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WHO AND COVID-19: MULTILATERAL INITIATIVES

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WHO and COVID-19: Multilateral Initiatives

The World Health Organization (WHO) has multiple ongoing initiatives to pool resources, knowledge, data, and technology to expedite access to COVID-19 solutions. WHO's work on COVID-19 falls into the following categories: advice including advice to the public and health workers; technical guidance; vaccines; and research. This brief focuses on WHO's work in the area of vaccines and discusses the global allocation mechanism for vaccines, the Access to COVID-19 Tools Accelerator (ACT-A) of which COVAX is a pillar, and the COVID-19 Technology Access Pool (C-TAP).

Key Issues

1 WHO's Global Allocation Mechanism lacks the backing of economically powerful countries, which have bought up majority of vaccine supplies available. As of March 2021, high income countries had secured an estimated 6 billion doses, whereas COVAX had only 700 million.

2 Bilateral deals signed between wealthy countries and pharmaceutical companies have also effectively undermined COVAX.

3 The COVAX Advance Marketing Commitment (AMC) mechanism employed to finance vaccine purchases for 92 eligible countries on a donation basis is faulty and facing a shortage in vaccine supply. The AMC mechanism that worked for a neglected disease, is not working for COVID-19.

4 C-TAP meant to be a technology pool is voluntary and opposed by pharmaceutical companies, making it yet unrealized.

Global Allocation Mechanism

The United Nations General Assembly's Resolution on "International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19" (A/RES/74/274) adopted on 20 April 2020, requests "The Secretary-General, in close collaboration with the World Health Organization and other relevant agencies of the United Nations system, including the international financial institutions, to identify and recommend options, including approaches to rapidly scaling manufacturing and strengthening supply chains that promote and ensure fair, transparent, equitable, efficient and timely access to and distribution of preventive tools, laboratory testing, reagents and supporting materials, essential medical supplies, new diagnostics, drugs and future COVID-19 vaccines, with a view to making them available to all those in need, in particular in developing countries".

The 73rd World Health Assembly held in May 2020 provided the mandate for the creation of an Allocation Framework calling on the Director-General to "rapidly" and "*in consultation with Member States with inputs from relevant international organizations, civil society, and the private sector, to identify and provide options that respect the provisions of relevant international treaties [...] to be used in scaling up development, manufacturing and distribution capacities needed for transparent equitable and timely access to quality, safe, affordable and efficacious diagnostics, therapeutics, medicines, and vaccines for the COVID-19 response, taking into account existing mechanisms, tools, and initiatives, such as the Access to COVID-19 Tools (ACT) Accelerator, and relevant pledging appeals, such as the Coronavirus Global Response pledging campaign, to be submitted for the consideration of the governing bodies*" (emphasis added).

Following this, the WHO in consultation with Member States developed a fair allocation mechanism for vaccines which would allocate an initial proportion of doses until all countries can cover 20% of their population. A follow-up phase would then expand coverage to other populations. If severe supply constraints persist, a weighted allocation approach would be adopted, taking account of a country's COVID-19 threat and vulnerability. However, in the absence of any legal obligation to stick to the allocation framework, developed countries including the European Union entered into bilateral deals with vaccine producers and acquired a substantial percentage of the vaccine doses in advance. As a result, the allocation mechanism is applicable only to countries who are depending on the COVAX facility. The lack of predictability of vaccine access forced the African Union to enter into bilateral deals to obtain vaccines for its Member States. As a result, the allocation mechanism has lost its relevance.

COVID-19 Technology Access Pool (C-TAP)

The COVID-19 Technology Access Pool (C-TAP) launched in May 2020 is an initiative based on a proposal from the Costa Rica government whereby President Carlos Alvarado Quesada urged WHO to “*undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.*”

Costa Rica proposed that WHO prepare “*an initial concise memorandum of understanding on the intent to share rights in technologies funded by the public sector and other relevant actors, and reach out to WHO Member States, non-profit institutions, industry and others, to sign such an MoU*” adding that “*The specific technologies and the terms of the assignments can be determined later, in the implementation stage of the pool, in consultation with R&D funders and rights holders*”. It also urged the WHO Global Observatory on Health Research and Development¹ to create a database of R&D activity related to COVID-19, including estimates of the costs of clinical trials, and the subsidies provided by governments and charities.

