

Submission by Third World Network to the Global Preparedness Monitoring Board (GPMB)

August 2021

1. Solidarity and the global COVID-19 response

In many ways, the collective response to COVID-19 has been defined by failed leadership, nationalism, inequalities and obstacles to cooperation and global solidarity.

- a) How have these issues impacted low- and middle-income countries' response to the pandemic?**
- b) How have the global community and the international system dealt with these issues? What have been successful elements of the global response? What have been the biggest failures?**

Since the start of the pandemic, there have been many promises of solidarity, treating vaccine as “global public goods” and universal access. These promises have failed to materialize, the international community and WHO has failed developing countries.

The first big failure was the setting up of ACT-A without due process and in the absence of transparency and without the involvement of WHO's membership. The WHO DG, together with the donor countries, the industry and other international organizations launched an non-transparent and unaccountable mechanism known as ACT-A that fragmented decision-making and pandemic response as each agency carved out its area of work. Civil society was excluded. IFPMA the lobby of the pharmaceutical industry was brought in as a partner. No binding commitments were obtained from developed countries, the donor community, or the pharmaceutical industry with regard to equitable allocation and affordable access. Decisions around the formation of ACT-A, and pandemic response at the international level is riddled with conflict of interest. At the heart of this conflict, is the Gates Foundation which has played a key role in decision-making that has primarily supported intellectual property monopolies that benefits the pharmaceutical corporations and high-income countries which subsidize those corporations at the expense of equitable access globally.¹

In the area of vaccines, WHO outsourced its role to ensure access to vaccines to GAVI, meaning that WHO members have no say over production, supply and access. Covax, since its beginning has been the subject of significant criticism, for the lack of transparency, accountability, equity and exclusion of civil society.² GAVI made promises of equitable access that were unrealistic from the very beginning. For instance it is incredible that Covax's supply became primarily dependent on one supplier from India, the Serum Institute of India (SII). Why did GAVI not ensure that Astra Zeneca and other originator pharmaceutical companies also license manufacturing to the many manufacturers in developing countries so that these manufacturers may also supply Covax? How could anyone expect that Astra Zeneca's exclusive license with SII would suffice for the vast populations in India as well as in other LMICs.³ Today even as huge amounts of vaccines have been reserved by high income countries, Covax has continued to supply some rich countries (Canada, Australia, UK etc) although some LMICs have yet to receive any vaccines.⁴ This situation reveals major

¹ <https://healthpolicy-watch.news/gates-foundation-address-systemic-covid-19/>

² https://www.twtn.my/title2/intellectual_property/info.service/2020/ip200605.htm

³ <https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable>

⁴ <https://apnews.com/article/joe-biden-middle-east-africa-europe-coronavirus-pandemic-5e57879c6cb22d96b942cbc973b9296c>

flaws in GAVI, Covax and even more importantly in WHO for it has simply failed its Member States. WHO developed an equitable allocation framework that has been sidelined by its partners in ACT-A i.e. international agencies, GAVI, the pharmaceutical industry and the high-income countries that are also major donors of ACT-A.

While most of the international focus is on vaccines, a similar scenario continues with respect to other medical products including diagnostics and therapeutics.⁵

Another failure is the absence of a mechanism in the WHO for the sharing of biological material and sequence information of potentially pandemic pathogens and fair and equitable benefit sharing from the use of the material and sequence information such as affordable vaccines and treatments⁶. A concrete precedent to follow in this regard is the WHO Pandemic Influenza Preparedness Framework (PIP Framework), which in exchange for sharing sequence and biological materials with the pharmaceutical industry, requires the industry to enter into legally binding agreement committing a certain percentage of its supply to WHO. There are also possibilities of other options for benefit sharing e.g. the company receiving biological material/sequence information could be required to offer manufacturing licenses to manufacturers around the world to ramp up production and supply. WHO is working to establish BioHub but yet again (as in the case of ACT-A) there is a failure of due process as the Secretariat is once again bypassing the WHO Membership to put in place inefficient and inequitable mechanisms.

In the midst of these massive failures and a continuing pandemic, WHO's management has decided to support a Pandemic Treaty, to address future pandemics. This Treaty, a European initiative is now supported by the DG of WHO. Notably Europe, has consistently failed to deliver on its promise of equitable access. The Treaty is a diversion from on-going challenges and failures. It will also further fragment pandemic response, and create confusion with respect to the status of the international health regulations.⁷ It has been 1.5 years since the beginning of the pandemic, and we are still failing in pandemic response. This shows that we are not in any position to negotiate a Pandemic Treaty. In fact we need instruments that require the pharmaceutical industry to undertake binding commitments, and this is not possible to be achieved via a Pandemic Treaty which is between governments. However it is possible to achieve this through an access and benefit sharing framework similar to the PIP Framework.

