

Re-thinking Global and Local Manufacturing of Medical Products After COVID-19

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RE-THINKING GLOBAL AND LOCAL MANUFACTURING OF MEDICAL PRODUCTS AFTER COVID-19

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ABSTRACT

The unprecedented global health crisis caused by the coronavirus (COVID-19) pandemic since the first quarter of 2020 has reopened the now-urgent discussion about the role of local pharmaceutical production in addressing the health needs in developing countries. The COVID-19 crisis has highlighted the interdependencies in the global production of pharmaceuticals—no country is self-sufficient. Many industrialized countries are making the decision to repatriate or initiate the production of active pharmaceutical ingredients (APIs) and medicines. Governments are beginning to talk about ‘pharmaceutical sovereignty’ or ‘health security’. If this becomes a reality and the production of pharmaceuticals is led by nationalistic policies, developing countries that still lack manufacturing capacity will have to start or expand the local production of pharmaceuticals, whether at the national or regional level. The war to get access to the future vaccine for COVID-19 does not look easy with these new developments.

La crisis sanitaria mundial sin precedentes provocada por la pandemia del coronavirus - COVID-19-, durante el primer semestre de 2020, hace que se vuelva a plantear con especial urgencia el debate sobre la producción farmacéutica local. La crisis de COVID-19 puso de manifiesto la interdependencia en la producción mundial de medicamentos, ningún país es autosuficiente. Muchos países industrializados están tomando la decisión de repatriar o desarrollar la producción de Ingredientes Farmacéuticos Activos (API). Muchos gobiernos están empezando a hablar de soberanía farmacéutica y/o seguridad sanitaria. Si esto se hace realidad, los países en desarrollo tendrán que desarrollar y/o fortalecer la producción local de medicamentos y vacunas. La guerra para obtener la futura vacuna para COVID-19 no parece fácil con estos nuevos desarrollos.

La crise sanitaire mondiale sans précédent provoquée par la pandémie de coronavirus (COVID-19), au cours du premier semestre 2020, ramène avec une urgence particulière la discussion sur la production pharmaceutique locale. La crise du COVID-19 a mis en évidence l'interdépendance de la production mondiale de médicaments—aucun pays n'étant autosuffisant. De nombreux pays industrialisés prennent la décision de rapatrier ou de développer la production de principes pharmaceutiques actifs (API). De nombreux gouvernements commencent à parler de souveraineté pharmaceutique et/ou de sécurité sanitaire. Si cela devient une réalité, les pays en développement devront développer et/ou renforcer la production locale de médicaments et de vaccins. La guerre pour obtenir le futur vaccin pour COVID-19 ne semble pas facile avec ces nouveaux développements.

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LIST OF ACRONYMS

ACT	Access to COVID-19 Tools (Accelerator)
AMC	Advance Market Commitment
API	active pharmaceutical ingredient
BARDA	Biomedical Advanced Research and Development Authority (United States)
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Global Vaccine Access (Facility)
COVID-19	Coronavirus disease
EU	European Union
FPP	finished pharmaceutical product
Gavi COVAX AMC	Gavi Advance Market Commitment for COVID-19 Vaccines
GPMB	Global Preparedness Monitoring Board (GPMB)
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property WHO
HICs	high income countries
IHR	International Health Regulations (2005)
LICs	low-income countries
LMICs	lower middle-income countries
LPP	local pharmaceutical production
MICs	middle income countries
NGOs	nongovernmental organizations
PHEIC	Public Health Emergency of International Concern
R&D	research and development
TAP	Tech Access Partnership
TWN	Third World Network
UN	United Nations
UNCTAD	United Nations Conference for Trade and Development
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization

INTRODUCTION

The objective of this document is to examine how the great challenge caused by COVID-19 in 2020 in the area of production of medicines and health products can be used as an opportunity to improve and strengthen access to medicines in developing countries: “Major crises bring about challenges but also opportunities. The strategic importance of a local pharmaceutical industry has been increasingly recognized as a result of the COVID-19 crisis. Developing countries should take advantage of this opportunity to strengthen their pharmaceutical industry, including biological medicines.”²

In the first section of the document (Background: The View of UN Agencies on Pharmaceutical Production in Developing Countries) the role of the United Nations (UN) agencies in the last 30 years is analyzed in relation to the local production³ of medicines. As examined there, although the United Nations Industrial Development Organization (UNIDO) and United Nations Conference on Trade and Development (UNCTAD) have tried to promote and support the local production of medicines, agencies such as the World Health Organization (WHO) have not been clear or have even advised against local production in developing countries.

In the second section (COVID-19 “Vaccine Nationalism”), the document analyzes the trends originated by the new realities that the health crisis has brought to light, notably the interdependence in terms of pharmaceutical production and the phenomenon that has been termed “vaccine nationalism”. This section also refers to the massive public subsidies to the private sector in some developed countries, without sufficiently clear rules and conditions.

Section III (COVID-19 Global Vaccine Access Facility), analyzes the role of the new initiative, the COVAX Facility, its shortcomings, and the concerns of some NGOs about the absence of conditions that should ideally accompany the unprecedented financial subsidies that have been largely granted with public funds.

Section IV (Global Preparedness Monitoring Board) shows that COVID-19 could not be regarded as a total surprise, something unexpected, – we had already been warned. In May 2011, a WHO document on pandemic influenza preparedness alerted countries to the “continuing risk of an influenza pandemic with potentially devastating health, economic and social consequences, particularly for developing countries, which have a higher disease burden and are more vulnerable”.

Section V (A COVID-19 Technology Sharing Platform: A UN recent initiative) addresses a recent (May 2020) initiative by three UN agencies, including WHO, to support access to technology for the local production of medicines and health products. It would seem that the challenge of COVID-19 has led the UN agencies to seek mechanism to improve access to technologies and thereby to medicines and other health products in developing countries.

The document concludes by noting that a reorganization of global pharmaceutical production could perhaps be beneficial to increasing access to medicines in developing countries, and States (public sector) should be more involved in the promotion of the production of essential

² Correa Carlos, “Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal”, SOUTHVIEWS No. 202 (South Centre, 17 July 2020). Available from <https://www.southcentre.int/southviews-no-202-17-july-2020/>.

³ For the purposes of this paper, “local production” refers to manufacturing of pharmaceuticals by local State-owned pharmaceutical companies, local private pharmaceutical companies, and joint-ventures of local private or State-owned and foreign pharmaceutical companies.

inputs for health systems. This could be an opportunity to ensure that health, rather than purely commercial gains, becomes the main objective of the pharmaceutical industry.

Finally, this paper does not refer to the necessary investments, technologies, scales of production, competitiveness etc., important aspects when talking about local production. The main objective of this document is to reopen the debate on an issue that had been somehow left aside and that now regains urgent relevance with the COVID-19 crisis.

I. BACKGROUND: THE VIEW OF UN AGENCIES ON PHARMACEUTICAL PRODUCTION IN DEVELOPING COUNTRIES⁴

The unprecedented global health crisis caused by the coronavirus disease (COVID-19) pandemic during the first quarter of 2020 has reopened the discussion about local pharmaceutical production, which has become now particularly relevant and urgent. The COVID-19 crisis has highlighted the global interdependence in the supply of pharmaceuticals. No country is self-sufficient. Many industrialized countries are taking the decision to repatriate or develop the production of active pharmaceutical ingredients (APIs). Many Governments are beginning to talk about pharmaceutical sovereignty and/or health security.⁵ If this becomes a reality,⁶ developing countries will have to begin and/or strengthen local production of medicines and vaccines. In particular, the war to obtain the future vaccine for COVID-19 does not look easy with these new developments as they may further concentrate the control over vaccines' production in a few developed countries. Currently, about 80 per cent of global vaccine sales come from five large multi-national corporations.⁷

As early as the 1980s, three agencies in the United Nations system were already interested in the local manufacturing of drugs in developing countries: UNIDO⁸ and UNCTAD, which provided technical assistance in the area of the transfer of technology in the pharmaceutical field,⁹ and WHO, which created the Action Programme on Essential Drugs.¹⁰

During its first 20 years, the WHO Action Programme on Essential Drugs gave priority to the development of national drug policies, and its position on drug manufacturing in developing countries was always ambiguous or openly contrary to it. Thus, Kapan and Laing stated in 2005 that "if a developing country with manufacturing facilities is able to finish off bulk active ingredients sourced from developed or other countries at high costs, such manufacture may have no impact whatever on patient access to needed medicines."¹¹

It is clear from the findings of Kaplan and Laing, (the latter was responsible for this area in the WHO Medicines Programme) that WHO was not, at that time, in favor of promoting the production of medicines in developing countries:

⁴ For the purposes of this paper, see Annex 1: "Basic Concepts and Definitions" for our definitions of pharmaceutical industry, local production, active pharmaceutical ingredients (APIs).