1- <https://www.who.int/research-observatory/en/>

The C-TAP initiative is meant to accelerate the development of tools necessary to fight COVID-19 and remove barriers to accessing these tools.² So far, it has been endorsed by 40 countries and international bodies such as the United Nations High Commissioner for Human Rights, UNAIDS and Unitaid, among others³.

There are five elements in the C-TAP initiative:⁴

1. Public disclosure of the gene sequences and data of the COVID-19 virus;
2. Transparency around publication of all clinical trial results;
3. Governments and other funders are encouraged to include clauses in funding agreements with pharmaceutical companies and other innovators about equitable distribution, affordability and publication of trial data;
4. Licensing of diagnostics, vaccines and treatments to the Medicine Patent Pool; and
5. Promotion of open innovation models and technology transfer that increases local and manufacturing supply capacity.

The call for action invites all stakeholders “*to voluntarily pool knowledge, intellectual property and data necessary for COVID-19. Shared knowledge, intellectual property and data will leverage our collective efforts to advance scientific discovery, technology development and broad sharing of the benefits of scientific advancement and its applications based on the right to health.*” However, the main implementation mechanism i.e. C-TAP, does not provide a platform to do such pooling.

The call for action further calls all stakeholders to “*Place, in the [WHO COVID-19 Technology Access Pool](#) or its implementing partner platforms, references to shared information and/or commitments to all relevant technologies,*

2- W. (n.d.). Operationalizing the COVID 19 Technology Access Pool [A Concept Paper]

3- W. (n.d.). Operationalizing the COVID 19 Technology Access Pool [A Concept Paper]

4- World Health Organization. (2020, May 29). WHO and Costa Rica launch landmark COVID-19 Technology Access Pool[Press release]. Retrieved December 26, 2020, from <https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19>

knowledge, intellectual property, and data on terms that facilitate their use in research, development and innovation and manufacturing and that would permit effective technology transfer and early access to key technologies for the detection, prevention, treatment and response of COVID-19”.

However, it is not clear whether WHO will establish a COVID-19 technology access pool platform.

The call for action asks the stake holders to place references to shared information or commitment with regard to knowledge, IP and data in either WHO platform i.e. C-TAP or implementing partner’s platform. Thus the platform is not to share the relevant technologies, knowledge, intellectual property, and data per se facilitate innovation, manufacturing and technology transfer but it is to share references or commitment to share technologies, knowledge, IP and data. Thus the C-TAP, if established, would serve only as a platform of information sharing about the reference of sharing or commitment to share a knowledge, IP and data sharing platform.

Stakeholders are also asked to place data on COVID-19 research and development in the WHO Global Observatory on Health R&D, and gather new information, where needed and feasible, to decide on priorities in research and development. This call is not about the sharing of R&D outcomes like vaccines, but rather about the sharing of information on R&D activities. Thus contrary to reports on the call for action, there is no new platform known as a C-TAP for sharing of knowledge, intellectual property, data for facilitating global wide production and technology transfer for local production. Moreover, WHO as an institutional sponsor of the C-TAP initiative has a very limited role in the implementation of the call for action.

