Framework for Action Partnerships of African Vaccine Manufacturing which was launched by the African Union to scale up vaccine manufacturing has underlined the critical importance of “Sovereign health security” and the need of a coordinated approach to reduce reliance on imports (African Union and Africa CDC 2022, p. 10).

The international environment is also much more conducive to promoting local production. International organizations concur that the status quo is not sustainable – import dependence and sufferings witnessed during the COVID19 should not continue. Indicative of the changed circumstances is the setting up of the mRNA technology hub by WHO. Any such initiative to manufacture high-technology vaccines would most likely have encountered questions such as: Will it be commercially viable in developing countries? Will it be competitive? Can the local producers withstand import competition from more experienced producers in more developed regions? What the WHO initiative signifies is that current difficulties and inadequacies cannot be a justification for not taking steps to develop capacities and capabilities and change the situation. The mRNA project is being implemented with great enthusiasm and there is widespread support for it.

However, attempts to remove IP barriers and to share technology to facilitate the manufacturing of medical products in developing countries have not yet succeeded. The MNCs backed by some developed country governments have continued to oppose any effective TRIPS waiver and binding commitments for technology transfer. In pandemics, in fact, in any situation concerning public health, the outcome should not depend on the discretion of some private companies backed by their governments. Developing countries should of course continue to participate in international deliberations including in the negotiations for a pandemic agreement with the hope of a favourable outcome. But rather than passively relying on MNCs and developed country governments, developing countries need to take proactive steps. The developing countries now need to start using the flexibilities that they enjoy under the TRIPS agreement to eliminate IP barriers. Developing countries have been unable to properly and

adequately use TRIPS flexibilities due to undue political and economic pressure exerted by some developed countries (UN High-Level Panel on Access to Medicines, 2016, p. 25). After the devastation that COVID-19 has caused, it is important for developing countries to withstand such pressures and start exercising their rights. Different options that developing countries have to remove IP barriers have been widely discussed for example 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. The US government has stepped down trade pressures against the use of compulsory licensing.⁴⁶ Developing countries need to explore how to use any such opportunity.

Developing countries also need to take steps to develop innovative and manufacturing capacities. The elimination of IP barriers does not automatically lead to the creation of such capacities. The abolition of product patent protection in India in 1972 is considered to be a major factor contributing to the rise of the generic pharmaceutical industry in India. But prior to that in the 1950s and the 1960s, India took several measures including public investments in manufacturing and R&D which empowered the Indian firms to take advantage of an environment free of patent restrictions. In Bangladesh, another country where the generic industry has prospered, product patent protection in pharmaceuticals was abolished in 2008. The generic industry was able to exploit the situation and manufacture and sell products patented elsewhere at a fraction of international prices because of the measures taken by the government 1980s onward to promote local industry (Chaudhuri 2020b). The argument is not that the elimination of IP is not important. Rather the point is other measures also need to be taken for promoting local manufacturing of medical products. We focus here on the latter.

V: Design and Implementation of Industrial Policy

In response to the COVID-19 pandemic, the primary focus has mainly been on expanding manufacturing capacities for COVID-19 vaccines, a crucial and understandable response. But African countries (and other developing countries) need vaccines not only for COVID-19 but for other epidemics and disease outbreaks as well. They need not only vaccines but essential pharmaceutical products for public health. In this uncertain and explosive world with conflicts happening in different regions, supply disruptions are a real concern, leading to public health hazards. Hence it is essential to adopt a strategy that promotes the manufacturing of not only vaccines but also other medical products.⁴⁷

Africa depends on imports for more than 70% of health technology requirements. But Africa has a long history of pharmaceutical manufacturing. There are currently more than 600 manufacturing plants in at least 29 African countries.⁴⁸ But manufacturing capacities and capabilities vary a lot between African nations. On the one hand, few countries such as South Africa and Egypt that had the capacity to produce both vaccines and pharmaceutical products when the pandemic struck. At the other extreme are several countries such as Burkina Faso, Gabon, Gambia, Somalia, Lesotho and Namibia which had no medical product manufacturing

capacities. In between there are several countries that manufactured pharmaceutical products but not vaccines such as Nigeria, Uganda, Kenya, Ghana and Tanzania. Even among the countries manufacturing pharmaceutical products, capacities vary ranging from South Africa, Nigeria and Egypt with more than 100 manufacturing plants to countries with only a few plants such as Zimbabwe (5), Malawi (3), Angola (2), Benin (1). The capacity to manufacture active pharmaceutical ingredients and active vaccine components is limited. Pharmaceutical manufacturers are involved in processing imported APIs and in vaccines, manufacturing is basically at the final stage of fill and finish. The pharmaceutical firms primarily manufacture low value-added generics rather than technologically more sophisticated and higher value-added products.

It is not possible to drastically change the manufacturing landscape in the short run. It is a question of giving it the priority it deserves and putting in place strategies to initiate manufacturing where there are no capacities at present and expand and diversify capacities where there are some capacities. It is a question starting with technologically simpler activities and then following it up with more complex activities. As the pharmaceutical industry develops, it is natural for Africa to diversify to API manufacturing but the focus of this paper is on formulations production.

To develop local industries, it is important to create an environment where entrepreneurs will be willing and able to undertake the necessary investments. Private entrepreneurs may not be willing or able to invest particularly in the initial stages because of the inability to compete against imports, to access affordable funds and to develop or acquire technical knowledge on their own.