⁵ See e.g., Carlos Correa, "Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal", SOUTHVIEWS No. 202 (South Centre, July 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/07/SouthViews-Correa.pdf>.

⁶ See Nirmalya Syam, "EU Parliament adopts resolution on public health strategy post-COVID-19 based on use of TRIPS flexibilities to ensure access to health technologies" SOUTHVIEWS No. 329 (South Centre, 12 August 2020). Available from <https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=dc238cfbb4>.

⁷ See WHO, Vaccine market. Global Vaccine Supply, available at https://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/.

⁸ ONUDI « La croissance de l'industrie pharmaceutique dans les pays en développement : Problèmes et perspectives » (New York, 1980).

⁹ M. Stork, and S. Wanandi, "Guidelines and recommendations for the establishment of a low cost pharmaceutical plant" (UNCTAD, Geneva, 1980) p. 72.

¹⁰ Germán Velásquez, *Salud, medicamentos y Tercer Mundo*, (Madrid, IEPALA, 1986).

¹¹ Warren Kaplan and Richard Laing, "Local production of pharmaceuticals: industrial policy and access to medicines – an overview of key concepts, issues and opportunities for future research" (English). Health, Nutrition and Population (HNP) discussion paper. (Washington, DC: World Bank). Available from <http://documents.worldbank.org/curated/en/551391468330300283/Local-production-of-pharmaceuticals-industrial-policy-and-access-to-medicines-an-overview-of-key-concepts-issues-and-opportunities-for-future-research>.

“[O]ur preliminary conclusions are:

- In many parts of the world, there is no reason to produce medicines domestically since it makes little economic sense.
- In the local pharmaceutical manufacturing sector, local production is often not reliable and, even if reliable, it does not necessarily mean that medicine prices are reduced for the end user.
- If many countries adopt local production, the result may be less access to medicines, since production facilities in many countries may mean forgoing economies of scale.
- It may be possible for small country markets to be coordinated or otherwise joined together to create economies of scale. (...)
- For many countries, technical expertise, raw materials, quality standards, and production and laboratory equipment need to be imported, with the result that foreign exchange savings may be small or non-existent.
- Few developing countries have the capacity to produce active ingredients for pharmaceutical manufacture.”¹²

A WHO literature review of local production and access to medicines in low- and middle-income countries published in 2011 concludes:

- “We note the predominance of case studies and surveys and the relative lack of econometric and time series studies linking local production and access.
- Our brief review of the UNCTAD technology transfer literature does not suggest any robust attempt to link local production and access to medicines, but this may not be surprising, as technology transfer may be considered industrial rather than health policy, and the case study methodology is not strictly applicable to investigate such a link.
- The business and economic literature that we have seen also is concentrated on the upstream side (e.g., supply side, industrial policy, knowledge spillovers, innovation etc.) with seemingly little information on the downstream issues of local production and access to medicines.
- The public health literature on the subject of local production is directed predominantly towards the issue of intellectual property rights and access to medicines.
- It seems quite remarkable that many of the pricing surveys do not distinguish the price of local versus foreign producers on a product-by-product basis.
- There is an almost complete absence of information on the link between local production and access to medical devices. (...)”¹³

Local production has been a subject of discussion in the World Health Assembly (WHA) since the 1970s. Element 4 of the resolution 61.21 (2008) on a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)¹⁴ is about the promotion and transfer of technology, and the production of health products in developing countries is the first recommended action.

In this context, and as recommended by the GSPOA, a project to explore ways in which local production and technology transfer could be strengthened in a number of low- and middle-income countries was launched by WHO in 2009 in cooperation with UNCTAD. The project,

¹² Kaplan and Laing, “Local production of pharmaceuticals”.

¹³ WHO “Local production and access to medicines in Low- and middle-income countries A literature review and critical analysis”, (Geneva 2011). Available from https://www.who.int/phi/publications/Local_Production_Literature_Review.pdf?ua=1.

¹⁴ WHA 61.21 The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, 2008. Available from https://www.who.int/phi/implementation/phi_globstat_action/en/.

titled “Improving access to medicines in developing countries through technology transfer related to medical products and local production,” concluded in September 2016.

Several UNCTAD publications, in the context of this project, analyze and promote the local production of medicines in developing countries.

In the document “Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production”¹⁵ for instance, UNCTAD presents an overview of policy tools that developing countries may consider to create a framework conducive for promoting local pharmaceutical production and access to medicines: “As the promotion of local pharmaceutical production depends on the coordination of various areas of policy, such as drug regulation, research and development (R&D), investment, trade and intellectual property, the Tool Box emphasizes the importance of ensuring coherence among policies that at first sight appear unrelated to each other.”¹⁶

In another publication, “Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries”,¹⁷ UNCTAD analyses several case studies from Argentina, Bangladesh, Colombia, Ethiopia, Indonesia, Jordan Thailand and Uganda.

By giving concrete examples of successful technology transfer initiatives in the area of pharmaceutical production, the UNCTAD case studies “provide a number of important lessons for policy-makers and other stakeholders in both developing and developed countries on issues of investment, science, technology and innovation, and intellectual property rights.”¹⁸

In April 2017, WHO convened an interagency consultation to discuss local production of essential medicines. The meeting was held in Geneva and was attended by representatives of 14 international agencies. Given the position that WHO had held on the issue, not surprisingly, one of the conclusions of the consultation was: “*While it may be feasible to develop local production initially, commercial sustainability remains a challenge when the medicines and health products produced through local production can be more expensive than the commercially available alternatives including imported products*”.¹⁹

Interestingly, another UN agency, UNIDO, has held a position quite different from that dominating in WHO. Since 2006, UNIDO has provided technical cooperation and advisory services to advance local pharmaceutical production (LPP) in developing countries with a wide range of partners. Under a global project, UNIDO contributed to improving the operational environment and technical capacities of local manufacturers and helped “mainstream” LPP as a global development theme. This engagement has established UNIDO as a leading organization on the LPP agenda. For UNIDO, LPP is important for developing countries for several reasons:

¹⁵ UNCTAD, “Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production”. Available from https://unctad.org/en/PublicationsLibrary/diaepcb2017d2_en.pdf.

¹⁶ UNCTAD “Tool Box for Policy Coherence”.

¹⁷ UNCTAD, “Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries. A series of case studies by the UNCTAD Secretariat” Available from https://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf.

¹⁸ UNCTAD, “Local Production of Pharmaceuticals”.

¹⁹ WHO, “Report of the interagency consultation on local production of essential medicines and health products”, 25 April 2017, Available from <https://apps.who.int/iris/bitstream/handle/10665/255847/WHO-EMP-2017.02-eng.pdf?sequence=1>.

- “More than two billion people worldwide cannot get the medicines they need.
- LPP can help vulnerable populations, especially those in remote rural areas, to access quality medicines, thus contributing to “leaving no one behind, and reaching the furthest behind first, the overarching principle of the 2030 Agenda for Sustainable Development.
- LPP can reduce dependency on international donations and the shrinking number of overseas companies that dominate the global market.
- LPP is easier to control and can help curb the vast influx of substandard medicines into developing countries.”²⁰

All of the above seems to indicate that the position of WHO in contrast to other UN agencies, such as UNCTAD and UNIDO, has been that if the production capacity of developed countries is sufficient to supply the world market, it is not worth promoting the production of medicines in developing countries. As we will see below, this assumption is challenged by the nationalism in the production of medicines and vaccines that seems to have emerged with COVID-19.

²⁰ UNIDO, “Pharmaceutical production in developing countries” (Vienna, 2020). Available from <https://www.unido.org/our-focus-advancing-economic-competitiveness-investing-technology-and-innovation-competitiveness-business-environment-and-upgrading/pharmaceutical-production-developing-countries>.