The WHO’s C-TAP database is expected to serve as the core of C-TAP operations and be the main repository of all data and knowledge on COVID-19 health technologies. In the long run, C-TAP’s focus is to incorporate a broader range of technologies and products in order to find preventive solutions to COVID-19.⁵

5- W. (n.d.). Operationalizing the COVID 19 Technology Access Pool [A Concept Paper]

However there are important shortcomings as follows:

Fragmentation of Platforms: The call for action urges the holders of knowledge, intellectual property and data to use the existing mechanisms like the Medicine Patent Pool or any other public health research and development mechanism or consortia or initiatives. It calls for the “sharing of intellectual property and data to enable widescale and worldwide production, distribution and use of such technologies and necessary raw materials through the Technology Access Partnership (TAP) hosted by the [UN Technology Bank](#) or the Open COVID Pledge Initiative.⁶ Thus C-TAP does not create a single platform for sharing of knowledge, intellectual property and data on vaccines, therapeutics and diagnostics.

These different platforms have different purposes and conditions for sharing. For instance, the purpose of the TAP platform initiated by UNDP, UNCTAD and WHO is to facilitate technology transfer for local manufacturing and it also provides handholding services like advisory services to ensure the local production. However, the Open COVID Pledge Initiative allows the use of pledges of patents for a limited period of time. It does not even list the pledged patents and their relevance to various medical products. Further, it is only a pledging platform for patents. Technology transfer goes beyond the permission to use intellectual property but also involves technical specifications, designs, drawings etc.

The pharmaceutical industry, which holds the majority of the rights to approved COVID-19 vaccines, data and research, has “dismissed” C-TAP and has been extremely reluctant to support it.⁷ The association of pharmaceutical transnational corporations, the International Federation of Pharmaceutical Manufacturers and Association (IFPMA) expressed concerns about C-TAP. In a statement IFPMA raised its reservations on a global non-exclusive voluntary license, stating that “By urging licenses or non-enforcement declarations for COVID-19 treatments and vaccines to be granted on a non-exclusive global basis,

6- <https://opencovidpledge.org>

7- Ren, G. (2020, September 26). Progress On COVID-19 Technology Pool Inches Along As Sister Initiative To Pool Vaccine Procurement Accelerates. Retrieved January 7, 2021, from <https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/>

the Solidarity Call to Action promotes a one-size-fits all model that disregards the specific circumstances of each situation, each product and each country. Different regions and countries will face different challenges regarding the manufacture and distribution of COVID-19 treatments and vaccines. Any access tools, including patent licensing mechanisms, should therefore allow for customized solutions to real-world problems that may arise”. This shows the stand of pharmaceutical TNCs to divide the market and to exclude middle income countries from the scope of voluntary licenses. Importantly, C-TAP has not initiated any activities to share vaccine technologies.

Access to COVID-19 Tools Accelerator (ACT-A)

The ACT-A is a collaborative effort meant to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. It is primarily a funding initiative and functions as a complementary initiative to C-TAP⁸. The ACT-A mobilizes funds, prioritizes needed technologies, and works to ensure these products are made available at the country level⁹. The initiative has outlined a total requirement of US\$ 38.1 billion in funding. However, as of March 2021 it has only managed to procure US\$ 11 billion of its funding, leaving a severe US\$ 22.1 billion shortage. The US\$ 11 billion is comprised of 87% public funding, 6% private funding, and 7% multilateral donors¹⁰. A substantial percentage of the US\$ 11 billion goes to the vaccine pillar. It is not very clear whether this amount also includes the donations received for COVAX.

The ACT-A is comprised of four pillars- Vaccines, Therapeutics, Diagnostics and the foundational Health System Connector. These four components are overseen by partners CEPI, FIND, GAVI, The Global Fund, The World Bank, Unitaid, Wellcome and the WHO. The much-discussed COVAX Facility falls under the Vaccine pillar of the ACT-A, which will be explored more in depth later on.¹¹

8- W. (n.d.). Operationalizing the COVID 19 Technology Access Pool [A Concept Paper]

9- The Access to COVID-19 Tools (ACT) Accelerator . (n.d.). Retrieved December 26, 2020, from <https://www.who.int/initiatives/act-accelerator>

10- Jayakumar, P. (2021, March 15). ACT-Accelerator, global coalition to Fight COVID-19, Faces Fund constraints. Retrieved April 09, 2021, from <https://www.businesstoday.in/current/economy-politics/act-accelerator-global-coalition-to-fight-covid-19-faces-fund-constraints/story/433906.html>