In all the countries where modern industries have developed, the government has played a coordinating role in addressing these three critical issues of Market, Technology and Finance. Despite sporadic attempts and occasional successes, in most African countries neither earlier government intervention, nor withdrawal of government in accordance with Washington Consensus policies have succeeded in developing pharmaceutical and vaccine industries. If modern industries are to develop in Africa it is no longer a question of either Government or Market. The government will have to actively intervene and lead the process.

To develop the industry some overall and general policies will not do. There is no ready-made solution. The specific conditions that different countries face should be taken into account. The African planners need to learn from their own experience in the past and also that of the countries which have succeeded in developing industries, and design and implement policies that will work. We will highlight in this paper a few issues of significance. The critical importance of Technology and Finance is widely acknowledged in the deliberations on localizing manufacturing in the context of COVID-19 pandemic. But the question of the Market has received much less attention. We will mainly focus on the latter below. But before we take up the issue of market access, we will briefly point out some of the complementary and supplementary measures that need to be taken concerning Technology and Finance.

Technology

As we have noted above several announcements have been made and some initiatives taken for providing financial assistance and particularly for technology transfer and technology development. Another noteworthy initiative is the Health Products Manufacturing Support Platform (HMSP). It was launched during the 2nd World Local Production Forum in November 2023 jointly by the African Union Development Agency New Partnership for Africa's Development (AUDA –NEPAD), UNITAID and World Health Organization. It will provide technical and regulatory support to African firms not only for vaccines but also for pharmaceutical formulations and APIs.⁴⁹

These are positive developments. But efforts must be made to ensure that these do not remain isolated instances of vaccine and pharmaceutical manufacturing. It is important to absorb and assimilate the technology and prepare the ground for an eco-system for R&D and technological development for self-reliant growth. BioNTech, for example, has started constructing manufacturing facilities for mRNA vaccines in Rwanda and Moderna has announced to do so in Kenya. If these are implemented without sharing technologies and without involving local technical personnel, the benefits will be limited. Learning from the experiences of successful countries, suitable technology policies need to be employed to ensure that these manufacturing initiatives lead to the development of expansive manufacturing and technological competencies in the countries. For sustainable development, the government's involvement in the R&D and technological development process is vital. Even in a mature capitalist economy such as the USA, government is heavily involved in funding R&D for technological development (Mazzucato 2013). Under the influence of the Washington Consensus and due to the fiscal crisis that African countries face, governments in Africa are hesitant to get involved. This will have to change if African countries are keen to develop the industry.

Finance

This is another area where the role of government is critical. Financial commitments for some large projects, though very important will not be adequate. There is a manufacturing base but firms already existing in Africa are in dire need of affordable funds. The risk-adjusted rate of interest of commercial banks is usually too high for undertaking investments for sustainable growth of the industry. If the experiences of other countries are any guide, then the government needs to play a direct role in arranging affordable funds. In the formative years of the pharmaceutical industry in India for example, development financial institutes (DFIs) set up by the government played a critical role.

Market

Expectations about the market are a basic determinant of private investment. If market prospects are uncertain, private firms are unlikely to invest. Whenever a late industrializing country tries to start a new industry, the production cost will be higher compared to those of more established foreign competitors because of their greater experience and higher skills. If

there is free trade, local manufacturers will find it difficult to compete against imports and this will be a major deterrent to investment. Thus, countries that have developed new industries, have invariably protected local firms in some form or the other against foreign competition. This provides the local firms the incentive to invest. It also gives them the time and the opportunity to upgrade their knowledge to be competitive and to withstand foreign competition in the future.

However, African countries are advised not to protect local industry even in formative stages. There is international pressure and African policy planners tend to passively accept the view that the industry should not be protected. Some countries for example Ghana restrict imports of some pharmaceutical products. Some countries provide some price incentives to local firms in the public procurement of medicines. But otherwise, foreign firms practically face a free trade regime in Africa for medical products.

The difficulty of local manufacturers in competing against imports is a critical constraint in Africa. Even when technology and funds are available, private firms are unlikely to undertake the nature and scale of investments necessary investments without the assurance of the market. But the problem has not received the attention it deserves even in the context of COVID-19 pandemic when the urgency to develop local capacities is widely shared both nationally and internationally.

Removal of intra Africa trade barriers not adequate

Africa with more than 50 countries has historically different regulatory systems and policies for approving products for marketing. Individually, the size of the market is also small. To address the problem of small fragmented markets, several initiatives have been taken in Africa, notably the harmonisation of regulatory systems through the African Medicines Regulatory Harmonisation Initiative (AMRH) and more recently, the Africa Medicines Agency (AMA) and the integration of the African market through the African Continental Free Trade Area (AfCFTA). These are significant initiatives and are expected to have some favourable impact including on the intra Africa pharmaceutical trade, though this may not be to the liking of smaller countries with less developed pharmaceutical industry, for example Burkina Faso which too desire to develop local production in their countries in the light of the unpleasant experience during the COVID-19 pandemic.⁵⁰ They will find it very difficult to compete against African firms from the larger and more developed African countries. But it is presumed that the creation of a large common market will enable African firms to compete against Asian counterparts because the former will be able to enjoy economies of scale. What is also expected is that the removal of trade barriers and the large market will attract foreign direct investments.⁵¹