II. COVID-19 “VACCINE NATIONALISM”

As noted, one of the realities that the health crisis caused by COVID-19 has made evident is the interdependence between all countries in terms of the production of medicines and vaccines. The pandemic has shown, for example, the extent to which developed countries depend on inputs from countries outside the United States (US) and the European Union (EU), notably from China and India.

Beyond the fights over drug markets or future vaccines related to the pandemic, the United States of America, Germany, France and the United Kingdom are now considering how to recover their pharmaceutical sovereignty in order to depend less on other countries.²¹

The European Commission launched an online public consultation on the Pharmaceutical Strategy for Europe. Coming in the wake of the COVID-19 pandemic, the Strategy, which will also inform the newly proposed EU4Health Programme and align with Horizon Europe for research and innovation, will aim to ensure Europe's supply of safe and affordable medicines to meet patients' needs and support the European pharmaceutical industry in remaining an innovator and world leader.²²

Stella Kyriakides, European Commissioner for Health and Food Safety, said: “The Pharmaceutical Strategy for Europe is a cornerstone of our policy in the area of health for the next five years, (...) we will be responding to the challenges amplified by the COVID-19 pandemic and all the structural issues on access, affordability and the strategic **autonomy** of our Union on medicines.”²³

The United States, the European Union and the United Kingdom have purchased the first 2.6 billion doses of vaccines currently in development. The United States Government has given more than \$11 billion to eight pharmaceutical companies in the “Operation Warp Speed” mostly for the development and manufacture of vaccines and has purchased more than 1.2 billion doses. By pre-purchasing doses from the most promising competitors in such large quantities, countries are hedging their bets on which vaccines will be approved first, and how many doses their immunity may require. The industrialized world will be supplied first, and the vaccine will take months or years to reach developing countries.²⁴

At the time the novel coronavirus started to spread in 2020, it was clear that the stocks or production capacity of masks or alcohol-based hand rub, breathing assistance devices or even the global capacity to produce vaccines, were unknown. Who were the producers and how could they respond to the quantities needed? Prices shot up and some countries imposed export restrictions.”²⁵ The European Union moved to limit exports of medical

²¹ Lopez Gironde, A. “El COVID 19 le hizo ver a la UE su dependencia en la industria farmacéutica”, May 2020 <https://www.tiempoar.com.ar/nota/el-covid-19-le-hizo-ver-a-la-ue-su-dependencia-en-la-industria-farmacéutica>.

²² European Commission – Press release “Pharmaceutical Strategy: European Commission launches open public consultation”, (16 June 2020). Available from https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1065.

²³ European Commission – Press release “Pharmaceutical Strategy (emphasis added).

²⁴ Jina Moore, “Vaccine nationalism is unfair and unwise”. By putting themselves at the front of the line for COVID-19 shots, the US and other countries might make poorer nations wait years for theirs. It does not have to be this way. In Globe Ideas, <https://www.bostonglobe.com/2020/08/29/opinion/vaccine-nationalism-is-unfair-unwise/>.

²⁵ Germán Velásquez, “Rethinking R&D for pharmaceuticals products after the novel coronavirus COVID-19 shock”, Policy Brief No. 75 (South Centre, April 2020). Available from <https://www.southcentre.int/policy-brief-75-april-2020/>.

equipment outside the EU: “We need to protect our health workers, who are in the first line of defense against the virus,” said Ursula von der Leyen on 15 March 2020.²⁶

The EU wants to recover the production of medicines “exiled” in Asia due to low labor costs in that continent. This would be the beginning of deglobalization in the pharmaceutical sector.²⁷

Germany’s Federal Minister of Health, Jens Spahn, announced his intention to initiate consultations with EU partners about the possibility to relocate the production of certain active pharmaceutical ingredients (APIs) back to Germany.²⁸

He is not the only one worried about pharma supply chains: Emmanuel Macron wants to relocate certain drug production to France. “The coronavirus pandemic has put the spotlight on health security issues (...) From Thursday, we will launch an initiative to relocate certain critical production”, announced the French president.²⁹ He recently referred to the relocation of pharmaceutical production as a matter of “pharmaceutical security and industrial sovereignty”.³⁰

By relocating production, industrialized countries have shown they are willing to pay more to protect their pharmaceutical autonomy. Paradoxically, as mentioned above, WHO has largely discouraged developing countries from producing medicines locally, arguing that locally manufactured products could cost more than imported ones and that the sole priority was to ensure access to low cost pharmaceuticals.

If the US and EU decide to relocate their pharmaceutical industries and become autonomous in their production of pharmaceuticals, including active ingredients, this would be an opportunity for many developing countries to start or strengthen local production (formulation) of medicines through the import of APIs from China and India as well as to develop, at the national or regional level, their capacity to move up in the value chain and growingly produce APIs. Biosimilars’ production offers an opportunity that developing countries should seize, as biologicals account for a growing share of the pharmaceutical market.³¹

A reorganization of global pharmaceutical production could perhaps be beneficial to increasing access to medicines and other pharmaceuticals in developing countries, and states (public sector) should be more involved in promoting the production of essential inputs for health systems. As States become more involved in the production of medicines and other health products, this could be an opportunity to emphasize and put health objectives ahead of commercial interests. This could be the occasion to make health, rather than purely commercial gains, the main objective of the pharmaceutical industry.

²⁶ Lili Bayer, Jillian Deutsch, Jakob Hanke Vela and Paola Tamma, “EU moves to limit exports of medical equipment outside the bloc”, *Politico*, 15 March 2020. Available from <https://www.politico.eu/article/coronavirus-eu-limit-exports-medical-equipment/>.

²⁷ Lopez Gironde, A. “El COVID 19 le hizo ver a la UE su dependencia en la industria farmacéutica”, May 2020 <https://www.tiempoar.com.ar/nota/el-covid-19-le-hizo-ver-a-la-ue-su-dependencia-en-la-industria-farmacéutica>.

²⁸ GTAI Germany Trade & Invest, “Covid-19 Fuels Debate over API Production Locations”, 14 April 2020. Available from <https://www.gtai.de/gtai-en/invest/industries/life-sciences/covid-19-fuels-debate-over-api-production-locations-239724>.

²⁹ See Capital, “Emmanuel Macron veut relocaliser en France des productions critiques de médicaments”, 17.06.2020. Available from <https://www.capital.fr/economie-politique/emmanuel-macron-veut-relocaliser-en-france-des-productions-critiques-de-medicaments-1372801>.

³⁰ Jean-Michel Bezat in *Le Monde* « Le gouvernement amorce une politique de relocalisation des médicaments », 19 Juin 2020.

³¹ See e.g., Pablo Lavarello, Graciela Gutman, Sebastián Sztulwark (Coordinadores), *EXPLORANDO EL CAMINO DE LA IMITACIÓN CREATIVA: La industria biofarmacéutica Argentina en los 2000*, (Libro, CEUR-CONICET, 2018).

According to Nature,³² as of 7 September 2020, there are more than 321 vaccine candidates against COVID-19 and 33 vaccine candidates are in clinical trials, that are being developed in different parts of the world. The current COVID-19 vaccine pipeline comprises a broad range of technology platforms, including traditional and novel approaches. Attempts by some Governments, such as that of the United States of America, to buy the future vaccine have led to talk of “vaccine nationalism.” The expression “vaccine nationalism” describes the circumstance when a country manages to secure doses of vaccine for its own citizens or residents before they are made available to other countries.³³ This can be done, for instance, through advance market commitments or pre-purchase agreements between a Government and a vaccine manufacturer. For instance, in April, the CEO of the French company Sanofi, whose COVID-19 vaccine work has received partial funding from the United States Biomedical Advanced Research and Development Authority (BARDA) announced that the USA had the “right to the largest pre-order” of its future vaccine.³⁴

The UK Government announced on 12 August 2020 two new agreements that would secure an additional 90 million coronavirus vaccines for its citizens. The in-principle agreements with Novavax and Johnson and Johnson’s Janssen bring the UK total number of advance arrangements for a coronavirus vaccine to six, involving four different types of vaccines. Novavax is slated to sell the UK 60 million doses of its candidate, with some to be manufactured in the UK by Fujifilm Diosynth Biotechnologies. The UK will support a Phase 3 clinical trial, with the National Institute for Health Research making its network and expertise available. Janssen would provide 30 million doses of its candidate, which is based on the formula from its successful Ebola vaccine, on a not-for-profit basis. The UK agreed to help pay for global clinical trials of the two-dose immunization.³⁵

