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## A response to COVID-19 and beyond: Expanding African capacity in vaccine production

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22 May 2023

# A Response to COVID-19 and Beyond: Expanding African Capacity in Vaccine Production

Carlos M. Correa



 **SOUTH  
CENTRE**





# RESEARCH PAPER

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## A RESPONSE TO COVID-19 AND BEYOND: EXPANDING AFRICAN CAPACITY IN VACCINE PRODUCTION

Carlos M. Correa<sup>\*</sup>

SOUTH CENTRE

22 MAY 2023

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## ABSTRACT

The unequal global distribution of vaccines against the deadly COVID-19 virus has cast a spotlight on the lack of access to vaccines on the African continent, and the vulnerability that such a lack places on both the economies of African nations and the health of their people. Various initiatives have been launched to overcome the dependence of African nations on vaccines produced elsewhere. If implemented in timely and effective ways, those initiatives will contribute to the diversification of African economies and strengthen the capacity of nations on the continent to address their public health needs during pandemics and at other times. While establishing a viable vaccine industry on the continent presents serious challenges, the African Continental Free Trade Area (AfCFTA) can provide the framework for leveraging economies of scale to stimulate the production of needed vaccines across the region.

*La répartition mondiale inégale des vaccins contre le virus mortel de la COVID-19 a mis en lumière le manque d'accès aux vaccins sur le continent africain et la vulnérabilité que ce manque fait peser sur les économies des nations africaines et sur la santé de leurs populations. Diverses initiatives ont été lancées pour surmonter la dépendance des nations africaines vis-à-vis des vaccins produits ailleurs. Si elles sont mises en œuvre de manière opportune et efficace, ces initiatives contribueront à la diversification des économies africaines et renforceront la capacité des nations du continent à répondre à leurs besoins en matière de santé publique pendant les pandémies ainsi qu'à d'autres moments. Si la mise en place d'une industrie viable du vaccin sur le continent présente de sérieux défis, la Zone de libre-échange continentale africaine (ZLECA) peut fournir le cadre permettant de tirer parti des économies d'échelle pour stimuler la production des vaccins nécessaires dans toute la région.*

*La desigualdad en la distribución mundial de vacunas contra el mortal virus de la COVID-19 ha destacado la falta de acceso a las vacunas en el continente africano y la vulnerabilidad que esa falta genera, tanto en las economías de las naciones africanas como en la salud de sus pueblos. Se han lanzado varias iniciativas para superar la dependencia de las naciones africanas de las vacunas producidas en otros países. Si se implementan de manera oportuna y efectiva, esas iniciativas contribuirán a la diversificación de las economías africanas y fortalecerán la capacidad de las naciones del continente para suplir sus necesidades de salud pública durante las pandemias y en otros momentos. Si bien establecer una industria de vacunas viable en el continente representa serios desafíos, el Área de Libre Comercio Continental Africana (AfCFTA) puede proporcionar el marco para aprovechar las economías de escala para estimular la producción de las vacunas necesarias en toda la región.*





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## I. INTRODUCTION

The unequal global distribution of vaccines and the low rate of vaccination in Africa against COVID-19 have revealed a great weakness of the African continent: its lack of vaccine manufacturing capacity. Despite being home to 17 percent of the world's population, less than 1 percent of vaccines used around the globe -against more than 20 life-threatening diseases- are produced in Africa.<sup>1</sup> This overwhelming dependence of African nations on vaccines has triggered the reaction of African leaders and institutions, as well as of the World Health Organization (WHO). A number of initiatives have been introduced to increase self-sufficiency in the vaccine sector.

The search for greater autonomy in the production of vaccines in Africa, and more generally in that of pharmaceuticals, predates the COVID-19 pandemic. The imposition of restrictions during the COVID-19 crisis by several governments on the export of medicines and other medical products,<sup>2</sup> and the supply shortage caused by the sudden increase in demand, highlighted the dependence of many countries on imports in a critical sector for public health (and the economy). Alerts about this situation were sounded in developed countries as well, as discussed below.

Global asymmetries in the production of pharmaceuticals, including vaccines, have been noted in many studies and reports. While many developing countries manufacture medicines, their value-added contribution—with the noticeable exception of China and India—is often limited to the formulation of imported active pharmaceutical ingredients.<sup>3</sup> In the case of vaccines, again with some exceptions,<sup>4</sup> the manufacturing process conducted in developing countries is generally limited to the last step of production, known as “fill and finish,”<sup>5</sup> often under manufacturing contracts with major vaccine producers based abroad.

Several organizations have studied and proposed expanding the capacity of developing countries to manufacture pharmaceuticals. A 2011 report by the United Nations Conference on Trade and Development (UNCTAD) encouraged both developing countries and least developed countries (LDCs) to expand pharmaceutical manufacturing capacity. Most of LDCs are in Africa and are not yet subject to the obligation to recognize patents imposed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).<sup>6</sup> The UNCTAD report, however, noted possible tensions between local production and the achievement of public-health objectives (which include the availability of

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<sup>1</sup> Toyin Abiodun, Hayley Andersen, Liya Temeselew Mamo, and Omaru Badara (OB) Sisay, *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 5. Accessed at <https://institute.global/sites/default/files/articles/Vaccine-Manufacturing-in-Africa-What-It-Takes-and-Why-It-Matters.pdf>.

<sup>2</sup> *Trade Measures Adopted by Countries in Response to COVID-19* (South Centre, April 2020). Accessed at <https://www.southcentre.int/covid-19/>.

<sup>3</sup> See, however, an analysis of the decline of local manufacturing in and exports of active pharmaceutical ingredients in India in the excellent study by T. C. James, Dinesh Kumar, and Deepika Chawla, *Public Policy and Economic Development Case Study of Indian Pharmaceutical Industry*, (RIS, 2021). Accessed at <https://www.ris.org.in/sites/default/files/Public%20Policy%20and%20Economic%20Development%20Case%20Study%20of%20Indian%20Pharmaceutical%20Industry-min.pdf>.

<sup>4</sup> Such as the production of active pharmaceutical ingredients in the Oxford/AstraZeneca vaccine against COVID-19 by a firm in Argentina, mAbxience News: “mAbxience enters into an Agreement with AstraZeneca to Produce Covid,-19 Vaccine,” (August 17, 2020). Accessed at <https://www.mabxience.com/mabxience-enters-into-an-agreement-with-astrazeneca-to-produce-covid-19-vaccine/>.

<sup>5</sup> Eric Monticello, *Explainer: What Is Fill-Finish?* (CSL Behring, June 3, 2021). Accessed at <https://www.cslobehring.com/vita/2021/explainer-what-is-fill-finish>.