Larger markets will provide opportunities for economies of scale for African firms if they can access the market. But with no import barriers, the large market will actually benefit more foreign firms exporting to Africa. Once the process of market integration is completed, it will

be more convenient for them to export because with only one harmonized registration of a product they will have access to the entire African market. Rather than incentivizing local production, this will actually intensify import competition and make the situation worse for African manufacturers. Foreign firms are also unlikely to set up manufacturing plants in Africa because of market integration. Consider the Indian pharmaceutical firms which are the most important source of pharmaceutical formulation imports into Africa. Except for a few, Indian firms have not undertaken direct investments in Africa. With no trade restrictions, these firms find it easier to export than to set up plants there to serve the market. Indian firms do not create separate plants for the African markets. They use their existing capacity – often excess capacity – for the purpose. Export activity does not involve huge investment, nor is it risky. Undertaking manufacturing activities in Africa is more difficult because of the various disadvantages African countries suffer from compared to the Indian pharmaceutical environment. As the Chairman of an Indian company exporting to Africa explained - if imported products are freely available in Africa, then it is difficult to induce Indian firms to go to Africa and set up plants. But if local production is somewhat protected, and if this is supplemented with few steps to take care of the disadvantages of local production in Africa including some incentives, then the prospects of foreign direct investment from India will be brighter. In fact, his company will be willing to explore the possibility actively (Chaudhuri 2016).

Together with the removal of intra Africa trade barriers, if some restrictions can be imposed on the flow of products imported into Africa, then it will not only help local firms to withstand import competition but Africa may also be able to attract more direct investments.

Protection for the development of competitive industry in Africa

Industry can be protected through tariffs or through non-tariff barriers. A tariff is an import duty imposed on the imported goods. This makes the imported goods costlier in the economy. Non-tariff measures take the form of restricting imports, for example by banning imports of designated products. If an import duty is imposed but local manufacturers are unable to develop capacities to produce, then import duties will make medicines costlier. Moreover, if an import duty is imposed then local manufacturers can charge a price higher than the international price. This involves a cost to the economy. Again, if imports are banned, then prices may go up due to reduced competition; and if local firms are unable to meet the demand, shortages will develop. Thus, restricting imports may not have the desired effects.

These are legitimate concerns, but they are not insurmountable. A mere protection is of course not adequate. The objective is not to promote inefficient industries but to help local firms to develop and to be competitive. What are crucial are associated measures to develop productive capacities, to reduce the cost differentials and to manage prices and quality. Successful countries that have used protection have also intervened to specifically manage the possible adverse impact of protection. It is also necessary and possible for African countries to do so, as we indicate below.

But the problem is overemphasized. Much of the opposition to protective measures in African countries emanates from some questionable assumptions: import prices are invariably lower than domestic prices; higher production costs necessarily lead to higher domestic prices; local production will not be viable unless a price higher than the imported price is charged. But the fact is that imported products are not necessarily cheaper and the domestic prices need not necessarily be higher because of higher costs, as we will see below.

The pharmaceutical markets are not homogeneous. The market can be classified between patented market and generic market. Generic products can be classified between retail and institutional. The institutional markets can be classified between products funded and procured by local governments and other local institutions and those procured by international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). In the institutional markets, drugs are purchased through a competitive bidding process. International donors restrict it to firms with WHO-prequalified products.

Patented markets

The prices of patented medicines are very high and typically have no correspondence with the cost of production. Out of the 46 countries designated as LDCs, 33 countries are located in Africa.⁵² As LDCs, these countries can take advantage of the flexibility that the TRIPS agreement provides to abolish product patents. This indeed can be an industrial policy initiative to promote local production of patented products. If a product patent is abolished then despite higher costs, local manufacturers can sell at a price lower than what patentees typically charge provided of course productive capacities are developed. As an LDC, Bangladesh abolished product patents in pharmaceuticals which further stimulated the growth of the industry. However, African LDCs have not yet chosen not to do so. In light of the Covid-19 experience and the renewed interest in promoting local production, this is an option that the African LDCs can explore.

Generic markets in Africa⁵³

Retail generic markets in African countries are primarily private branded generic market. It is served mainly by local firms, MNCs and Indian and other generic firms. In most countries, the local firms are involved in the highly competitive segment. They manufacture and sell a limited range of drug products - restricted to OTC formulations and simple prescription medicines covering cough and cold preparations, vitamins, analgesics, simple sedatives, anti-malarials, anti-helminthics, older generation antibiotics, first generation anti-hypertensives, anti-diabetics, etc. They produce simple dosage forms such as plain tablets, capsules, lotions, suspensions etc. They have similar product portfolios and mainly compete among themselves in essentially the same market.

Opposition to protection is based on the presumption that prices of imported products are lower than the local cost of production and hence local manufacturers need to charge prices higher than the imported prices to be able to survive in the market. But despite higher costs, local firms are able to manufacture and sell products and earn profits. This is true not only for firms which are yet to upgrade facilities to GMP standards but those with GMP compliant plants.