In August 2020, Russian President Vladimir Putin stated that a COVID-19 vaccine, dubbed “Sputnik V” and developed by Russia’s Gamaleya Research Institute, had been green-lit for use in the country. The vaccine is being produced primarily for the domestic market, but Moscow is already in talks about exports, the health ministry said. Campaigns of mass vaccinations could start in Russia in December or January.³⁶

On 12 August 2020, the US Government announced the purchase of 100 million doses of Moderna’s experimental coronavirus vaccine for about \$1.5 billion, the Department of Health and Human Services said. The deal gives the government an option to buy another 400 million doses. The US Government has now committed up to \$2.48 billion to Moderna’s vaccine — including support for late-stage clinical trials, expanded manufacturing and other development activities along with the latest purchase.³⁷

³² Tung Thanh Le, Jakob P. Kramer, Robert Chen & Stephen Mayhew “Evolution of the COVID-19 development landscape”, *Nature Reviews Drug Discovery* (7 September 2020). Available from <https://www.nature.com/articles/d41573-020-00151-8>.

³³ Santos Rutschman A., “How ‘vaccine nationalism’ could block vulnerable populations’ access to COVID-19 vaccines” 17 June 2020, <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689>. This expression was used by WHO Director-General Tedros Adhanom Ghebreyesus at a panel discussion on 6 August 2020. See <https://www.swissinfo.ch/eng/reuters/global-recovery-could-be-faster-if-covid-vaccine-made-available-to-all---who-chief/45951960>.

³⁴ P. Benkimoun, « Sanofi et un vaccin contre le Covid-19 en priorité pour les Etats-Unis : une polémique vite devenue politique en France » *Le Monde* (15 May 2020).

³⁵ UK Government Press Release, “UK government secures new COVID-19 vaccines and backs global clinical trial”, 14 August 2020. Available from <https://www.gov.uk/government/news/uk-government-secures-new-covid-19-vaccines-and-backs-global-clinical-trial>.

³⁶ Laura Kayali, “Russia produces first batch of its coronavirus vaccine”, *Politico*, 15 August 2020. Available from <https://www.politico.eu/article/russia-begins-production-of-coronavirus-vaccine/>.

³⁷ Zachary Brennan “The next unprecedented vaccine hurdle: Making hundreds of millions of doses”, *Politico* (13 August 2020), <https://money.yahoo.com/next-unprecedented-vaccine-hurdle-making-235507169.html>.

Vaccine nationalism is not new. In 2009, during the influenza A (H1N1) pandemic, a similar “nationalism” arose. Access to vaccines and treatments was determined by purchasing power, and the high-income countries secured the supplies for their populations before the rest of the world.³⁸ Most of the vaccines for influenza A (H1N1) were bought and stored by the USA, Germany, Belgium, Spain, France, Italy, the Netherlands and Switzerland.³⁹ Many developing countries never received their orders, which were placed at the same time as the industrialized countries made their purchase.⁴⁰

At that time, several industrialized countries entered into pre-purchase agreements with some vaccine manufacturers. It was said that the global production capacity was 2 billion doses, of which the United States pre-purchased 600 million; All of the pre-purchases came from developed countries.⁴¹

Some of the world’s richest countries fought to be the first to get the vaccines and treatments. Developing countries—among the worst affected—were pushed to the back of the queue, as Western nations signed deals with pharmaceutical producers to guarantee access to vaccines. Australia even stopped a domestic producer from exporting doses to the US until it had immunized its entire population. For many global health experts, the swine flu was a warning for the far more serious coronavirus crisis, which has already killed more than 800,000 people as of 26 August 2020 and brought economies around the world to a standstill. The current COVID-19 pandemic could lead to a geopolitical fight over vaccines that would exceed the one that occurred over the influenza A (H1N1) pandemic.⁴² It has been rightly noted in this regard that:

For those who believe that a vaccine for COVID-19 will end or largely contain this pandemic or who hope that new drugs will be discovered to combat its effects, there is plenty cause for concern. Instead of working together to craft and implement a global strategy, a growing number of countries are taking a “my nation first” approach to developing and distributing potential vaccines or other pharmaceutical treatments.⁴³

The result of this vaccine nationalism will be that the vaccine may take months, if not years, to reach most developing countries. Perhaps, as in the past, companies or countries will make a symbolic donation of their vaccines to poor countries through WHO.⁴⁴ This will not be a sustainable solution.

This approach towards moving away from a collective, global and equitable strategy to confront and combat the pandemic is exemplified by a number of recent events and statements:

- Access to COVID-19 Tools (ACT) Accelerator: on 4 May 2020, the EU “Commission registered €7.4 billion, equivalent to \$8 US billion, in pledges from donors worldwide

³⁸ Rebecca Weintraub, Asaf Bitton and Mark L. Rosenberg, “The Danger of Vaccine Nationalism”, *Harvard Business Law Review* (June 2020). Available from <https://hbr.org/2020/05/the-danger-of-vaccine-nationalism>.

³⁹ Germán Velásquez, “Managing an A(H1N1) Pandemic: Public Health or Healthy business”, in *Protecting the Health of the Poor*, Karan A. and Sodhi G., eds. (London, Zed Books, 2015).

⁴⁰ Personal communication with Argentine Minister of Health Ginés Gonzalez Garcia.

⁴¹ Santos Rutschman A., “How ‘vaccine nationalism’ could block vulnerable populations’ access to COVID-19 vaccines” 17 June 2020, <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689>.

⁴² Milne, R., and Vrow D. “Why vaccine ‘nationalism’ could slow coronavirus fight”, *Financial Times* (14 May 2020). Available from <https://www.ft.com/content/6d542894-6483-446c-87b0-96c65e89bb2c>.

⁴³ Weintraub, Bitton, and Rosenberg, “The Danger of Vaccine Nationalism”.

⁴⁴ WHO, « Don de vaccins contre la grippe pandémique H1N1, 10 novembre 2009 ». Available from https://www.who.int/mediacentre/news/statements/2009/pandemic_vaccine_agreement_20091110/fr/.

during the Coronavirus Global Response pledging event.”⁴⁵ Leaders said that each euro or dollar will be channeled through global health organizations such as CEPI⁴⁶, Gavi, the Vaccines Alliance, and the Global Fund and Unitaid.⁴⁷ CEPI and Gavi will work under the umbrella of the Access to COVID-19 Tools (ACT) Accelerator Vaccine Taskforce.⁴⁸ Who will be the partners in this ACT Accelerator initiative? Public sector, industry, research, funders, regulators and international organizations. “Business partners will in principle not be required to forgo their intellectual property”.⁴⁹ Countries initially involved include France, Germany, the United Kingdom, Saudi Arabia, South Africa, Italy, Norway, Spain and Malaysia. Many countries have not joined the Accelerator initiative.⁵⁰

- Cyrus Poonawalla, the chief executive of the Serum Institute of India, the world’s largest producer of vaccine doses, said: “A majority of the vaccine, at least initially, would have to go to our countrymen before it goes abroad.”⁵¹ This statement is understandable considering the size of the Indian population. A bit problematic when you know that India has the highest capacity in the world for vaccine production.
- AstraZeneca reported that due to the \$79 million investment from the UK, the first 30 million doses of the vaccine it is developing with the University of Oxford would be allocated to that country. Then, on 21 May 2020, the United States pledged as much as \$1.2 billion to the company in order to obtain at least 300 million doses, with the first to be delivered as early as October 2020.⁵²
- According to the map of COVID-19 temporary trade measures (11 June 2020)⁵³:
COVID-19 Temporary Export Measures Affected products include personal protection equipment (e.g., masks, gloves), pharma products, hand sanitizer, food and certain other products.
Export restrictions/bans (95 countries)
Export liberalizations (2 countries)
Export restrictions and liberalizations (3 countries)
None (139 countries)
- The Donald Trump Government reached a controversial agreement to take the entire global supply for the next three months of remdesivir (for which the result of published

⁴⁵ European Commission Press release, “Coronavirus Global Response: €7.4 billion raised for universal access to vaccines Brussels”, (4 May 2020). Available from [file:///Users/German/Downloads/Coronavirus_Global_Response_7.4_billion_raised_for_universal_access_to_vaccines%20\(2\).pdf](file:///Users/German/Downloads/Coronavirus_Global_Response_7.4_billion_raised_for_universal_access_to_vaccines%20(2).pdf).