<sup>6</sup> South Centre, *Statement by the South Centre on the extension of the transition period for LDCs under the TRIPS Agreement* (June 2021). Accessed at <https://www.southcentre.int/wp-content/uploads/2021/07/SC-LDC-Extension-Statement-FINAL.pdf>.

affordable medicines) and recommended reviewing procurement practices and regional options, among other measures, to ensure markets for locally made medicines.<sup>7</sup> The UNCTAD 2011 report found that in Ethiopia, Tanzania, and Uganda, “significant gains in the local production of pharmaceuticals had been made,”<sup>8</sup> while it was in fact Bangladesh, also a least-developed country, that made the most progress in developing a strong pharmaceutical industry.<sup>9</sup>

Three years before the COVID-19 pandemic, a report produced jointly by the United Nations Industrial Development Organization (UNIDO), the African Vaccine Manufacturing Initiative (AVMI), and the WHO had signaled the need to increase vaccine production in Africa by developing the vaccine industry on the continent.<sup>10</sup> The report found that:

...developing vaccine production in Africa is a debatable and contentious question. As things stand, established external manufacturers and suppliers are responding to most of Africa’s funded demand. However, there is a place for existing and potential African manufacturers to develop their capacities for manufacturing in the next 10-20 years, when considering, for example, economic and population growth projections for the continent over the next 30 years. It must be noted that the conditions required for entering a new stage in a dynamic process such as this, in all aspects of manufacturing, are still to be studied.<sup>11</sup>

While there have been hesitations in Africa on the need to expand vaccine production and overcome the dependence of African nations on foreign-made vaccines, whether purchased or donated, these have been cast aside since the COVID-19 pandemic took hold.<sup>12</sup> Bolstering vaccine production has now become a priority for the continent. This paper discusses, first, recent progress towards greater autonomy in the manufacture of pharmaceuticals in Africa. Second, it presents an overview of the main features of the vaccine industry. Third, it examines the current capacity of African countries to produce vaccines and recent initiatives to increase local manufacturing. Fourth, it addresses the vaccine strategy put in place by the African Union (AU) and the factors that may contribute to its effective implementation, including the disciplines in the African Continental Free Trade Agreement (AfCFTA).

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<sup>7</sup> UNCTAD, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries* (United Nations, 2011). Accessed at [https://unctad.org/system/files/official-document/diaepcb2011d7\\_en.pdf](https://unctad.org/system/files/official-document/diaepcb2011d7_en.pdf).

<sup>8</sup> UNCTAD, *Local Production of Pharmaceuticals* (2011).

<sup>9</sup> South Centre, *The End of the Transition Period for Pharmaceutical Products under the TRIPS Agreement upon LDC Graduation: Implications for Bangladesh* (May 2020).

<sup>10</sup> UNIDO, AVMI, and WHO, *Vaccine Manufacturing and Procurement in Africa* (2017), 4. An analytical assessment of vaccine manufacturing capacity and procurement mechanisms for establishing sustainable vaccine manufacturing capacity in Africa. Accessed at <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>.

<sup>11</sup> UNIDO, AVMI, and WHO, *Vaccine Manufacturing and Procurement in Africa* (2017), 3. Accessed at <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>.

<sup>12</sup> Carlos Correa, “Vaccination inequalities and the role of the multilateral system,” *SouthViews* no. 224 (South Centre, July 19, 2021). Accessed at <https://www.southcentre.int/wp-content/uploads/2021/07/SouthViews-Correa.pdf>.

## II. SEEKING AUTONOMY<sup>13</sup>

The vulnerability of countries during the COVID-19 pandemic due to an uncertain supply of vaccines and other products needed to address the crisis calls attention to an often-neglected aspect of globalization: the dependence of some countries, including in the developed world, on imports of pharmaceuticals. Such dependence is of concern from the perspective not only of public health, but also of national security.<sup>14</sup> This is exemplified by the United States government's use of the Defense Production Act in 2020 to speed vaccine production.<sup>15</sup> At the height of the COVID-19 crisis, it was noted that Chinese pharmaceutical companies supplied 97 percent of the US market for antibiotics,<sup>16</sup> more than 90 percent of vitamin C, 95 percent of ibuprofen, and 91 percent of hydrocortisone, according to a report by Yanzhong Huang, a senior fellow for global health at the Council on Foreign Relations. The report found a global dependence in US markets on imported active pharmaceutical ingredients of about 80 percent.<sup>17</sup> The same report found the United States to be similarly dependent on firms in India for the production of antibiotics, painkillers, hormones, antiviral drugs, and vitamins B1, B6, and B12.<sup>18</sup>

Similarly, 80 percent of active pharmaceutical ingredients of medicines marketed in the European Union are imported, also mainly from China and India; the need to reduce this external dependence emerged during the COVID-19 pandemic as a common and urgent objective for the European Union, where policy makers have considered granting financial incentives to relocate the production of active pharmaceutical substances to Europe.<sup>19</sup> According to the European Union's Commissioner for Health and Food Safety, "It is now more evident than ever that we need a strategic approach to limit dependence on manufacturers and countries and that the means to produce essential medicines in the [European Union] must be created."<sup>20</sup> The response to this situation is also reflected in the

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<sup>13</sup> This section is partly based on a report by Carlos Correa, "Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal," *SouthViews* no. 202 (South Centre, July 17, 2020). Accessed at <https://www.southcentre.int/wp-content/uploads/2020/07/SouthViews-Correa.pdf>.

<sup>14</sup> Katherine E. Bliss, Heidi J. Larson, and J. Stephen Morrison, *Vaccine Confidence & National Security in the Covid-19 Crisis* (Center for Strategic and International Studies). Accessed at <https://www.csis.org/features/vaccine-confidence-national-security-covid-19-crisis>. See also Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper no. 116 (South Centre, August 2020). Accessed at <https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf>.

<sup>15</sup> The Act was used to broker a deal between two pharmaceutical companies, Merck and Johnson & Johnson, to increase the vaccine supply. See, e.g., *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines*. Accessed at <https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html>. The Defense Production Act gives the US President, *inter alia*, the power to require a pharmaceutical company to share technology and data with a rival. See Olga Gurgula, *Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer*, Policy Brief no. 102 (South Centre, September 2021). Accessed at [https://www.southcentre.int/wp-content/uploads/2021/09/PB102\\_Accelerating-COVID-19-Vaccine-Production-via-Involuntary-Technology-Transfer\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2021/09/PB102_Accelerating-COVID-19-Vaccine-Production-via-Involuntary-Technology-Transfer_EN.pdf).