The problem is that they face intense competition from importers. In the absence of protection, local producers face competition from both reputed foreign companies and also from less quality-conscious foreign suppliers that charge very low prices. In the branded market, the reputed foreign firms can afford to sell at higher prices due to the perception that their quality is better and also because they can spend much more on marketing and branding their products compared to what local firms can do. To withstand such competition from reputed foreign companies, local firms are often forced to charge lower prices. Competition from low-priced imported products also exerts significant downward pressure on the prices of local manufacturers, resulting in very low prices. The combined effect of all these factors is that local firms operate in these markets with low-profit margins and low volumes. Because of the low volumes much of the capacity remains under-utilized.

Protection against import protection in these markets can ensure larger volumes and higher profits without any adverse impact on affordability and access. Higher profits resulting from higher sales will also enable local firms to invest more including in upgrading facilities leading to the development of the industry. While opposing protection what is not appreciated is that in most countries local manufacturers are already active in manufacturing and marketing several products with adequate capacities. Import restriction will eliminate foreign competition but not domestic competition. The competition already existing among local manufacturers is expected to keep prices under check. In any case, it is not difficult to put in place a watchdog mechanism to ensure that local firms do not take advantage of protection to charge higher prices.

In the case of procurement by local governments too, local firms mainly manufacture and supply simple products but face intense competition from foreign supplies. The policy of import restrictions may be extended to these institutional markets. The process of competitive bidding may be restricted to local manufacturers for the products where local firms have the capacity to manufacture and supply. Local competition can keep prices low. As in the case of retail markets, here too, prices may be monitored to avoid unreasonably high prices.

Generic products currently not manufactured by local firms

To develop the pharmaceutical industry, it is important to diversify – to go beyond the simple products currently manufactured. As mentioned above, local firms are primarily involved in manufacturing and selling simple prescription drugs and OTCs in simple dosage forms. They are not involved in advanced formulations and complex products. Most of the biologics including those not patented are not manufactured by local producers. MNCs and Indian and other generic firms import these and sell them in the retail markets. The African governments procure these from foreign countries.

These products are quite different from the simple products that local firms currently manufacture. Can local firms with higher costs of production import survive competition? In

such cases, if local producers are protected then will not prices be higher leading to reduced access? Obviously if the sale price of a product is so low that the cost of production is not covered, then local production will not be viable. But if the international competitive price is higher than the local cost of production, can local production be viable?

Data are not available to address this important counterfactual question. But some simulation and modelling studies suggest that despite higher costs, production in Africa can be viable.

Starting from the concrete cost structure of a GMP compliant plant in India for five types of tablets from different therapeutic groups and then making necessary adjustments based on cost and other differences between India and Ghana for the year 2012, a study by Chaudhuri and West (2014) done as a part of a UNIDO project, estimated that even if the local manufacturers charge the international reference prices (i.e., the cheapest prices at which medicines are bought and sold internationally),⁵⁴ local production is viable in Ghana with about 15% profit margin. The required volumes of production are not beyond the reach of local firms. They have capacities which are not utilized. The study implies that if the required market is available, growth of local production is possible without inflicting the burden of higher prices.

Similarly, a modelling study for Ethiopia and Nigeria by Mckinsey (Conway et.al 2019) shows that for a range of products, including tablets, capsules, and creams, costs of production tend to be lower than the landed price of imports from India if the scale of production is the same in these African countries and India. In reality, costs are higher because of the lower utilization of plant capacities in the former.

These studies for specific products and specific countries may not be generally valid. The matter needs further investigation. Unless other studies or real experiences indicate otherwise, the presumption should not be that local production is necessarily not viable. A strategy of providing necessary support to local firms, generating a degree of competition in the local industry together with some protective measures to assure the required market can create the environment necessary for the development of the local industry.

International donor funded market

International donors such as the Global Fund have contributed significantly to enhancing access to medicines such as for AIDS, tuberculosis and malaria in Africa. But a major criticism in the past was that the donors were not mindful of the negative impact their procurement had on the demand for locally produced medicines in Africa. Medical products supplied by them were procured through an international competitive bidding process based on the prices quoted and restricted to manufacturers with WHO prequalification for the products concerned. African manufacturers unable to upgrade manufacturing facilities to WHO standards and with higher costs of production were locked out of this market.

This has changed. Donors have taken some initiatives so that African manufacturers can access the medical products procured by them. For vaccines, Gavi, the Vaccine Alliance (GAVI) is the largest single purchaser for use in Africa. After the Partnerships for African Vaccine

Manufacturing (PAVM) was launched in 2021 to scale-up vaccine manufacturing in Africa, the AU Bureau of Heads of State and Government requested GAVI and other partners to buy at least 30% of the vaccines produced in the continent for global consumption. GAVI has responded by taking several initiatives, the most important being the proposed African Vaccine Manufacturing Accelerator (AVMA) awaiting final decision by the GAVI Board. It will provide early years financial support to African manufacturers to offset the higher initial costs of obtaining WHO prequalification. The goal is to help African manufacturers to win some tenders. The African firms still have to compete. The plan is not to restrict competitive bidding to African manufacturers even when supplying WHO prequalified products.

The Global Fund no longer uses price as the only factor. It uses the “total landed cost” which also considers other factors such as shorter supply times (Banda et.al 2022, p. 51). As a result, it has started buying some products such as antimalarials, insecticide treated nets for malaria from Africa-based manufacturers. The Global Fund acknowledges the importance of localized manufacturing for improving equitable access to medical products and recognises the need of buying from local firms in Africa. It has plans to explore procuring HIV rapid diagnostic tests manufactured in Africa including through an accelerated process for regulatory approval. But the Global Fund too does not propose to restrict tendering to African manufacturers. It insists on cost competitiveness. To quote the Executive Director of the Global Fund, Sands (2023): “When millions of people in Africa are still denied access to lifesaving medicines because of affordability, it is hard to justify paying more than a very modest or transitional premium for African-manufactured health products.”