⁴⁶ The Coalition for Epidemic Preparedness Innovations (CEPI) is a foundation endowed by donations from governments, philanthropic organizations and civil society organizations. It was established to fund independent research projects for the development of vaccines.

⁴⁷ P. Wintour P. “World leaders pledge €7.4bn to research Covid-19 vaccine”, *The Guardian* (4 May 2020). <https://www.theguardian.com/world/2020/may/04/world-leaders-pledge-74bn-euros-to-research-covid-19-vaccine>

⁴⁸ Global Vaccine Summit on 4 June 2020, “Chair’s Summary”, <https://www.Gavi.org/sites/default/files/2020-06/4-June-2020-Global-Vaccine-Summit-Gavi-3rd-Replenishment-Chairs-Summary.pdf>.

⁴⁹ European Commission Questions and Answers, Brussels 28 May, https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_958.

⁵⁰ European Commission Questions and Answers, op cit.

⁵¹ Zeba Siddiqui, “India’s Serum Institute to make millions of potential coronavirus vaccine doses”, Nasdaq (29 April 2020). Available from <https://www.nasdaq.com/articles/indias-serum-institute-to-make-millions-of-potential-coronavirus-vaccine-doses-2020-04-29>.

⁵² Sara Marley, “AstraZeneca Aims for 30 Million U.K. Vaccine Doses by September” Bloomberg (17 May 2020). Available from <https://www.bloomberg.com/news/articles/2020-05-17/astrazeneca-aims-for-30-million-u-k-vaccine-doses-by-september>.

⁵³ Map of COVID-19 temporary trade measures, 11 June 2020, <https://www.macmap.org/covid19>.

clinical trials do not show efficacy⁵⁴), one of the drugs being used in the treatment of COVID-19. The drug, produced by the US pharmaceutical company Gilead Sciences, is the first to be approved by US authorities for the treatment of the disease. According to the announcement by the Department of Health and Human Services, the agreement with Gilead guarantees 500,000 treatments, equivalent to 100 per cent of July production, 90 per cent of production in August and 90 per cent of production in September.⁵⁵

Never in the history of the pharmaceutical industry have such massive pledges of public funds for getting access to medicines or vaccines been seen. It is difficult to calculate and distinguish the sums channeled to the ACT Accelerator, CEPI, WHO, Gavi and to the pharmaceutical companies themselves through the so-called "Advance market commitments" (AMC). It is not very clear what the ownership status of the products resulting from these efforts will be. The costs and prices of the future vaccines are not clear either. Governments are buying and paying in advance for products that do not yet exist and whose safety and efficacy, if obtained, is uncertain.

Beyond the massive funding there is a need for a real global coordination capacity to ensure safety, efficacy of the products and equity in vaccine and treatment distributions according to well-defined priorities. Health workers and vulnerable people in all affected countries should be the first to receive the vaccine.

Ultimately, the race to develop and distribute a vaccine to prevent COVID-19 is overwhelmingly dominated by the private sector with a few large pharmaceutical companies playing a central role. How will we ensure that this "commercial marathon" will end up with COVID-19 vaccines and related treatments that are safe and effective?

Massive public subsidies to the private sector, provided blindly, without clear conditions on products' characteristics, intellectual property protection, prices and distribution priorities, puts at risk the global solution that is needed. If the problem is planetary, the solution has to be structured in a global way. Who will be the arbiter to avoid the "vaccines nationalism"?⁵⁶ This should be the role of WHO, but as the World Health Assembly of 18-19 May 2020 made it clear, industrialized countries are not willing to have WHO implement binding normative or governance instruments.⁵⁷ Thus, WHO recommends priorities for the distribution of the vaccines at national level: first health personnel, for example, then vulnerable people over 65, then people with other health problems. The key question is what can WHO do to secure that those priorities are respected?

A number of initiatives to address the COVID-10 health crisis have been launched or reformulated, as discussed below, by WHO and other organizations. How can it be ensured that the global interests pursued by WHO, the Global Fund, Gavi, CEPI, COVAX will not be overridden by national and commercial interests? According to *Le Monde's* health specialist, Paul Benkimoun, "The technological and financial battle being waged by the world's pharmaceutical companies to develop a vaccine is furious. It is a savage competition that

⁵⁴ Jin-Hong Yoo, "Uncertainty about the Efficacy of Remdesivir on COVID 19", *Journal of Korean Medical Science* (10 June 2020) DOI: 10.3346/jkms.2020.35.e221.

⁵⁵ BBC Mundo, "Remdesivir: la polémica compra de EE. UU. de casi toda la existencia mundial del prometedor fármaco para combatir el covid-19", 1 July 2020, <https://www.bbc.com/mundo/noticias-internacional-53254231>.

⁵⁶ See e.g., Francisco Sercovich, "Coronavirus pandemic: the vaccine as exit strategy A GLOBAL HURDLE RACE AGAINST TIME WITH A SPLIT JURY", *SOUTHVIEWS* No. 203, 24 July 2020, Available from <https://www.southcentre.int/southviews-no-203-24-july-2020/>.

⁵⁷ Nirmalya Syam, Mirza Alas, and Vitor Ido, "The 73rd World Health Assembly and Resolution on COVID-19: Quest of Global Solidarity for Equitable Access to Health Products", Policy Brief No. 78 (South Centre, May 2020). Available from <https://www.southcentre.int/policy-brief-78-may-2020/>.

suffers from a lack of collaboration and clear objectives”.⁵⁸ Future vaccines and treatments for COVID-19 are being considered as unprecedented commercial opportunities rather than a necessary tool to avoid suffering and deaths at a global scale in response to a humanitarian need.

One of the clear lessons of COVID-19 is, as noted, the interdependence of countries in the production of medicines and APIs. Interdependence that in cases of emergency can lead to a nationalistic response, which -aggravated by the inequalities between developed and developing countries- will inevitably lead to rich countries supplying themselves first. In this context, a central element of a well-articulated Global Preparedness for Health Emergencies would be the strengthening of local production of medicines and vaccines. It is local production that will be able to secure health sovereignty so that developing countries can ensure the availability of pharmaceuticals for prevention and treatment.

⁵⁸ Paul Benkimoun, « Coronavirus : la guerre sans merci des laboratoires pour un vaccin », *Le Monde*, 24 Juin 2020.

III. COVID-19 GLOBAL VACCINE ACCESS FACILITY (COVAX FACILITY)⁵⁹

The WHO ACT Accelerator is a global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. Launched at the end of April 2020, it brings together Governments, scientists, businesses, civil society, and philanthropists and global health organizations.⁶⁰

The ACT Accelerator launched a COVID-19 Global Vaccine Access Facility (COVAX Facility) in June 2020. The new facility will pool resources and share vaccine development risk. COVAX is co-led by Gavi,⁶¹ the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. Ninety-two low- and middle-income countries and economies will be able to access COVID-19 vaccines through.⁶²

According to WHO, “demand guarantees for vaccine manufacturers will create access to substantial volumes of vaccines that will ultimately be safe and efficacious; better allocate capital; and support the manufacturing and procurement of sufficient volumes of vaccines to support equitable access globally. All countries will be invited to participate in the COVAX Facility. This investment opportunity of US\$ 2 billion will provide vital seed funding to the Gavi Advance Market Commitment (AMC) for COVID-19 Vaccines (Gavi COVAX AMC) to support high-risk populations in low-income countries (LICs) and lower middle-income countries (LMICs), as part of the new COVAX Facility.”⁶³

As a result of the mechanism put in place, however, the COVAX Facility will enter into AMCs with the big pharmaceutical companies. This announcement has created a strong global reaction from various civil society organizations, particularly in developing countries, which are concerned about equitable access to future vaccines.⁶⁴

In June 2020, Gavi released a document titled “The COVAX Facility: an insurance policy for COVID-19 vaccines.”⁶⁵ Several aspects of this document are still unclear.