<sup>16</sup> The bipartisan proposal for the "Pasteur Act" aims at creating incentives for the development of new antibiotics in the United States. See Pew Charitable Trusts, *Legislation Aims to Jump Start Antibiotic Development to Battle Superbugs* (September 9, 2021). Accessed at <https://www.pewtrusts.org/en/research-and-analysis/articles/2021/09/09/legislation-aims-to-jump-start-antibiotic-development-to-battle-superbugs>.

<sup>17</sup> Yanzhong Huang, *The Coronavirus Outbreak Could Disrupt the U.S. Drug Supply?* (Council on Foreign Relations, March 5, 2020). Accessed at <https://www.cfr.org/in-brief/coronavirus-disrupt-us-drug-supply-shortages-fda>.

<sup>18</sup> Huang, *The Coronavirus Outbreak Could Disrupt the U.S. Drug Supply?*

<sup>19</sup> BAE Negocios, *La UE busca depender menos de Asia en el rubro medicamentos* (May 12, 2020). Accessed at <https://www.baenegocios.com/mundo/La-UE-busca-depender-menos-de-Asia-en-el-rubro-medicamentos-20200512-0042.html>.

<sup>20</sup> BAE Negocios, *La UE busca depender menos de Asia en el rubro medicamentos* (May 12, 2020). Accessed at <https://www.baenegocios.com/mundo/La-UE-busca-depender-menos-de-Asia-en-el-rubro-medicamentos-20200512-0042.html>.

“Pharmaceutical Strategy for Europe,” which includes the objective “to reduce direct dependence on raw materials from non-[European Union] countries.”<sup>21</sup> Asian countries have also begun to stress the strategic importance of domestic manufacturing, including India<sup>22</sup> and Japan, which announced subsidies for companies that repatriate factories.<sup>23</sup>

The recognition of the problems associated with dependence on imports of pharmaceuticals and the recognition of the strategic importance of a local pharmaceutical industry (including the production of vaccines), have occurred in the context of a deeper and more general reconsideration of the benefits of economic globalization.<sup>24</sup> The COVID-19 crisis has highlighted to governments around the world, including those of industrialized nations, the vulnerabilities of a production system based on global value chains. These value chains geographically fragment production processes to exploit economies of scale and lower labour costs.<sup>25</sup> Those vulnerabilities were exacerbated by the recent trade war launched by the United States against China by the Trump’s Administration<sup>26</sup> and later by the rise of economic nationalism amidst the COVID-19 pandemic,<sup>27</sup> as well as by “techno-nationalism” as a means to advance a state’s power on the international scene.<sup>28</sup>

These trends towards more government activism and protectionism among industrialized countries pose new challenges to developing countries. The nations in the developing world cannot provide the same level of support to existing or nascent industries as the more industrialized countries<sup>29</sup> and cannot offer comparable infrastructure, qualified human resources, and financing to enter such a race for autonomy. Increasing their manufacturing capacity in the technology-intensive sector of pharmaceuticals (including vaccines) would contribute to a much-needed diversification of their economies. This is particularly important in the case of countries that are overdependent on the production and export of commodities.<sup>30</sup> By creating or expanding their vaccine manufacturing capacity either individually or, as suggested in the report by UNIDO, AVMI, and WHO, with a regional approach, African and other developing countries would become more self-reliant and less

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<sup>21</sup> European Commission, *Pharmaceutical strategy for Europe* (November 25, 2020). Accessed at [https://ec.europa.eu/health/human-use/strategy\\_en](https://ec.europa.eu/health/human-use/strategy_en).

<sup>22</sup> Rajesh Roy, “India’s Leader Calls for Economic Self-Sufficiency, Promises Relief” (*The Wall Street Journal*, May 12, 2020). Accessed at <https://www.wsj.com/articles/indias-leader-calls-for-economic-self-sufficiency-promises-relief-11589306423>.

<sup>23</sup> “Globalisation unwound: Has covid-19 killed globalisation?” (*The Economist*, May 14, 2020).

<sup>24</sup> S. Javed Maswood, *Revisiting Globalization and the Rise of Global Production Networks* (Springer, 2018).

<sup>25</sup> Eduardo Bianchi and Carolina Szpak, “Cadenas globales de valor, comercio internacional y actuación empresarial,” *Revista Argentina de Investigación en Negocios* 1, no 1. (April 2015). Accessed at [https://redib.org/Record/oai\\_articulo1598814-cadenas-globales-de-valor-comercio-internacional-y-actuaci%C3%B3n-empresaria](https://redib.org/Record/oai_articulo1598814-cadenas-globales-de-valor-comercio-internacional-y-actuaci%C3%B3n-empresaria).

<sup>26</sup> Peter Lunenborg and Fernando Rosales, *Global Cooperation Instead of Confrontation* (South Centre, January 2021). Accessed at <https://www.southcentre.int/wp-content/uploads/2021/01/Global-Cooperation-Instead-of-Confrontation-FINAL.pdf>.

<sup>27</sup> Willy C. Shih, “Global Supply Chains in a Post-Pandemic World,” *Harvard Business Review* (September–October 2020). Accessed at <https://hbr.org/2020/09/global-supply-chains-in-a-post-pandemic-world>.

<sup>28</sup> ‘Techno-nationalism’ is based on the belief that the success of a nation can be determined by how well that nation innovates and diffuses technology across its people. See Yadong Luo, “Illusions of techno-nationalism,” *Journal of International Business Studies* (2021). Accessed at <https://link.springer.com/article/10.1057/s41267-021-00468-5>.

<sup>29</sup> As shown, for example, by the major differences in the size of recovery packages adopted in the context of the COVID-19 crisis. In 2020, advanced economies on average deployed about 24 percent of GDP in fiscal measures, compared with only 6 percent in emerging markets and less than 2 percent in low-income countries. See Kristalina Georgieva, “The Great Divergence: A Fork in the Road for the Global Economy” (*IMF Blog*, February 24, 2021). Accessed at <https://blogs.imf.org/2021/02/24/the-great-divergence-a-fork-in-the-road-for-the-global-economy/>.

<sup>30</sup> UNCTAD, *Commodities & Development Report 2021—Escaping from the Commodity Dependence Trap through Technology and Innovation* (Geneva, 2021). Accessed at [https://unctad.org/system/files/official-document/ditcom2021d1\\_en.pdf](https://unctad.org/system/files/official-document/ditcom2021d1_en.pdf).

vulnerable.<sup>31</sup> Given the characteristics of the vaccine industry, however, this will require sustained efforts and a conducive policy framework.