Thus, despite the devastating experiences during the COVID-19 pandemic, the contradiction between local production and access to medicines continues to be highlighted in influential circles. If bidding is restricted to those who set up plants to satisfy the quality standard insisted on by the donors, then it will be a very effective way of providing the market and incentivising local production. Adequate local competition can ensure that local firms do not take advantage of the protected market. Moreover, with experience local firms are expected to be more competitive over time.

If even temporary higher prices are not acceptable, if based on the apprehension that prices will be higher, competitive bidding is not restricted to African manufacturers, then with no certainty that they will be able to access the market, African manufacturers may not be keen to undertake the necessary investments and hence import dependence may continue. Higher prices may not be desirable. But is the situation witnessed during the COVID-19 pandemic when despite the best intentions and efforts of donors and others, Africa was unable to get any supplies from competitive sources any better?

Bibliography

Abbott, Frederick (2023) *Intellectual Property (IP) and Technology Transfer for COVID-19 Vaccines: Assessment of the Record*, World Intellectual Property Organization (<https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf>).

African Union (2012) *Pharmaceutical Manufacturing Plan for Africa: Business Plan*, in partnership with UNIDO (https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf).

African Union and Africa CDC (2022) *Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action* (<https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>)

Amsden, Alice H (1989) *Asia's Next Giant: South Korea and Late Industrialization*, Oxford: Oxford University Press.

Banda, Geoffrey et. al (2022) “The Localisation of Medical Manufacturing in Africa”, Institute for Economic Justice, Johannesburg, South Africa (https://oro.open.ac.uk/87114/1/IEJ-LoMMiA-report_Nov2022.pdf).

Chang, Ha-Joon (2002) *Kicking away the Ladder: Development Strategy in Historical Perspective*, London: Anthem Press.

Chaudhuri, Sudip (2005) *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS and Developing Countries*, New Delhi: Oxford University Press.

Chaudhuri, Sudip (2016) “Can Foreign Firms Promote Local Production of Pharmaceuticals in Africa?” in Mackintosh et.al 2016.

Chaudhuri, Sudip (2020a) “Making Covid-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS Flexibilities”, *Southviews*, No 200, June 2020, South Centre (<https://www.southcentre.int/wp-content/uploads/2020/06/SouthViews-Chaudhuri.pdf>).

Chaudhuri, Sudip (2020b) “Evolution of the Pharmaceutical Industry in Bangladesh, 1982 to 2020”, Working Paper No 495, Centre for Development Studies, Trivandrum (<https://cds.edu/wp-content/uploads/WP495Sudip.pdf>).

Chaudhuri, Sudip (2022a) “Patent Protection and Access to Covid-19 Medical Products in Developing Countries”, in M Dutta, Z Husain and A K Sinha (eds), *The Impact of Covid-19 on India and the Global Order*, Springer, 2022 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=39023140).

Chaudhuri, Sudip (2022b) “COVID-19 Vaccines, Patent Barriers and Local Production in Developing Countries”, edited version of a study commissioned by LDC Watch/SAAPE (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4293565).

Chaudhuri, Sudip and Alastair West (2014) “Can local producers compete with low-cost imports? A simulation study of pharmaceutical industry in low-income Africa”, *Innovation and Development*, November. The paper can be accessed from: https://www.researchgate.net/publication/272120208_Can_local_producers_compete_with_low-cost_imports_A_simulation_study_of_pharmaceutical_industry_in_low-income_Africa#fullTextFileContent.

Clinton Health Access Initiative (2022) *LVM Landscaping Takeaways*, (<https://chai19.wpenginepowered.com/wp-content/uploads/2021/10/LVM-Landscape-Summary-June-01-2022.pdf>), accessed 17 October, 2022. As this report has cautioned, not all capacity announced expected to materialize.

Conway, Michael et.al (2019) “Should sub-Saharan Africa make its own drugs?”, January (<https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs>).

Correa, Carlos M. (2021) “Expanding the Production of COVID-19 Vaccines to Reach Developing Countries: Lift the Barriers to Fight the Pandemic in the Global South”, South Centre, Policy Brief No 92, April (<https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>).

Frischtak, Claudio R (1994) “Learning and Technical Progress in the Commuter Aircraft Industry: an Analysis of Embraer’s Experience”, *Research Policy*, 23, pp 601-612.

Gozzi, Nicolo (2023) “Estimating the impact of COVID-19 vaccine inequities: a modeling study”, *Nature Communications*, 6 June (<https://www.nature.com/articles/s41467-023-39098-w>).

Harwit, Eric (2008) *China’s Telecommunications Revolution*, Oxford; Oxford University Press

Mackintosh, Maureen et.al (eds.) (2016) *Making Medicines in Africa: Political Economy of Industrializing for Local Health*, Houndmills: Palgrave Macmillan (<https://link.springer.com/book/10.1007/978-1-137-54647-0>).