According to TWN,⁶⁶ it is estimated that the proposed COVAX Facility will require funding of up to US\$ 18.1 billion for the 2020/2021 vaccine supply. Of this total, US\$ 11.3 billion is sought urgently to cover investments within the next 6 months, including US\$ 2 billion in funding for advance market commitments to secure doses for low- and middle-income countries. However, the justifications, including assumptions, for these estimates have not been provided. Conditions of how public funds will be used in advance market commitments are not known.

⁵⁹ See in Annex II, “Comment on the Expression of Interest Request to Self-Financing Countries to Join the COVAX Facility as Part of the ACT Accelerator”, sent by the South Centre Secretariat to its Members States on 9 July 2020.

⁶⁰ See <https://www.who.int/initiatives/act-accelerator>.

⁶¹ Gavi’s beneficiary countries have only included the poorest, those with a Gross National Income (GNI) per capita of less than or equal to US\$ 1,580. See <https://www.gavi.org/types-support/sustainability/eligibility>.

⁶² See <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>.

⁶³ Gavi, “The Gavi COVAX AMC: An investment opportunity”, June 2020. Available from <https://www.Gavi.org/sites/default/files/2020-06/Gavi-COVAX-AMC-IO.pdf>.

⁶⁴ Sangeeta Shashikant, “COVID-19: Global Concern that Gavi’s Vaccine Initiative Promotes Inequitable Access”, (Third World Network, 29 June 2020).

⁶⁵ Gavi, “The Gavi COVAX AMC”.

⁶⁶ Shashikant, COVID-19.

The Gavi COVAX AMC will produce a supply of vaccines for low-income countries (LICs) and low-middle-income countries (LMICs). It is unclear what terms and conditions will be attached to the financial instruments for developing countries. In short, the COVAX facility prioritizes the needs of self-financing countries that participate in its scheme. On pricing, the proposal states “flat pricing strategy...will be encouraged,” but **firms are free to set their own prices.**

As noted by one commentator, “Demand for a particular vaccine (albeit with unproven effectiveness) through various competing advance purchase agreements (the COVAX facility, the European Union and United States agreements), each presumably trying to outbid one another, only serves to benefit the pharmaceutical industry’s profiteering through high prices.”⁶⁷

The proposal states that the “Facility has access to doses of vaccine candidates through agreements that provide manufacturer-specific contingent volume guarantees to procure vaccines that meet WHO Target Product Profile to de-risk and incentivise timely investment in expansion of manufacturing capacity.”

A recent MSF paper⁶⁸ points out that Gavi is a Swiss-based foundation with a mandate to finance vaccines for the world’s poorest countries—currently 58 eligible countries (of an original 73 eligible countries). However, it questions Gavi’s role in hosting a global “facility” for COVID-19 vaccines, which “is beyond the organization’s mandate and expertise,” stressing that “Gavi has no experience working with most MICs nor any high-income countries (HICs) on procuring for the countries’ vaccine needs” and “does not have experience negotiating with pharmaceutical companies on behalf of these countries.”

On 23rd June 2020, 45 civil society organizations sent a letter to the board members of Gavi highlighting concerns about the fact that “pharmaceutical companies are allowed to retain and pursue rights to vaccines under development, resulting in vaccines that are proprietary and under the monopoly control of individual companies. Since there has been no change in how intellectual property is handled during the pandemic, pharmaceutical companies are able to monopolize future COVID-19 vaccines and decide who does and does not get access.”⁶⁹ The letter points out that more than US\$ 4.5 billion of public and philanthropic funding has already been given to companies for COVID-19 vaccine research and development (R&D), and “Gavi is now designing a fund to award further money to pharmaceutical corporations.”⁷⁰ It further notes that “The public and philanthropic funding already awarded should result in the delivery of effective vaccines that are designated as global public goods: sold at cost and free from monopoly control,”⁷¹ and suggests a number of criteria to finance, price and allocate vaccines.

These concerns justifiably focus on the equitable access to the vaccines to be developed. There is, however, a need to address other facets of the current situation in terms of the participation of developing countries not just as mere recipients of vaccines made abroad but as partners in their production. In fact, part of the response to the current supply crisis should be the creation or strengthening of vaccine production capacity in developing countries. Why not to think about a modality of AMCs with developing countries’ producers that have the

⁶⁷ Sangeeta Shashikant, “COVID-19: Global Concern that Gavi’s Vaccine Initiative Promotes Inequitable Access”, (Third World Network, 29 June 2020).

⁶⁸ MSF, “COVID-19 Vaccine Global Access (COVAX) Facility: key considerations for Gavi’s Global financing mechanism”, June 2020, https://msfaccess.org/sites/default/files/2020-06/MSF-AC_COVID-19_Gavi-COVAXFacility_briefing-document.pdf.

⁶⁹ See letter https://msfaccess.org/sites/default/files/2020-06/Vax_LetterToGaviBoard_22June2020-final_0.pdf.

⁷⁰ Ibid.

⁷¹ Ibid.

capacity to manufacture the new vaccines? Why not to support the technological upgrading of plants in those countries to expand the global capacity to respond to this and future vaccination needs? Why not to put in place a program for building additional manufacturing capacity in developing countries in this field so as to overcome the current oligopolistic market for vaccines? These actions should be based on the understanding that a vaccine in time of a pandemic should be in the public domain and considered a global public good.⁷²

In summary, the current response to the development and production of vaccines to address COVID-19 raises many questions and concerns. More attention should be given to the potential role of developing countries in the production (not only consumption) of such vaccines and on the policy measures that would need to be adopted (as developed countries are doing now) to ensure greater autonomy in their supply as well as to increase those countries' participation in the global production.

⁷² See, "COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security", Open letter from Dr. Carlos Correa, Executive Director of the South Centre, to Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization; Francis Gurry, Director-General of the World Intellectual Property Organization; Roberto Azevêdo, Director-General of the World Trade Organization CC: António Guterres, United Nations Secretary-General CC: Verónica Michelle Bachelet, United Nations High Commissioner for Human Rights, <https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf>.

IV. GLOBAL PREPAREDNESS MONITORING BOARD⁷³

The Global Preparedness Monitoring Board (GPMB) Is an independent monitoring and advocacy body. It urges political action to prepare for and mitigate the effects of global health emergencies. Co-convened in May 2018 by the World Bank Group and the World Health Organization, the Board builds on the work of the Global Health Crises Task Force and Panel, created by the United Nations Secretary-General in the wake of the 2014-2016 Ebola epidemic. The Board works independently of all parties, including its co-conveners, to provide the frankest assessments and recommendations possible. The 15-member Board is made up of political leaders, heads of agencies, and experts, led jointly by Dr Gro Harlem Brundtland, formerly Prime Minister of Norway and Director-General of the World Health Organization and Mr. Elhadj As Sy, Secretary General of the International Federation of Red Cross and Red Crescent Societies. The goals of the Board are to assess the world's ability to protect itself from health emergencies, identify critical gaps to preparedness across multiple perspectives; advocate for preparedness activities with national and international leaders and decision-makers.

The Preparedness Monitoring Board of WHO and the World Bank reviewed recommendations from previous high-level panels and commissions following the 2009 H1N1 influenza pandemic and the 2014–2016 Ebola outbreak, along with its own commissioned reports and other data.

The recommendations in this report relate to the following seven points, **one of which (point 4) speaks on ensuring adequate investment in developing innovative vaccines and therapeutics and surge manufacturing capacity.** This report, published in 2019, was supposed to capture all the experiences and lessons about pandemic preparedness, but it does not mention anything about possible "vaccine nationalism". Nor does it anticipate what COVID-19 has highlighted, such as the need to strengthen production capacity in developing countries. Here are the seven points of the report⁷⁴:

1. Heads of Government must commit and invest.

Heads of Government in every country must commit to preparedness by implementing their binding obligations under the International Health Regulations (IHR) (2005).

2. Countries and regional organizations must lead by example.

G7, G20 and G77 Member States and regional intergovernmental organizations must follow through on their political and funding commitments for preparedness.

3. All countries must build strong systems.

Heads of Government must appoint a national high-level coordinator with authority to maintain effective preparedness.