11- The Access to COVID-19 Tools (ACT) Accelerator . (n.d.). Retrieved December 26, 2020, from <https://www.who.int/initiatives/act-accelerator>

With respect to each pillar, the ACT-A has set these goals for itself:¹²

- 1.** To equitably distribute approximately 2 billion doses of vaccines by the end of 2021
- 2.** To provide approximately 245 million treatment courses within 12 months to LMICs
- 3.** To enable the completion of approximately 900 million diagnostic tests in LMICs by mid-2021
- 4.** To help countries use the new tools/technologies being developed as they become available, and supply Personal Protective Equipment and Oxygen, through the Health Systems pillar. It is important to note here that the Health Systems pillar is meant to act as the connector between the other three pillars.

The main achievements of the ACT-A so far are as follows¹³

Diagnostics:

- Reserved 120 million rapid antigen tests for low- and middle-income countries
- Procured over 32 million molecular tests and 32 million rapid antigen tests for low- and middle-income countries
- Provided training for over 23 000 health workers in almost 200 countries
- 2021 aim: 900 million tests procured for LMICs by end of the year.

Therapeutics:

- Procured 2.9 million doses of dexamethasone – the only WHO-approved treatment for COVID-19
- Supported 15 clinical trials, investigating 21 therapies in 47 countries, with 85 000 patients enrolled
- 2021 aim: 100 million courses of treatment throughout the year

12- WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination (pp. 1-13, Tech.). (2020). World Health Organization

13- WHO, ACT now, ACT together 2020-2021 Impact Report, <https://www.who.int/initiatives/act-accelerator>

Vaccines:

- 190 countries signed up to the COVAX Facility
- As of May 4, 2021 COVAX has shipped over 53 million doses to 121 participating economies
- 2021 aim: 2.5 billion safe and effective doses delivered by the end of the year.

Health Systems Connector:

- Procured personal protective equipment (PPE) with a total value of over US\$ 500 million
- Conducted national surveys in 129 countries to assess bottlenecks
- Developed global guidance and training across multiple critical areas of the health system to ensure the world is better prepared for the next pandemic.

Given the scale of the needs as the pandemic enters into yet another new wave, the achievements of ACT-A so far are not impressive.

WHO is hosting the ACT-A Hub but not leading any of the pillars. Thus it has little say in the governance of ACT-A. Further, there is no clarity with regard to the accountability of ACT-A towards WHO Member States. There is a multi-stakeholder governance framework for the facilitation council of the ACT-A. The council is to address the strategic, policy and financial issues and political advocacy for the ACT-A. There is no mandate for the council to take any substantive decision with regard to the ACT-A, as this is the purview of each pillar consisting of a few actors including certain donors. Thus, the council acts as a group to garner the political support from WHO Member States.

Intellectual property protection is another area that lacks clarity. The products developed through the ACT-A partnerships are mainly publicly funded. The FAQ states that “For publicly funded research, there should be open access to results, i.e., data, knowledge and intellectual property to the extent needed to ensure global deployment and access”. However, on intellectual property the FAQ sets a different tone. It states: “Business partners will in principle not be required

to forgo their intellectual property, but funding pledges will be accompanied by commitments from donors in support of global access and fair deployment of new diagnostics, treatment and vaccines against coronavirus”.¹⁴

COVAX Facility and the AMC Mechanism

As stated above, the COVAX facility is one of the four pillars that make up the ACT-Accelerator. COVAX is a vaccine procurement effort set up and supported by GAVI the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the WHO. Currently, around 190 countries support the initiative.¹⁵

The initiative intends to procure 2 billion doses of COVID-19 vaccines by the end of 2021 and provide those vaccines to nations supporting the initiative. Their goal is to provide doses for an average of 20% of each member country’s population, giving priority to frontline healthcare workers and vulnerable members of the population. Additional doses will be made available through the facility based on financing, country need, vulnerability, and potential threat of the virus.¹⁶ The original idea was for COVAX to be the global COVID-19 vaccines procurer, but wealthy countries led by the US, European Union and the UK chose to first secure vaccines for themselves through bilateral advance purchase agreements with the manufacturers that were developing vaccines.