Makenga, Geoffrey et. al (2022) “COVID-19 vaccine development, production and regulatory oversight in African countries”, *Bull World Health Organ* 2022 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9511670/pdf/BLT.22.287958.pdf>).

Mazzucato, Mariana (2013) *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, London: Anthem Press.

Momeni, Yalda (2023) *Gavi's Strategy to Support African Regional Manufacturing* (<https://www.unicef.org/supply/media/19216/file/UNICEF-VIC2023-Session12-AVMAUpdate-Gavi-2023.pdf>).

Moore, Sam et al (2022) “Retrospectively modeling the effects of increased global vaccine sharing on the COVID-19 pandemic”, *Nature Medicine*, 27 October (<https://www.nature.com/articles/s41591-022-02064-y>).

Sands, Peter (2023) “Taking A Smart Approach To Making Medicines in Africa Will Save Lives”, November (<https://www.forbes.com/sites/petersands/2023/11/07/taking-a-smart-approach-to-making-medicines-in-africa-will-save-lives/?sh=5ab8563e756a>).

Shadlen, Kenneth C (2023) “Technology Transfer for Production of COVID-19 Vaccines in Latin America” in In H. Sun, M. Sunder (eds.), *Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures*, Cambridge: Cambridge University Press.

Tibandebage, Paula et. al (2016) “Pharmaceutical Manufacturing Decline in Tanzania: How Possible is a Turnaround to Growth?” in Mackintosh et. al (2016).

UNCTAD (2011) *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies by the UNCTAD Secretariat*. United Nations (https://unctad.org/system/files/official-document/diaepcb2011d7_en.pdf).

UNDP (2016) *How Local Production of Pharmaceuticals can be Promoted in Africa: The case of the United Republic of Tanzania*. United Nations Development Programme (https://adphealth.org/upload/resource/Tanzania_Local_Production.pdf).

UN High Level Panel on Access to Medicines (2016) *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*. New York: United Nations Development Programme.

UNIDO, AVMI and WHO (2017) *Vaccine Manufacturing and Procurement in Africa*, 2017 (<https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>), accessed 18 October, 2023.

Wade, Robert (1990) *Governing the Market: Economic Theory and the Role of Government in East Asian Industrialization*. Princeton: Princeton University Press.

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](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext)).

West, Alastair and Geoffrey Banda (2016) “Finance and Incentives to Support the Development of National Pharmaceutical Industries” in Mackintosh et. al (2016).

WHO (2011) *Local Production for Access to Medical Products: Developing a Framework to Improve Public Health.* World Health Organization (https://iris.who.int/bitstream/handle/10665/77934/9789241502894_eng.pdf?sequence=1).

WHO (2023a) *Proposal for Negotiating Text of the WHO Pandemic Agreement* (https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf).

WHO (2023b) *Zero draft of the WHO CA+ for the Consideration of the Intergovernmental Negotiating Body at its Fourth Meeting* (https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf).

End Notes

¹ <https://covid19.trackvaccines.org/vaccines/approved/#vaccine-list>, accessed on 14 October, 2023.

² <https://covid19.trackvaccines.org/vaccines/approved/#vaccine-list>, accessed on 6 October, 2023.

³ <https://covid19.who.int/who-data/vaccination-data.csv>, accessed on 6 October, 2023.

⁴ <https://pandem-ic.com/the-50-least-vaccinated-countries-in-the-world/>, accessed on 8 October, 2023.

⁵ <https://www.who.int/publications/m/item/covid-19-vaccination-insights-report---24-april-2023>, accessed on 6 October, 2023.

⁶ All countries other than high-income countries, as per World Bank classification, viz., low, lower middle and upper middle countries have been considered as developing countries.

⁷ <https://ourworldindata.org/covid-vaccinations>, accessed on 14 October, 2023.

⁸ <https://github.com/UNDP-Data/Vaccine-Equity-Dashboard-Data/blob/main/Summary%20Statistics/vaccination-timeseries.csv#L1>, accessed 16 October, 2023.

⁹ <https://ourworldindata.org/covid-vaccinations>, accessed on 28 September, 2022.

¹⁰ <https://www.unicef.org/supply/covid-19-market-dashboard>, accessed on 6 October, 2023

¹¹ <https://www.unicef.org/supply/covid-19-market-dashboard>, accessed on 6 October, 2023.

¹² <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.

¹³ <https://pandem-ic.com/local-vaccine-manufacturing-pays-off/>, accessed on 9 October, 2023.

¹⁴ <https://www.unicef.org/supply/covid-19-market-dashboard>, accessed on 6 October, 2023.

¹⁵ Used the UNICEF Covid 19 Market Dashboard (<https://www.unicef.org/supply/covid-19-market-dashboard>), accessed on 6 October, 2023. “Production Locations” under “Vaccines”

list Vaccine Developer, Vaccine Name, Manufacturer and Country of Production. Countries not listed are considered to have no Covid 19 production facilities.

¹⁶ <https://www.who.int/initiatives/covid-19-technology-access-pool>, accessed on 25 October, 2023.

¹⁷ <https://medicinespatentpool.org/progress-achievements/licences>, accessed on 25 October, 2023.

¹⁸ US International Trade Commission Report on *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*, 2023 cited by Public Citizen and others, “Three Reasons to Support the TRIPS Decision Extension: Contributing to COVID-19 Test and Treatment Access through Overdue Action at WTO,” November, 2023 (https://www.citizen.org/wp-content/uploads/Three_reasons_support_TRIPS_extension_nov_28.pdf.pdf), accessed on 30 November, 2023.