4. Countries, donors and multilateral institutions must be prepared for the worst.

A rapidly spreading pandemic due to a lethal respiratory pathogen (whether naturally emergent or accidentally or deliberately released) poses additional preparedness

⁷³ See, Global Preparedness Monitoring Board, *A WORLD AT RISK, Annual report on Global Preparedness for Health Emergencies*, (Geneva, World Health Organization, 2019). Available from https://apps.who.int/gpmb/assets/annual_report/GPMB_Annual_Report_English.pdf.

⁷⁴ Global Preparedness Monitoring Board Report, September 2019. https://apps.who.int/gpmb/annual_report.html.

requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries.

5. Financing institutions must link preparedness with economic risk planning.

To mitigate the severe economic impacts of a global pandemic, the International Monetary Fund (IMF) and the World Bank must urgently renew their efforts to integrate preparedness into economic risk and institutional assessments.

6. Development assistance funders must create incentives and increase funding for preparedness.

Donors, international financing institutions, global funds and philanthropies must increase funding for the poorest and most vulnerable countries through development assistance for health and greater/earlier access to the United Nations Central Emergency Response Fund to close financing gaps for their national actions plans for health security.

7. The United Nations must strengthen coordination mechanisms.

WHO should introduce an approach to mobilize the wider national, regional and international community at earlier stages of an outbreak, prior to a declaration of an IHR (2005) Public Health Emergency of International Concern (PHEIC).

These recommendations for pandemic preparedness due to a lethal respiratory pathogen have been re-stated, annually in WHO documents and resolutions since the 2009 H1N1 pandemic. If they had been taken seriously, there would have been no shortage of masks and breathing apparatus at the beginning of 2020, and the capacity to produce vaccines would have been increased. We currently do not have the vaccine, but we also know that if the vaccine arrives tomorrow, we do not have enough production capacity installed.

V. A COVID-19 TECHNOLOGY SHARING PLATFORM: A UN RECENT INITIATIVE⁷⁵

In May 2020, the United Nations Technology Bank, together with the UNDP, UNCTAD, and WHO launched the Tech Access Partnership (TAP) as part of a coordinated approach to strengthen developing countries' responses to COVID-19 and increase access to lifesaving health technologies.

TAP aims to address critical shortages of essential health technologies and equipment by connecting manufacturers with critical expertise and emerging manufacturers in developing countries to share the information, technical expertise and resources necessary to scale up production of these tools. The Partnership will also support countries to develop affordable technologies and equipment that meet quality and safety standards.

"Now, more than ever, the global community needs to unite to save lives and secure sustainable futures. Inequalities are exacerbating the technology and digital divide when it comes to opportunities for youth, creating a divide that threatens to leave them behind," says Amina J. Mohammed, Deputy Secretary-General of the UN. "Increasing access to necessary technologies through partnerships is a crucial component of the United Nations' COVID-19 health, humanitarian and socio-economic response."⁷⁶

TAP will be led by the UN Technology Bank for Least Developed Countries, established in 2016 to assist Governments with the development and adaptation of new technologies. The initiative, which is open to all developing countries, will also be supported by its core partners, UNDP, UNCTAD and WHO.

The key functions of TAP will include⁷⁷:

- Product information – a digital warehouse of manufacturing and design specifications, technical knowledge and information required to increase capacity.
- Technical Guidance – a technical support line to help manufacturers.
- Partnerships – a platform to match companies based on expertise, needs and capacity.

The Tech Access Partnership (TAP) aims **to support developing countries to scale up local production of critical health technologies needed to combat COVID-19**, including personal protective equipment, diagnostics and medical devices such as ventilators.

This UN initiative seems to confirm that COVID-19 requires rethinking of local production in developing countries.

⁷⁵ See A COVID-19 Technology Sharing Platform, <https://techaccesspartnership.org/>.

⁷⁶ UNDP, "UN agencies launch Tech Access Partnership in joint effort to scale up local production of life-saving health technologies for COVID-19", New York, 12 May 2020. Available from https://www.undp.org/content/undp/en/home/news-centre/news/2020/UN_agencies_launch_Tech_Access_Partnership_in_joint_effort_to_scale_up_local_production_of_life-saving_health_technologies_for_COVID-19.html.

⁷⁷ UNDP, "UN agencies launch Tech Access Partnership".

VI. CONCLUDING REMARKS

During the 73rd World Health Assembly (WHA) in May 2020, the United Nations Secretary-General and several Heads of State made important declarations of principle. These declarations stressed that all possible treatments, present and future, including vaccine(s) related to the COVID-19 pandemic, should be considered as global public goods and should be available, to all, at the same time and in sufficient quantities. These statements are not viable when they clash with the reality of how the global pharmaceutical market is organized and with growing nationalistic trends regarding the production and distribution of vaccines to address the pandemic.

The 73rd WHA was a little paradoxical, full of solemn declarations and a few substantial financial pledges, without precedent, while at the same time an unambitious resolution, “COVID-19 response,” was approved. The resolution was far from containing clear instruments to put into practice the intentions expressed in the solemn declarations.

The COVID-19 pandemic has shown renewed efforts by developed countries to ensure autonomy in the manufacturing of pharmaceuticals and has given rise to nationalistic approaches. At the same time, it is clear that even if one or more vaccines against COVID-19 are successfully developed, there is no sufficient global manufacturing capacity to produce the billions of doses needed to protect the world population. In this context, it seems urgent to reopen the discussion about the local pharmaceutical production and how developing countries can expand their capacity to participate in the global market for APIs and pharmaceuticals, including biologicals. A portion of the public funds in the form of AMC's should go to developing countries that have the technological capacity to produce vaccines.

ANNEX I – BASIC CONCEPTS AND DEFINITIONS

The concept of “pharmaceutical industry” may be interpreted in different ways depending how it is used. In fact, this industry produces different outputs ranging from active ingredients to final products. The latter, on the hand, are not homogeneous, as they encompass products resulting from chemical synthesis, biologicals for prevention or treatment and diagnostic kits. It is useful, therefore, to clarify what is meant by that concept since policy actions that Governments can undertake differ depending on what type of products or segment of the industry’ value chain are addressed.

By the expression “pharmaceutical industry” we mean a branch of manufacturing industry that produces, on an industrial scale, and commercializes therapeutic substances (medicines) presented as having preventive, diagnostic, curative or treatment properties, for human or animal diseases, as well as active ingredients for the manufacture of those substances of, synthetic or biological origin, including from plants, biochemicals and products of genetic engineering.¹

The production activities of the pharmaceutical industry can be divided into the following categories:²

1. Chemical synthesis – the manufacture of pharmaceutical products by chemical synthesis.
2. Fermentation – the production and separation of medicinal chemicals, such as antibiotics and vitamins, from microorganisms.
3. Extraction – the manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials or animal tissues.
4. Biological production – the use of microorganisms and genetic engineering tools to produce vaccines, monoclonal antibodies, etc.
5. Formulation – the production of bulk pharmaceuticals into various dosage forms, such as tablets, capsules, injectable solutions, ointments, etc., that can be taken by the patient.

The UNIDO³ typology on pharmaceutical production in developing countries makes some useful distinctions that reflect the level of technological sophistication and value added:

1. Packaging of already formulated medicines and small-scale local production of sterile or non-sterile formulations.
2. Formulation of drugs in final dosage form and some production from imported intermediates.
3. Production from imported intermediates and manufacture of some intermediates from local materials.

¹ All these products are generically termed as “pharmaceuticals”. See, e.g. Germán Velásquez, “Algunas reflexiones sobre la industria farmacéutica y la salud pública”. In *Propiedad Intelectual, Presente y futuro*, Homenaje al profesor Carlos Correa. Directores Bergel, S. Negro, S., Ed. IBDeF Buenos Aires 2019.

² Warren Kaplan and Richard Laing, “Local production of pharmaceuticals: industrial policy and access to medicines – an overview of key concepts, issues and opportunities for future research” (English). Health, Nutrition and Population (HNP) discussion paper. (Washington, DC: World Bank). Available from <http://documents.worldbank.org/curated/en/551391468330300283/Local-production-of-pharmaceuticals-industrial-policy-and-access-to-medicines-an-overview-of-key-concepts-issues-and-opportunities-for-future-research>.