COVAX has an Advance Market Commitment (AMC) financing scheme that procures vaccine doses for donation to 92 eligible low and a few low middle countries with a Gross National Income per capita under US \$4000.¹⁷ Wealthy countries are currently participating in COVAX by pledging donations to the AMC.

14- https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_731

15- ACT-Accelerator FAQ. (n.d.). Retrieved December/January, 2020-2021, from <https://www.who.int/initiatives/act-accelerator/faq>

16- 92 low- and middle-income economies eligible to get access to COVID-19 vaccines through Gavi COVAX AMC. (2020, July 31). Retrieved December/January, 2020-2021, from <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>

17- 92 low- and middle-income economies eligible to get access to COVID-19 vaccines through Gavi COVAX AMC. (2020, July 31). Retrieved December/January, 2020-2021, from <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>

Those 92 countries can buy additional doses through COVAX with their own funds. Other middle-income countries are self-financing and can buy vaccines for up to 20% of their population through COVAX.

High and middle-income countries that are a part of the facility first enter into legally binding agreements to purchase doses through COVAX. These agreements are then confirmed by making upfront financial contributions on the part of high and middle-income countries, which in turn will provide funding for COVAX to enter into procurement deals with vaccine manufacturers.¹⁸ In addition to upfront payments, GAVI intends to use official development assistance funds (ODA) from OECD donors.¹⁹

By providing funding for vaccine doses before approval, COVAX was supposed to guarantee large supply volumes and market-demand for manufacturers. These guarantees are meant to incentivize manufacturers to produce enough doses for AMC-eligible countries, where almost half of the world's population live. The rationale for an AMC financing scheme is that if vaccines were left to market dynamics or government investment, matching potential demand with an aggregate supply of COVID-19 vaccines over the next 18 months would become a problem.²⁰

The COVAX AMC financing scheme is based on an identical scheme that was used to boost supply of pneumococcal conjugate vaccines (PCV) in 2009. GAVI employed the same AMC mechanism in order to ensure there were sufficient doses of the vaccine, given that childhood pneumococcal disease is one of the biggest killers of children under the age of five. The PCV AMC was launched with support from donors such as Italy, the UK, Canada, Russia, Norway, and the Bill and Melinda Gates Foundation.²¹ A total of US\$1.5 billion was donated in capital, which enabled GAVI to incentivize vaccine manufacturers with this upfront payment.²²

18- 92 low- and middle-income economies eligible to get access to COVID-19 vaccines through Gavi COVAX AMC. (2020, July 31). Retrieved December/January, 2020-2021, from <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>

19- The GAVI COVAX AMC- An Investment Opportunity (pp. 1-5, Publication). (2020). GAVI the Vaccine Alliance.

20- The GAVI COVAX AMC- An Investment Opportunity (pp. 1-5, Publication). (2020). GAVI the Vaccine Alliance.

21- Gavi launches innovative financing mechanism for access to COVID-19 vaccines. (2020, June 4). Retrieved January 3, 2021, from <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines>

22- The GAVI COVAX AMC- An Investment Opportunity (pp. 1-5, Publication). (2020). GAVI the Vaccine Alliance.

As a result of this AMC, the price of the PCV fell from US\$ 3.50 in 2010, to US\$ 2.00 in 2020 (a 43% decrease).²³ But this model is not working for COVID-19 vaccines because a pandemic requires volumes that cannot be met by a few monopolistic manufacturers and wealthy nations are putting their own populations first.