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<sup>31</sup> UNIDO, AVMI, and WHO, *Vaccine Manufacturing and Procurement in Africa* (2017). Accessed at <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>.



### III. THE VACCINE INDUSTRY

The global vaccine industry has been dominated by a small number of multinational enterprises based in developed countries, operating in an oligopolistic market structure. In 2014, for example, just four vaccine companies accounted for 85 percent of all global vaccine sales.<sup>32</sup> According to the WHO, nearly one-third (32 percent) of vaccines are produced by fewer than four suppliers, while nearly two-thirds (63 percent) have two or fewer WHO prequalified products.<sup>33</sup> Unlike some other pharmaceuticals, vaccines are not available as generic products.<sup>34</sup>

The vaccine industry has been characterized by a lack of investment in research and development, but has historically received significant government support.<sup>35</sup> Vaccines typically take a long time to develop—five to seven years on average—and just one in 15 vaccines in development reach the market. Once developed, vaccine production is dependent on a large number of inputs by third-party producers while know-how is key in the production process which is subject to significant economies of scale.<sup>36</sup>

The vaccine industry is also capital intensive, particularly compared with the production of pharmaceuticals by chemical synthesis. Estimates of the cost of establishing a new manufacturing plant for vaccines vary. One study found that “[f]acilities can cost US\$50–500 million per antigen based on the high complexity of design, automation, segregation, utilities, and contamination controls, and as much as US\$700 million for multiple vaccines.”<sup>37</sup> The UNIDO, AVMI, and WHO report estimated the cost of building a manufacturing facility at between US\$60 million and US\$130 million.<sup>38</sup> More recently, the chief executive officer of South African company Biovac estimated that a facility capable of producing up to one billion doses of vaccines would cost between \$200 million and \$336 million.<sup>39</sup> Whatever the real

<sup>32</sup> Felix Lobo, *Restructuring the Global Vaccine Industry*, Research Paper no. 134 (South Centre, September 2021), 34. Accessed at

[https://www.southcentre.int/wp-content/uploads/2021/09/RP134\\_Restructuring-the-Global-Vaccine-Industry\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2021/09/RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf).

<sup>33</sup> UNCTAD, *COVID-19 heightens need for pharmaceutical production in poor countries* (May 27, 2020).

Accessed at <https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries>.

<sup>34</sup> Improvements in regulations are still needed to put in place abbreviated pathways for the marketing approval of follow-on non-originator vaccines. See K.M. Gopakumar, Chetali Rao, and Sangeeta Shashikant, *Trade secrets protection and vaccines: The role of medicine regulatory agencies*, Briefing Paper (Third World Network, June 2021). Accessed at

[https://www.twn.my/title2/briefing\\_papers/twn/Trade%20secrets%20TWNBP%20Jun%202020%20Gopakumar%20et%20al.pdf](https://www.twn.my/title2/briefing_papers/twn/Trade%20secrets%20TWNBP%20Jun%202020%20Gopakumar%20et%20al.pdf).

<sup>35</sup> The support received by Western companies to develop COVID-19 vaccines has been exceptional, but in line with past practices. See, e.g., Anthony McDonnell and Flavio Toxvaerd, *How Does the Market for Vaccines Work?* (Center for Global Development, May 14, 2021). Accessed at <https://www.cgdev.org/blog/how-does-market-vaccines-work>. See also Mariana Mazzucato, Jayati Ghosh, and Els Torreale, “On waiving covid patents,” (*The Economist*, April 20, 2021), Accessed at <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torreale-on-waiving-covid-patents> (“In America alone, six vaccine companies have received an estimated \$12bn of public money. Development of the AstraZeneca/Oxford vaccine is estimated as having been 97% publicly funded.”). See also Richa Chintan, *Big Pharma—Maximum Earnings, Minimum Responsibilities*, August 23, 2021. Accessed at <https://www.newsclick.in/Big-Pharma%E2%80%93Maximum-Earnings-Minimum-Responsibilities>.

<sup>36</sup> Felix Lobo, *Restructuring the Global Vaccine Industry*, Research Paper no. 134 (South Centre, September 2021). Accessed at

[https://www.southcentre.int/wp-content/uploads/2021/09/RP134\\_Restructuring-the-Global-Vaccine-Industry\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2021/09/RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf).

<sup>37</sup> Stanley Plotkin, James M. Robinson, Gerard Cunningham, Robyn Iqbal, and Shannon Larsen, “The complexity and cost of vaccine manufacturing—An overview,” *Vaccine* 35, Issue 33 (July 24, 2017), 4069.

<sup>38</sup> UNIDO, AVMI, and WHO, *Vaccine Manufacturing and Procurement in Africa* (2017). Accessed at <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>.

<sup>39</sup> Toyin Abiodun et al., *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 13.

costs are,<sup>40</sup> they are considerably higher than for a plant producing pharmaceuticals through the process of chemical synthesis. Given the scale of such costs, countries willing to move forward in the production of vaccines will have to consider the amount of financial support needed and how to ensure, through appropriate procurement policies, sustained demand to avoid overcapacity or entirely frustrating an industrial project.

High capital investment, the need for qualified resources, a complex production function, and the tacit nature of production knowledge can, among other factors, explain the oligopolistic structure of the vaccine industry. A frequent argument has also been the low profitability of vaccine production. Although empirical information on this issue is lacking, prof. Scherer of Harvard University found a 56.4 percent price cost margin for vaccines, compared with an average of 28 percent for the manufacturing industry, suggesting that the industry is profitable.<sup>41</sup> Although the circumstances under which COVID-19 vaccines are being produced are exceptional—notably global demand and urgency by governments to obtain vaccines at whatever price they are available—the recent profitability of producers of vaccines against COVID-19 seems to widely confirm Scherer’s observation.<sup>42</sup>

Although the production of vaccines is more complex than that of most pharmaceutical products, many manufacturers in developed and developing countries<sup>43</sup> may be able to produce vaccines (including against COVID-19), in some cases by repurposing plants used to produce biologicals. One barrier, often noted during the current pandemic, has been the importance of know-how in vaccine production. In accordance with Gavi, the Vaccine Alliance,

Vaccine production involves high investment costs for research and development, and for production facilities. It also requires significant know-how. Know-how is difficult to acquire and so technology transfer requires a strong cooperative relationship between the partners. All these factors create barriers of entry into vaccine production.<sup>44</sup>

Access to know-how and data would allow new entrants to move fast. But developing the required know-how would not be impossible if scientific and industrial support is available for the various phases of manufacturing (active ingredient, formulation, and fill and finish). While many developing countries have the skills to produce vaccines with conventional

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<sup>40</sup> The African Development Bank aims to help finance at least two technology platforms for vaccine production, which will be capable of producing at least 300 million doses per year. They will need, in accordance with source, investments of up to US\$400 million. See Aisling Irwin, “How COVID spurred Africa to plot a vaccines revolution,” *Nature* (April 21, 2021). Accessed at <https://www.nature.com/articles/d41586-021-01048-1>.