³ United Nations Industrial Development Organisation (UNIDO), *Appropriate industrial technology for drugs and pharmaceuticals*, New York, NY, 1980. Monographs on Appropriate Industrial Technology, 10.

4. Production of active substances and processing to produce the required pharmaceutical dosage forms.

Local pharmaceutical production may be undertaken by:

1. Local State-owned public pharmaceutical companies.
2. Local National private pharmaceutical companies
3. Multinational pharmaceutical companies
4. Joint ventures of local private national and foreign pharmaceutical companies.
5. Joint ventures of State-owned and foreign pharmaceutical companies.

In some cases, local production takes place on the basis of technology in possession of the company, eventually protected under patents or trade secrets, or is carried out under licenses granted by other firms. In developing countries, the latter has been a common situation. The licensing agreements usually allow the licensees to get know how, active ingredients and the data files necessary for the marketing approval of the licensed products.⁴

The concept of Active Pharmaceutical Ingredient (API) has been defined by WHO in 2011.⁵ It is a substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.⁶

The active pharmaceutical ingredient (API) is the central component of any drug. Production of APIs has traditionally been done by specialized chemical companies or pharmaceutical companies themselves in their home countries. The marketing of APIs for the pharmaceutical industry, produced by the chemical industry is often done by brokers who do not produce, they only speculate with the purchase and sale of APIs.

In recent years, many pharmaceutical companies have opted to undertake manufacturing of APIs overseas to cut costs. A leading manufacturer of APIs is TEVA Pharmaceuticals (Israel). With over 300 API products, it has the industry's largest portfolio. Another leading manufacturer is the Indian company Dr. Reddy's, with more than 60 APIs in use today. Other industry giants are Pfizer, Novartis, Sanofi, Boehringer Ingelheim, and Bristol-Meyers Squibb. Each of these companies specializes in different APIs, producing most of them in Asia.⁷

Pharmaceutical companies in developed countries used to produce the APIs, build the capsule, tablet, etc. and package the medicine, but this is no longer the case.⁸ While many pharmaceutical companies are located in the United States and in the EU, most API manufacturers are overseas. The largest are located in Asia, particularly in India and China.⁹

⁴ See e.g., Daniel Simonet, "Licensing Agreements in the Pharmaceutical Industry", *Journal of Medical Marketing* 2(4):329-341 (September 2002). DOI: [10.1057/palgrave.jmm.5040090](https://doi.org/10.1057/palgrave.jmm.5040090).

⁶ WHO, "Definition of Active Pharmaceutical Ingredient", Working document QAS/11.426/Rev.1 (Geneva, July 2011). Available from https://www.who.int/medicines/areas/quality_safety/quality_assurance/DefinitionAPI-QAS11-426Rev1-08082011.pdf.

⁷ Kathlyn Stone, "What Is an Active Pharmaceutical Ingredient (API)?", In Verywell Health, November 2019, <https://www.verywellhealth.com/api-active-pharmaceutical-ingredient-2663020>.

⁸ Ibid.

⁹ Ibid.

ANNEX II – COMMENT ON THE EXPRESSION OF INTEREST REQUEST TO SELF-FINANCING COUNTRIES TO JOIN THE COVAX FACILITY AS PART OF THE ACT ACCELERATOR

9 July 2020

The new COVID-19 Vaccines Global Access (COVAX) Facility is a new procurement mechanism for COVID-19 vaccines. It is the vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator. Currently there is no safe and effective vaccine for COVID-19, while there is a pipeline of over 130 candidates at various stages of development.¹ The COVAX Facility is offering Governments that decide to join, which are self-financing,² and commit to make payment; that it will supply them with enough vaccine doses to immunize 20 per cent of their country's population.³ This is assuming that one or more of the vaccine candidates in the COVAX-supported portfolio of vaccine candidates would be successful. Governments that join the COVAX Facility will be required to make a binding commitment to procure sufficient doses to immunize 20 per cent of their population with successful vaccine candidates through the Facility, and to make an upfront payment of a proportion of the total cost of procurement, which to date is not known. The structure of the commitment is also not known, to be worked out in July-August 2020. The governance mechanism is also not clear on who will be influencing the decisions, including on pricing. However, it is being noted that countries that do not join, may not have better options, given the need for early access to doses and challenge of direct negotiation with manufacturers to procure doses of vaccines that may or not be successful.

While the COVAX Facility is being framed as global procurement for COVID-19 vaccines, it is not a global, centralized purchasing mechanism for vaccines. It also has limited capacity to steer vaccine developers and manufacturers. Many deals are being made for pre-purchasing doses of potential vaccines that cast doubt as to whether sufficient production may be possible to meet global demand and whether available doses will be priced affordably. Vaccine manufacturers do not have exclusive contracts to supply the COVAX Facility, through GAVI or otherwise. This means that the efforts within the COVAX facility can be undermined by unilateral contracts that countries may undertake with vaccine manufacturers in a country or group of countries. To offset this, vaccine developers and manufacturers are being approached to join COVAX and to secure agreements for procuring certain number of doses. However, the scope and terms of the agreements and which vaccine manufacturers will join, is unclear.

The objective of the COVAX facility appears to be two-fold. On the one hand, to support the vaccine developers and manufacturers by re-risking their investments given the uncertainty as to whether their vaccine candidate will be successful. There is no lack of demand for a successful vaccine, as may be the case for other immunization programs. But manufacturers may more likely increase investment in building or scaling-up their production facilities if they

¹ See WHO landscape of vaccine candidates as of 6 July 2020, draft. [Available from https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines](https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines).

² Self-financing countries refer to those that are not eligible for vaccine financing from Gavi, generally those classified as Upper Middle Income Countries (UMICs) and High Income countries, <https://www.gavi.org/programmes-impact/programmatic-policies/eligibility-and-transitioning-policy>.

³ The engagement of self-financed countries in the COVAX Facility is distinct from the Gavi Advance Market Commitment for COVID-19 Vaccines (Gavi COVAX AMC), that is to support high-risk populations in low-income countries (LICs) and lower middle-income countries (LMICs), as part of the new COVAX Facility. LICs and LMICs may receive financial support from Gavi.

would not have to fully absorb the losses from vaccine failure. The COVAX facility will indeed increase the security of demand for vaccine manufacturers. This is a key motivating factor for them to agree to commit to supply a certain number of doses the COVAX facility.

The other main objective of the facility is to support countries to receive a fair allocation of doses, so that at the minimum the higher risk populations such as health and care workers can receive the vaccine. This effort is supported by the WHO Global Allocation Framework for Vaccines, that in principle should be made applicable to all countries, including those that choose not to participate in the COVAX facility. Yet the WHO allocation framework is voluntary and is not linked to any broader WHO-wide agreement for implementation, it is being considered only as part of the ACT Accelerator initiative. The challenge for self-financing countries to participate in COVAX is that they have little information and influence on what are the conditions under which the manufacturers procure to the facility –that has bearing on costs of doses for participating countries–, the scope of manufacturers involved, and whether technology may be shared by any successful vaccine producer to allow fast expansion of manufacturing capacity. To date there is no commitment from manufacturers to pool voluntarily IP and know-how to the Technology Access Pool (C-TAP) that is part of the ACT Accelerator, but no linkage has been made to it in the COVAX pillar.

While the COVAX facility works to de-risk investment for producers and vaccine manufacturers, there is less security for the countries involved particularly in the present conditions where the terms for purchase are not known but payment is required up front and, most importantly, there is much uncertainty as to what vaccine candidates may be successful, and which ones will be included in the COVAX portfolio. Depending on which vaccine candidates are excluded, as may be the case of the advanced candidate Sinovac in Phase 2 and CanSino Biological Inc./Beijing Institute of Biotechnology in Phase 2, self-financing countries may be better off purchasing directly, or do so through other regional procurement mechanisms to seek assured volumes of doses at affordable prices. Payments made to the COVAX facility may not be reimbursable even if better options emerge or the conditions of supply are unsatisfactory.

In this regard, while countries that would be self-financing consider whether to join the COVAX Facility, they should also consider and prioritize strengthening the regional procurement mechanisms, and support for the roll out of the immunization programs for COVID-19.

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