¹⁹ <https://medicinespatentpool.org/licence-post/vaccine-mvc-cov1901>, accessed on 28 October, 2023; Abbott 2023, p. 49.

²⁰ <https://www.who.int/initiatives/covid-19-technology-access-pool>, accessed on 25 October, 2023; <https://medicinespatentpool.org/progress-achievements/licences>, accessed on 25 October, 2023.

²¹ Elaine Ruth Fletcher & Stefan Anderson, “Second World Local Production Forum Launches New Collaborations; Civil Society Protests IP Barriers,” 10 November, 2023, <https://healthpolicy-watch.news/second-world-local-production-forum-launches-new-collaborations-civil-society-protests-ip-barriers/>, accessed on 20 November, 2023.

²² For an assessment of the achievements of MPP and also the limitations of voluntary licensing model, see Chaudhuri 2020a.

²³ In fact, the chief executive of Pfizer is reported to have said – “I think it is nonsense and at this point of time it’s also dangerous.” See, Sarah, Newey, “WHO patent pool for potential Covid-19 products is ‘nonsense’, pharma leaders claim”, *The Telegraph*, 29 May, 2020 (<https://www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/>), accessed on 26 October, 2023.

²⁴ For a more elaborate critique of the TRIPS Waiver Decision, see Chaudhuri 2022b.

²⁵ Kerry Cullinan, “Draft Pandemic Accord: IP Waivers and Benefits for Sharing Pathogen Information Are In – For Now”, Health Policy Watch, 17 October, 2023 (<https://healthpolicy->

[watch.news/draft-pandemic-accord-ip-waivers-and-benefits-for-sharing-pathogen-information-are-in-for-now/](https://healthpolicy-watch.news/wp-content/uploads/2023/10/advance-DRAFT_Negotiating-Text_INB-Bureau_16-Oct-2023.pdf)), accessed on 28 October, 2023. The text was released in advance by Health Policy Watch (https://healthpolicy-watch.news/wp-content/uploads/2023/10/advance-DRAFT_Negotiating-Text_INB-Bureau_16-Oct-2023.pdf).

²⁶ Thomas Cueni, “The Risk in Suspending Vaccine Patent Rules”, *New York Times*, 10 December, 2020 (<https://www.nytimes.com/2020/12/10/opinion/coronavirus-vaccine-patents.html>) cited in Chaudhuri 2022a.

²⁷ “Written statements by relevant stakeholders”, https://apps.who.int/gb/inb/e/e_inb-7-written-statements.html , accessed on 11 November 2023.

²⁸ See the text of the Political Declaration (<https://www.un.org/pga/77/wp-content/uploads/sites/105/2023/06/Zero-draft-PPPR-Political-Declaration-5-June.pdf>), accessed on 15 October, 2023).

²⁹ South Centre Statement to the High Level Meeting on Pandemic Prevention, Preparedness and Response, 20 September 2023 <https://www.southcentre.int/wp-content/uploads/2023/09/Statement-of-the-SC-to-the-HLM-on-PPR.pdf>, accessed on 15 October, 2023).

³⁰ “African Union and Africa CDC launches Partnerships for African Vaccine Manufacturing (PAVM), framework to achieve it and signs 2 MoUs”, 12-13 April, 2021 (<https://africacdc.org/news-item/african-union-and-africa-cdc-launches-partnerships-for-african-vaccine-manufacturing-pavm-framework-to-achieve-it-and-signs-2-mous/>).

³¹ “African Development Bank’s Board approves landmark institution: Establishment of African Pharmaceutical Technology Foundation to transform Africa’s pharmaceutical industry”, 27 June, 2022 (<https://www.afdb.org/en/news-and-events/press-releases/african-development-banks-board-approves-landmark-institution-establishment-african-pharmaceutical-technology-foundation-transform-africas-pharmaceutical-industry-52727>).

³² “African Development Fund invests over \$6 million to develop the pharmaceutical sector in Southern and Eastern Africa”, 11 November, 2022 (<https://www.afdb.org/en/news-and-events/press-releases/african-development-fund-invests-over-6-million-develop-pharmaceutical-sector-southern-and-eastern-africa-56398>).

³³ *Expanding Sustainable Vaccine Manufacturing in Africa: Priorities for Support*, November 2022 (<https://www.gavi.org/sites/default/files/document/2022/Gavi-Expanding-Sustainable-Vaccine-Manufacturing-in-Africa-2022.pdf>) (Figure 4, p. 6).

³⁴ <https://www.unicef.org/supply/COVID-19-market-dashboard>, accessed on 6 October, 2023.

³⁵ *Current and Planned Vaccine Manufacturing in Africa: Results of a Joint Assessment by Africa CDC, CHAI and PATH*, August, 2023 (<https://africacdc.org/download/current-and-planned-vaccine-manufacturing-in-africa-results-from-a-joint-assessment-by-africa-cdc-chai-and-path/>).

³⁶ “FAQ - The mRNA vaccine technology transfer hub” (<https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq>), accessed on 25 November, 2011.