<sup>41</sup> Felix Lobo, *Restructuring the Global Vaccine Industry*, Research Paper no. 134 (South Centre, September 2021), 6. Accessed at [https://www.southcentre.int/wp-content/uploads/2021/09/RP134\\_Restructuring-the-Global-Vaccine-Industry\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2021/09/RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf).

<sup>42</sup> Moderna’s profits on the COVID-19 vaccine could be as high as US\$14 billion (in 2019, it reported total revenue of US\$60 million). See “Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor” (*The New York Times*, October 10, 2021). Accessed at <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html>. Pfizer is reported to have obtained a 20 percent gross profit margin with its COVID-19 vaccine. See Pierre-Alexandre Sallier, “Efficace, l’ARN messenger s’avère aussi très rentable” (*Tribune de Genève*, August 10, 2021). Accessed at [https://www.tdg.ch/efficace-larn-messenger-savere-aussi-tres-rentable-846625366598?utm\\_source=sfmc&utm\\_medium=email&utm\\_campaign=TG\\_ED\\_9\\_ENG\\_EM\\_NL\\_MATIN\\_NOU\\_VELLE\\_XX\\_AO&utm\\_term=2021-08-10&utm\\_content=1498089](https://www.tdg.ch/efficace-larn-messenger-savere-aussi-tres-rentable-846625366598?utm_source=sfmc&utm_medium=email&utm_campaign=TG_ED_9_ENG_EM_NL_MATIN_NOU_VELLE_XX_AO&utm_term=2021-08-10&utm_content=1498089). See also Julia Kollwe, “A year that changed the world—and medical companies’ fortunes,” (*The Guardian*, September 11, 2021). Accessed at <https://www.theguardian.com/business/2021/sep/11/a-year-that-changed-the-world-and-medical-companies-fortunes>.

<sup>43</sup> CEPI, *CEPI Survey Assesses Potential COVID-19 Vaccine Manufacturing Capacity* (August 5, 2020).

Accessed at [https://cepi.net/news\\_cepi/cepi-survey-assesses-potential-covid-19-vaccine-manufacturing-capacity/](https://cepi.net/news_cepi/cepi-survey-assesses-potential-covid-19-vaccine-manufacturing-capacity/).

<sup>44</sup> WHO, *Key Concepts: Economics of Vaccine Production*. Accessed at [https://www.who.int/immunization/programmes\\_systems/financing/analyses/en/briefcase\\_vacproduction.pdf](https://www.who.int/immunization/programmes_systems/financing/analyses/en/briefcase_vacproduction.pdf).

technologies, some, such as Thailand<sup>45</sup> and China,<sup>46</sup> have also engaged in the development of vaccines based on the mRNA technology used by Moderna and Pfizer/BioNTech. If the companies that developed vaccines for COVID-19 had shared their know-how, supply could have been expanded and reached developing countries in a timely manner.<sup>47</sup> While a compulsory license system for know-how (in addition to the compulsory license system applied for patents) has not been implemented to date at either the national or regional level, governments may start to consider this option. Such a system is conceivable and would be compatible with the TRIPS Agreement.<sup>48</sup>

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<sup>45</sup> “Thailand’s very own mRNA vaccine ‘will be ready for use by yearend’” (*The Star*, July 22, 2021). Accessed at <https://www.thestar.com.my/aseanplus/aseanplus-news/2021/07/22/thailands-very-own-mrna-vaccine-will-be-ready-for-use-by-yearend>.

<sup>46</sup> Josephine Ma, “Domestic clinical trials planned for China’s mRNA Covid-19 vaccine,” (*South China Morning Post* July 22, 2021). Accessed at <https://www.scmp.com/news/china/science/article/3142084/domestic-clinical-trials-planned-chinas-mrna-covid-19-vaccine>.

<sup>47</sup> However, companies did not share their technologies despite the establishment, under WHO auspices, of a “technology access pool” designed with that end. See <https://www.who.int/initiatives/covid-19-technology-access-pool>.

<sup>48</sup> Olga Gurgula, *Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer*, Policy Brief no. 102 (South Centre, September 2021). Accessed at [https://www.southcentre.int/wp-content/uploads/2021/09/PB102\\_Accelerating-COVID-19-Vaccine-Production-via-Involuntary-Technology-Transfer\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2021/09/PB102_Accelerating-COVID-19-Vaccine-Production-via-Involuntary-Technology-Transfer_EN.pdf).

## IV. VACCINE PRODUCTION IN AFRICA

As noted in the UNCTAD report referred to above, some African countries, including those classified as least developed, have made significant gains in domestic production of pharmaceuticals (by chemical synthesis), with firms in these countries manufacturing a wide range of products. South Africa, Algeria, Ethiopia, Ghana, Nigeria, Egypt, and Tunisia currently undertake or have plans to initiate vaccine production,<sup>49</sup> although generally limited to the last stages of “fill and finishing” and packaging.<sup>50</sup>

Of the 40 vaccine manufacturers in 14 countries that are members of the Developing Countries Vaccine Manufacturers Network,<sup>51</sup> only one is African: the Biovac Institute based in Cape Town, South Africa, which currently delivers more than 25 million doses of measles, polio, and tuberculosis vaccines each year. “Sanofi and Pfizer have worked with Biovac for modernising its production site, transferring technology, and upskilling staff; only now is the plant capable of diversifying from packaging into fill and finish, and it is still some way off fully integrated manufacture” (Abodium et al., 2021).<sup>52</sup> The Institut Pasteur of Senegal is the only WHO pre-qualified vaccine manufacturer in Africa. It currently produces small quantities of yellow fever vaccines and has plans to expand manufacturing capacity at a new facility (the AfricAmaril project) and is developing other products.<sup>53</sup> Other initiatives for expanding COVID-19 vaccine production in Africa are summarized in Box 1.

### Box 1: Initiatives for COVID-19 vaccine production in Africa

Galenica (Morocco) has signed a deal with the Russian Direct Investment Fund to produce Russian Covid-19 vaccines.