As of May 4, 2021, the COVAX facility has shipped only 53 million vaccine doses to 121 countries. COVAX procures only those vaccines listed under WHO's Emergency Use Listing (EUL) and these are currently by Pfizer, AstraZeneca/Oxford, AstraZeneca/SKBio, AstraZeneca/SII, Johnson & Johnson and Moderna.

Though COVAX is projected as the mechanism to ensure fair and equitable access to vaccines for low- and middle-income countries, the target of the facility is very low to start with to have a public health impact. From a public health perspective, there is a need to vaccinate a substantial percentage of the population. The minimum requirement is to the tune of 70-80% but COVAX aims to cover only 20% of the population. This is too low to achieve the desired effectiveness of vaccines on populations.²⁴

With the vaccine shortage COVAX is still quite far even from this goal, given that high income countries alone have secured approximately 6 billion vaccine doses for themselves.²⁵ Although some progress has been made, it does not offset the fact that high-income countries will be able to secure vaccines to meet their own needs, which lowers the chances of enough vaccine doses being available to lower-income countries through COVAX. The new wave of infections, worsened by more infectious variants of the COVID-19 virus, has escalated the global outcry against inequitable access for the South and vaccine hoarding by a handful of wealthy countries. With more than they need or a decision to restrict or not use the AstraZeneca vaccine because of blood clot risk, the US, France and Sweden are donating doses to COVAX.

23- The GAVI COVAX AMC- An Investment Opportunity (pp. 1-5, Publication). (2020). GAVI the Vaccine Alliance.

24- Green, A. (2020, December 15). At WTO, a battle for access to COVID-19 vaccines. Retrieved January 10, 2021, from <https://www.devex.com/news/at-wto-a-battle-for-access-to-covid-19-vaccines-98787>

25- KS, J. (2020, December 14). Intellectual property monopolies block vaccine access. Retrieved January 8, 2021, from <https://www.ksjomo.org/post/intellectual-property-monopolies-block-vaccine-access>

COVAX is banking on the AstraZeneca vaccine for supplies, given it is cheaper and easier to transport. However, with only one such vaccine it is difficult for COVAX to achieve its volume guarantees. The Serum Institute of India, which is manufacturing the AstraZeneca vaccine, was slated to provide COVAX with 50 million doses by April 2021.²⁶ However, COVAX had only been supplied with 28 million doses by late March. With India in the throes of a second, fresh wave of COVID cases, exports from the SII had been delayed through March and April 2021 in favor of supplying vaccines domestically²⁷ and now exports have been temporarily suspended.

Finally, leaked documents contain statements from GAVI which state that COVAX has been suffering from a lack of funding, supply risks, and “complex” contractual agreements. The non-binding contracts COVAX has signed with AstraZeneca, Novavax and Sanofi allows the companies to back out of supplying doses, which could push up the price of the vaccine from the current \$5.20 per dose. If this happens, the initiative will have failed at its goal of supplying affordable, equitably accessible vaccines, and it would have failed to meet the demands for it. According to an internal report to the GAVI board, a number of people could be left without access to a vaccine until 2024 if the COVAX initiative fails.²⁸

26- Mohan, G. (2021, March 26). UN-backed Covax vaccine supplies from India may get delayed. Retrieved April 8, 2021, from <https://www.indiatoday.in/coronavirus-outbreak/vaccine-updates/story/vaccine-drive-covaxin-covax-india-un-backed-vaccination-1783752-2021-03-26>

27- Mohan, G. (2021, March 26). UN-backed Covax vaccine supplies from India may get delayed. Retrieved April 8, 2021, from <https://www.indiatoday.in/coronavirus-outbreak/vaccine-updates/story/vaccine-drive-covaxin-covax-india-un-backed-vaccination-1783752-2021-03-26>

28- Beaumont, P. (2020, December 16). Scheme to get Covid vaccine to poorer countries at ‘high risk’ of failure. Retrieved January 3, 2021, from <https://www.theguardian.com/world/2020/dec/16/scheme-to-get-covid-vaccine-to-poorer-countries-at-high-risk-of-failure>



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