³⁷ Press Release of Moderna, “Moderna Finalizes Agreement with the Government of the Republic of Kenya to Establish an mRNA Manufacturing Facility”, 30 March, 2023 (<https://investors.modernatx.com/news/news-details/2023/Moderna-Finalizes-Agreement-with-the-Government-of-the-Republic-of-Kenya-to-Establish-an-mRNA-Manufacturing-Facility/default.aspx>).

³⁸ Press Release of Pfizer, “Pfizer and BioNTech Announce Collaboration with Biovac to Manufacture and Distribute COVID-19”, July 21, 2021 (<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac>); Carley Petesch , “BioNTech to work with Senegal, Rwanda to Make mRNA Vaccines”, October 26, 2021 , <https://apnews.com/article/coronavirus-pandemic-business-health-rwanda-coronavirus-vaccine-f800599b45c433f09a03bdd625c46ddb>.

³⁹ Press Release of BioNTech, June 23, 2022, “BioNTech Starts Construction of First mRNA Vaccine Manufacturing Facility in Africa”, <https://investors.biontech.de/news-releases/news-release-details/biontech-starts-construction-first-mrna-vaccine-manufacturing>.

⁴⁰ Another developed country vaccine developer, Johnson & Johnson provided technology to Aspen of South Africa to manufacture its COVID-19 vaccine. But the project failed to take off African countries were reluctant to buy Aspen’s viral vector vaccine because of the availability of free doses through donations and also because of the preference for mRNA vaccines. See, “Africa CDC warns COVID-19 vaccine production could cease”, *The Lancet*, Vol 399, April 30, 2022 (<https://www.thelancet.com/action/showPdf?pii=S0140-6736%2822%2900775-9>); Kerry Cullinan, “Important Lessons From the African Vaccine Manufacturer That Could Not Sell a Single Dose”, 11 May, 2023 (<https://healthpolicy-watch.news/important-lessons-from-the-african-vaccine-producer-that-never-sold-a-single-dose/>).

⁴¹ Sara Jerving and Jenny Lei Ravelo, “Prospects for local manufacturing of Covid-19 vaccines in Africa”, 6 January 2022 (<https://www.devex.com/news/prospects-for-local-manufacturing-of-covid-19-vaccines-in-africa-102300>); “FAQ - The mRNA vaccine technology transfer

hub”, (<https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq>), accessed on 18 October 2023.

⁴² This account of the mRNA hub is primarily based on information available in the WHO website, <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub>, accessed on 18 October, 2023.

⁴³ This account of CEPI is based on information available in the CEPI website, <https://cepi.net/about/whoweare/>; https://cepi.net/news_cepi/cepi-and-bio-farma-partnership-boosts-rapid-response-vaccine-manufacturing-for-the-global-south/) accessed on 25 October, 2023.

⁴⁴ The term is used to refer to the economic policies that three Washington based institutions – the International Monetary Fund, the World Bank, and the U.S. Department of the Treasury started prescribing in the 1990s for the countries in distress which approached them for financial and other assistance.

⁴⁵ “African Pharmaceutical Technology Foundation receives strong endorsement at AfDB Annual Meetings in Sharm El-Sheikh”, <https://www.dailynewsegypt.com/2023/05/25/african-pharmaceutical-technology-foundation-receives-strong-endorsement-at-afdb-annual-meetings-in-sharm-el-sheikh/>.

⁴⁶ Public Citizen and others, “Three Reasons to Support the TRIPS Decision Extension: Contributing to COVID-19 Test and Treatment Access through Overdue Action at WTO,” November, 2023 (https://www.citizen.org/wp-content/uploads/Three_reasons_support_TRIPS_extension_nov_28.pdf.pdf).

⁴⁷ In this paper we focus only on vaccines and pharmaceutical products – not on diagnostics.

⁴⁸ The information in this para is based on Banda et.al 2022.

⁴⁹ *The Health Products Manufacturing Support Platform (HMSP): Enhancing Regional Manufacturing of Health Technologies in Africa*, UNITAID, AUDA-NEPAD and WHO (<https://unitaid.org/assets/HMSP-Enhancing-Regional-Manufacturing-of-Health-Technologies-in-Africa.pdf>); see endnote 21 above.

⁵⁰ Burkina Faso has built its first pharmaceutical plant in 2022 to manufacture simple formulation products such as paracetamol. After visiting the plant, the Prime Minister of the country said that it was realized during the pandemic that the country needs to initiate pharmaceutical manufacturing. See, “Burkina Faso launches its first pharmaceutical production plant”, 24/08/2022, <https://www.africanews.com/2022/08/24/burkina-faso-launches-its-first-pharmaceutical-production-plant/>), assessed on 24 October, 2023.

⁵¹ *AfCFTA: A New Era for Global Business and Investment in Africa: Insight Report*, January 2023

(https://www3.weforum.org/docs/WEF_Friends_of_the_Africa_Continental_Free_Trade_Area_2023.pdf).

⁵² “List of Least Developed Countries (as of 25 August 2023)”

(https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf), accessed 11 October 2023

⁵³ The discussion on pharma markets in Africa is based on the studies that the author did for UNIDO and UNDP including those which have been published – Chaudhuri 2016, UNDP 2016 and Chaudhuri and West 2014.

⁵⁴ The international reference prices considered in the study were the average (median) prices at which the products were available for purchase in 2012 by national and international drug procurement agencies through competitive bidding. Hence these prices can be considered to be the cheapest prices at which medicines were bought and sold.