Morocco and China National Biotec Group Company Limited signed two cooperation agreements on Covid-19 vaccine trials to allow Morocco to produce a vaccine.

The Federal government of Nigeria has announced plans to set up a vaccine production company in Nigeria to boost local COVID-19 Vx production.

Aspen Pharmacare signed a production agreement with Johnson & Johnson for “fill and finish” of the COVID-19 vaccine. A €600 million funding package will be provided by the International Finance Corp. in cooperation with the US International Development Finance Corp., DEG—the German Development Finance Institution, and Proparco, a subsidiary of France’s Agence Française de Développement. The fund includes money for the entire vaccine supply chain. Aspen aims to produce more than 500 million doses of the Johnson & Johnson single-dose vaccine by the end of 2022.

<sup>49</sup> Aisling Irwin, “How COVID spurred Africa to plot a vaccines revolution,” *Nature* (April 21, 2021). Accessed at <https://www.nature.com/articles/d41586-021-01048-1>.

<sup>50</sup> Institut Pasteur de Dakar is likely to be the first on the continent to manufacture the substance of vaccines in parallel with fill-and-finish. See Zainab Usman and Juliette Ovidia, *Is There Any COVID-19 Vaccine Production in Africa?* (CARNEGIE ENDOWMENT FOR INTERNATIONAL PEACE, September 13, 2021). Accessed at <https://carnegieendowment.org/2021/09/13/is-there-any-covid-19-vaccine-production-in-africa-pub-85320>.

<sup>51</sup> <http://www.dcvmn.org/>.

<sup>52</sup> Toyin Abiodun et al., *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 8. Accessed at <https://institute.global/sites/default/files/articles/Vaccine-Manufacturing-in-Africa-What-It-Takes-and-Why-It-Matters.pdf>.

<sup>53</sup> Toyin Abiodun et al., *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 8. Accessed at <https://institute.global/sites/default/files/articles/Vaccine-Manufacturing-in-Africa-What-It-Takes-and-Why-It-Matters.pdf>.

In Egypt, VACSERA plans to produce more than 200 million doses per year of the Sinovac coronavirus vaccine to cover national needs. A second factory is planned to produce around 1 billion doses per year.

BioNTech signed an agreement with the government of Rwanda and Institut Pasteur de Dakar in Senegal on the construction of the first mRNA vaccine manufacturing facility in Africa. It is scheduled to produce 50 million doses of the company's COVID-19 vaccine beginning in mid-2022.

Sources: Toyin Abiodun et al., *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 8-9. Accessed at <https://institute.global/sites/default/files/articles/Vaccine-Manufacturing-in-Africa-What-It-Takes-and-Why-It-Matters.pdf>; Ludwig Burger, "BioNTech eyes construction start for African mRNA vaccine factory in mid-2022" (*Reuters*, October 26, 2021). Accessed at [https://www.reuters.com/world/africa/BioNTech-says-aims-start-building-mrna-vaccine-factory-africa-mid-22-2021-10-26/?taid=617816c80fbc4500016cc66d&utm\\_campaign=trueAnthem:+Trending+Content&utm\\_medium=trueAnthem&utm\\_source=twitter](https://www.reuters.com/world/africa/BioNTech-says-aims-start-building-mrna-vaccine-factory-africa-mid-22-2021-10-26/?taid=617816c80fbc4500016cc66d&utm_campaign=trueAnthem:+Trending+Content&utm_medium=trueAnthem&utm_source=twitter); Shabtai Gold, "World Bank to finance vaccine production in Africa, increase fund to \$20B" (*Devex*, July 1, 2021). Accessed at <https://www.devex.com/news/world-bank-to-finance-vaccine-production-in-africa-increase-fund-to-20b-100284>; "Egypt to produce 1 billion Sinovac vaccines a year" (*Africanews*, September 1, 2021). Accessed at <https://www.africanews.com/2021/09/01/egypt-to-produce-1-billion-sinovac-vaccines-a-year/>.

In addition to the initiatives mentioned in Box 1, WHO and its COVAX partners have contributed to the creation of a COVID mRNA vaccine technology transfer hub with a South African consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities, and the Africa Centres for Disease Control and Prevention.<sup>54</sup> The purpose of this hub<sup>55</sup> is to expand the capacity of low- and middle-income countries to produce COVID-19 vaccines and scale up the manufacturing output through "a hub and spoke model to transfer a comprehensive technology package and provide appropriate training to interested manufacturers in low- and middle-income countries."<sup>56</sup>

The value of Africa's current vaccine market is estimated at US\$1.3 billion, and is expected to grow to US\$2.35 billion by 2030.<sup>57</sup> During the COVID-19 pandemic—which may have affected more people in the continent than reported<sup>58</sup>—a large investment has been made in vaccines manufactured outside Africa. For instance, the African Export-Import Bank

<sup>54</sup> WHO, *WHO supporting South African consortium to establish first COVID mRNA vaccine technology transfer hub* (June 21, 2021). Accessed at <https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>.

<sup>55</sup> Another regional hub with the same purpose is being established by the Pan American Health Organization (PAHO) with two partners in Argentina and Brazil. See PAHO, *PAHO selects centers in Argentina, Brazil to develop COVID-19 mRNA vaccines* (September 21, 2021). Accessed at <https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines>.

<sup>56</sup> WHO, *Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing* (April 16, 2021). Accessed at <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

<sup>57</sup> Toyin Abiodun et al., *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 6. Accessed at <https://institute.global/sites/default/files/articles/Vaccine-Manufacturing-in-Africa-What-It-Takes-and-Why-It-Matters.pdf>.

<sup>58</sup> "The World Health Organization (WHO) data found that fewer than 15 percent of covid-19 cases in African countries are correctly reported," from "Why you are not hearing about Covid-19 outbreaks in Africa," *Quartz Africa* (October 26, 2021). Accessed at <https://qz.com/africa/2079064/only-one-in-seven-cases-of-covid-19-in-africa-is-reported/>.

approved an outlay of US\$2 billion in February 2021 to support the acquisition of COVID-19 vaccines.<sup>59</sup>

If some funding received by African countries to tackle the pandemic by importing finished vaccines could have been directed to creating or strengthening vaccine manufacturing capacity on the continent, Africa could have transformed a major crisis into an opportunity for its development. Understandably, there was urgency to obtain vaccines from whatever reliable producer was available, but one of the lessons of the pandemic is that African dependence on imported vaccines can be overcome in the future if needed actions are taken.

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<sup>59</sup> "Afreximbank approves \$2 billion for African nations to secure COVID-19 vaccines" (*Reuters*, February 23, 2021). Accessed at <https://www.reuters.com/article/us-health-coronavirus-afreximbank-vaccin-idUSKBN2AN1JZ>.

## V. THE AFRICAN UNION STRATEGY

In August 2020, the AU's Bureau of Heads of State and Government endorsed a Continental COVID-19 Vaccine Development and Access Strategy aimed at the "Successful immunisation of a critical mass of the African population with one or several safe and efficacious COVID-19 vaccines." The strategy aims to establish "a sustainable vaccine development and manufacturing ecosystem in Africa" with the "proposed ambition to manufacture 60 percent of Africa's routine immunisation needs on the continent by 2040, aligned with the call for a New Public Health Order."<sup>60</sup>

Financing this initiative will be challenging, but not beyond the reach of the African Union and its partners. It is worth noting in this regard the approval of "The Team Europe initiative on manufacturing and access to vaccines, medicines, and health technologies in Africa" with the purpose of supporting "local vaccines manufacturing in Africa and tackl[ing] barriers on both supply and demand sides, backed by €1 billion from the European Union budget and the European development finance institutions."<sup>61</sup>

Implementing the AU strategy would require appropriate financing for setting up or expanding manufacturing facilities, training needed technical personnel, and a coordinated and active role by African States to support the long-term development of the industry consistently with the public health needs of the continent. As noted by Abiodun *et al.*, "with large, state-backed investments and grants to manufacturers for production of Covid-19 vaccines in richer countries, African manufacturers are likely to face an uneven playing field and higher unit-production costs unless similar support is replicated."<sup>62</sup>

Appropriate procurement policies, the use of flexibilities permitted under the TRIPS Agreement to overcome eventual barriers imposed by intellectual property rights,<sup>63</sup> and an adequate regulatory framework for the marketing approval of vaccines will be essential components of the African vaccine production strategy. The pandemic has actually "prompted calls to accelerate efforts to establish an African Medicines Agency (AMA)—similar to the European Medicines Agency (EMA)—which would provide national African regulators with regulatory guidance on new medicines, as the EMA does in Europe."<sup>64</sup>

South-South and Triangular cooperation can make a critical contribution to executing the AU strategy. Such cooperation has expanded in scope and intensity in recent years, as reflected in the outcome document of the BAPA+40 Conference in 2019, which marked the 40th anniversary of the Buenos Aires Plan of Action for Promoting and Implementing Technical

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<sup>60</sup> African Union and Africa CDC launch Partnerships for African Vaccine Manufacturing (PAVM), framework to achieve it and signs 2 MoUs (African Union, April 16, 2021). Accessed at <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/>.

<sup>61</sup> European Commission, €1 billion Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (May 21, 2021). Accessed at [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_2594](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594).

<sup>62</sup> Toyin Abiodun et al., *Vaccine Manufacturing in Africa: What It Takes and Why It Matters* (Tony Blair Institute for Global Change, 2021), 13. Accessed at <https://institute.global/sites/default/files/articles/Vaccine-Manufacturing-in-Africa-What-It-Takes-and-Why-It-Matters.pdf>.

<sup>63</sup> See on this matter, e.g., Carlos Correa, *Interpreting the Flexibilities Under the TRIPS Agreement*, Research Paper no. 132 (South Centre, June 2021). Accessed at <https://www.southcentre.int/wp-content/uploads/2021/06/RP-132.pdf>; Yousuf A. Vawda and Bonginkosi Shoji, *Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa*, Research Paper no. 103 (South Centre, February 2020). Accessed at [https://www.southcentre.int/wp-content/uploads/2020/02/RP103\\_Eighteen-Years-After-Doha-An-Analysis-of-the-Use-of-Public-Health-TRIPS-Flexibilities-in-Africa\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2020/02/RP103_Eighteen-Years-After-Doha-An-Analysis-of-the-Use-of-Public-Health-TRIPS-Flexibilities-in-Africa_EN.pdf).

<sup>64</sup> See Aisling Irwin, "How COVID spurred Africa to plot a vaccines revolution," *Nature* (April 21, 2021). The project, led by the African Union and the Africa CDC, will cost US\$100 million.

Cooperation among Developing Countries.<sup>65</sup> Several developing countries, including India, China, Cuba, Brazil, and Argentina, have significant capacities in vaccine production and may provide knowledge, equipment, and other support to African countries. Notably—and in contrast to some Western companies—vaccine producers from developing countries that have developed their own vaccines for COVID-19 are active in the transfer of technology to partners in developing countries.<sup>66</sup>

Of course, many issues would have to be addressed in implementing the AU strategy. It is unclear, for example, how many vaccine manufacturers the continent could host to ensure the achievement of industrial and public health objectives. It is also uncertain how to attract a large number of manufacturers but still ensure their economic viability.<sup>67</sup> Also in question is what vaccines<sup>68</sup> will be manufactured and whether mRNA technology, given its advantages in terms of cost and speed of production at scale,<sup>69</sup> is likely to become dominant in vaccine production.<sup>70</sup>

The African Continental Free Trade Agreement may play a significant role in ensuring the viability of vaccine production in the continent.<sup>71</sup>

While at present no African country is implementing preferential tariff concessions under the agreement, pursuant to the Ministerial Directive on the application of Provisional Schedules of Tariff Concessions adopted by the 7<sup>th</sup> Council of Ministers responsible for Trade in charge of the AfCFTA on October 10, 2021, State Parties that attained a level of liberalization of 90 percent in terms of tariff lines will start implementing tariff concessions (vis-à-vis other State Parties that have done the same, in line with the principle of reciprocity).<sup>72</sup> The tariff treatment that vaccines and vaccine inputs receive within the continent will influence the possibility of domestic producers to compete with foreign producers, reach economies of scale, and reduce costs. If vaccines and vaccine inputs are given preferential access or duty-free status in intra-African trade, it could stimulate the production of vaccines in Africa.<sup>73</sup>

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<sup>65</sup> See <https://www.un.org/pga/73/wp-content/uploads/sites/53/2019/03/6March-Outcome-document-SSCooperation-6-March-2019.pdf>.

<sup>66</sup> See transfer of technology agreements for COVID-19 vaccines in <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>.

<sup>67</sup> In accord with the UNIDO, AVMI, and WHO report, *Vaccine Manufacturing and Procurement in Africa* (2017), 4, accessed at <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>, Africa can develop capacities in the next 10-20 years, but “there may be limited place for more than two or three sub-regional hubs.”

<sup>68</sup> There are different types of vaccines: conventional vaccines include Live-attenuated vaccines, Inactivated and Toxoid vaccines; more modern vaccines include subunit, recombinant protein, polysaccharide, and conjugate vaccines; Virus-like particles and Nucleic acid vaccines; mRNA vaccines are one of the most important development in the latter category.

<sup>69</sup> The manufacturing of mRNA vaccines is a cell-free, biochemical process performed with synthetic enzymes, according to David Verga, *mRNA and the future of vaccine manufacturing* (PATH, February 10, 2021). Accessed at <https://www.path.org/articles/mrna-and-future-vaccine-manufacturing/>.

<sup>70</sup> One disadvantage of mRNA vaccines, particularly in developing countries, is “because RNA is so fragile, all RNA vaccines would require ultra-cold chain storage, which carries enormous costs and significantly limits usability in countries with low- and middle-income economies.” David Verga, *mRNA and the future of vaccine manufacturing* (PATH, February 10, 2021). Accessed at <https://www.path.org/articles/mrna-and-future-vaccine-manufacturing/>.

<sup>71</sup> I thank Peter Lunenborg for the analysis of the possible impact of the AfCFTA on vaccine production and trade, as presented below.

<sup>72</sup> The first group of customs unions / countries expected to implement tariff concessions are: Economic and Monetary Community of Central Africa (CEMAC), Democratic Republic of the Congo, Economic Community of West African States (ECOWAS), Egypt, Madagascar, Mauritius, Seychelles, Zambia, and Zimbabwe. Other African countries will follow (e.g., Southern African Customs Union (SACU), Morocco, and Tunisia are well advanced to reach the threshold of 90 percent).

<sup>73</sup> There is no standardized list of Harmonized System (HS) / tariff line codes that represent vaccine inputs. Nonetheless, the WTO started reviewing this and published an information note on COVID-19 vaccine production



The Trade Facilitation commitments contained in Annex 4 to the Protocol on Trade in Goods of the AfCFTA Agreement are also relevant, as vaccines require many inputs from different locations. African countries have made divergent commitments under the WTO Trade Facilitation Agreement, as specific provisions can be allocated by each country in different categories. The AfCFTA Agreement incorporates provisions of the WTO Trade Facilitation Agreement, providing for harmonization in the level of commitments across African countries. Thus, Article 15—which may be applicable to vaccines and their inputs as perishable goods—incorporates the same commitments contained in Article 7.9 of the WTO Trade Facilitation Agreement (Articles 7.9.1 to 7.9.3; Article 7.9.4 has not been inserted in the AfCFTA Agreement text).

Conformity assessment procedures serve legitimate policy goals but might also hinder the flow of necessary medical goods. Article 5 of Annex 6 (Technical Barriers to Trade) to the Protocol on Trade in Goods of the AfCFTA Agreement provides that State Parties shall cooperate *inter alia* in the development and implementation of conformity assessment procedures, to facilitate trade within the AfCFTA. This Article is not very specific, but could be the basis for developing directives and guidelines under the AfCFTA Agreement. Possible measures might include committing State Parties to ensure their domestic regulations incorporate the WHO's Good Manufacturing Practices guidelines, or mutual recognition of inspections and approvals to ensure that quality assurance for vaccines produced in one country is valid for all.<sup>74</sup>

Finally, commitments around services, for instance, those related to the transport sector, might be relevant for the production and distribution of vaccines.<sup>75</sup>

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and tariffs on vaccine inputs. See WTO information note, October 8 2021. Accessed at [https://www.wto.org/english/tratop\\_e/covid19\\_e/vaccine\\_production\\_report\\_e.pdf](https://www.wto.org/english/tratop_e/covid19_e/vaccine_production_report_e.pdf).

<sup>74</sup> Carlos Kuriyama, *Promoting Trade in Vaccines and Related Supplies and Equipment*, Policy Brief no. 40 (APEC Policy Support Unit, May 2021). Accessed at [https://www.apec.org/docs/default-source/Publications/2021/5/Promoting-Trade-in-Vaccines-and-Related-Supplies-and-Equipment/221\\_PSU\\_Promoting-Trade-in-Vaccines-and-Related-Supplies-and-Equipment.pdf](https://www.apec.org/docs/default-source/Publications/2021/5/Promoting-Trade-in-Vaccines-and-Related-Supplies-and-Equipment/221_PSU_Promoting-Trade-in-Vaccines-and-Related-Supplies-and-Equipment.pdf).

<sup>75</sup> Under the AfCFTA Agreement, State Parties are submitting offers for liberalization in five priority sectors: business, communication, financial, tourism, and transport services. A total of 36 offers had been submitted when this article was published. While substantive progress had been made in negotiations in the five priority sectors, some work remained. Negotiations also were underway on cross-cutting regulatory frameworks.

## **VI. CONCLUSION**

The unequal distribution of COVID-19 vaccines hit the African continent particularly hard. The continent has the lowest rate of vaccination in the world, despite the efforts of African governments and donations from the United States, the European Union, China, and Russia, among others. The pandemic drew attention to the fact that 99 percent of vaccines administered on the African continent are not produced there.

The COVID-19 crisis represented a wake-up call for many countries, both developed and developing, that have become overly dependent on the supply of pharmaceuticals from outside their borders. Some developed countries seek greater autonomy in what they view now as a strategic sector, in a context of the rebirth of economic and techno-nationalism.

The oligopolistic structure of the vaccine industry at the time of the COVID-19 outbreak, with a few multinational enterprises dominating much of the market, reflected the many barriers to entry prevailing in this sector. Among those barriers were and still are its capital-intensive character, the role played by tacit knowledge and economies of scale, and long and risky processes of product development. Nevertheless, the emergence of new vaccine producers, many of them from developing countries, demonstrates room for diversification in the vaccine supply.

Africa can play a new role in this scenario. Some initiatives already underway, although initially limited to final stages of the manufacturing process, will increase vaccine production capacity on the continent. Developing a vaccine manufacturing industry in Africa will involve significant financial, technical, and regulatory challenges. It will be also crucial to improve or put in place adequate health delivery systems, procurement, and other supportive policies.

The AU initiative to satisfy 60 percent of African vaccine demand with production on the African continent by 2040 promises the possibility of transforming crisis into a major opportunity, to promote industrial development and to bolster self-sufficiency in addressing the health needs of the African population. To significantly expand vaccine production in Africa is a sound proposition, not just from a public health perspective, but also from an economic one, especially as economies of scale may be harnessed in the context of the AfCFTA Agreement.

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