Developed countries supported by the donor community and international agencies such as GAVI view access as an issue of charity and donations. They continue to refuse to accept that to address timely access during a health emergency requires the lifting of intellectual property monopolies, patents and trade secret protection in particular. They continue to object to the TRIPS waiver proposal of India and South Africa that has received massive international support.⁸ It is clear that so long as vast populations remain unvaccinated, the threat of mutations remains and no one is safe until everyone is safe. Even so, the international community, the Gates Foundation, Gavi, CEPI have failed to show strong support for lifting IP monopolies and the sharing of technology so that local production can happen everywhere. There is

⁵ <https://msfaccess.org/tocilizumab-second-drug-ever-recommended-who-covid-19-will-remain-unaffordable-and-inaccessible>

⁶ <https://twm.my/title2/resurgence/2020/343-344/cover17.htm>

<https://www.thehindubusinessline.com/news/un-who-urged-to-ensure-benefit-sharing-of-covid-related-data/article31452044.ece>

⁷ <https://www.twm.my/title2/health.info/2021/hi210702.htm>

⁸ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W668.pdf&Open=True>;

https://www.twm.my/title2/intellectual_property/trips_waiver_proposal.htm; https://www.twm.my/title2/intellectual_property/ip_new.htm

significant manufacturing capacity in developing countries.⁹ Many vaccine producers in developing countries are WHO prequalified.

Another failing is the emphasis on voluntary approaches especially by high income countries, the donor community, international agencies including the WHO with respect to scaling up manufacturing. The public sector has invested at least €93 billion in R&D of COVID-19 vaccines and therapeutics in 2020¹⁰. However, donors have failed to obtain any binding commitments from the pharmaceutical industry with respect to equitable licensing to manufacturers in developing countries to diversify production and supply. Hence the originator pharmaceutical industry have mostly entered into contract manufacturing agreements with selective manufacturers whereby they control the production, supply and prices of the vaccines, therapeutics and diagnostics. These agreements are secretive and artificially constraining global supply.¹¹

A clear example of this is remdesivir which in mid 2020 was thought to be important for the treatment of COVID-19. Gilead entered into non-exclusive secret voluntary licensing agreements with a few generic firms to manufacture and distribute remdesivir in 127 countries. About 70 countries, accounting for nearly half the world's population, were excluded from the license meaning could not be supplied by the licensees under the terms of the license. This restrictive agreement was signed, as LMICs especially suffered from a global shortage of remdesivir as supplies were snapped up by developed countries. This example should have sparked outrage. Instead, the international community did not censure Gilead. Originator vaccines companies followed suit, engaging in similar behavior. Astra Zeneca for instance only licensed production of its vaccine to Serum Institute of India with the unreasonable expectation that somehow SII would supply the vast population of India as well as the huge population of LMICs. This is despite the fact that there are about 20 vaccine manufacturers in India. And Indian manufacturers have typically supplied a significant part of the global vaccine market. Hence despite the world facing a global emergency with consequences for lives and livelihoods around the world, the international community has failed to require originator pharmaceutical companies to engage in global licensing so that independent production and supply can happen. In short, even during a pandemic, “business as usual” practices have prevailed, as pharmaceutical companies artificially limit supply to generate profits with the support of high income countries, the donor community, especially the Gates Foundation, CEPI and GAVI. It is also a huge failure on the part of WHO for many divisions of WHO continue to prop up the status quo and business as usual practices. There is a massive gap in testing, treatment and vaccination in LMICs, and hence the pandemic has been prolonged with catastrophic impact in developing countries.

Analysis suggests that the number of deaths are more than double what is officially reported especially in developing and least developed countries.¹² According to Economist report of 15 May 2021: “*The Economist* has attempted to model the level of excess mortality over the course of the pandemic in countries that do not report it. This work gives a 95% probability that the death toll to date is between 7.1m and 12.7m, with a central estimate of 10.2m. The official numbers represent, at best, a bit less than half the true toll, and at worst only about a quarter of it.”¹³

⁹ https://www.who.int/immunization/programmes_systems/procurement/mi4a/platform/module2/MI4A_Global_Vaccine_Market_Report.pdf

¹⁰ <https://emergingrisks.co.uk/vaccine-investments-close-to-reaching-e100-billion/>

¹¹ <http://infojustice.org/archives/43142> and <https://msfaccess.org/voluntary-licenses-access-medicines>

¹² For e.g. <http://www.healthdata.org/news-release/covid-19-has-caused-69-million-deaths-globally-more-double-what-official-reports-show>

¹³ <https://www.economist.com/briefing/2021/05/15/there-have-been-7m-13m-excess-deaths-worldwide-during-the-pandemic>

“Unsurprisingly, most of the deaths caused by covid-19 but not attributed to it are found in low- and middle-income countries. Our figures give a death rate for the mostly rich countries which belong to the OECD of 1.17 times the official number. The estimated death rate for sub-Saharan Africa is 14 times the official number.Overall, the pandemic is increasingly concentrated in developing economies and continuing to grow.”¹⁴

“We estimate that, by May 10th, there was a 95% probability that the pandemic had brought about between 2.4m and 7.1m excess deaths in Asia (official covid-19 deaths: 0.6m), 1.5m-1.8m deaths in Latin America and the Caribbean (v 0.6m), 0-2.1m deaths in Africa (v 0.1m), 1.5m-1.6m deaths in Europe (v 1.0m) and 0.6m-0.7m deaths in America and Canada (v 0.6m).¹⁵

Apart from deaths, national lock-downs has had severe impact on social and economic development, with millions more pushed into poverty, with education, mental health, nutrition, civil liberties, employment etc greatly affected.

II. Systemic inequity in the global health emergency ecosystem

The COVID-19 pandemic has exposed longstanding systemic inequities in the global health emergency ecosystem and the broader international system.

- a) What are some key structural elements of the ecosystem that contributes to these inequities ?**
- b) What impact do these structural elements have on effective and equitable health emergency preparedness and response?**

The key structural elements contributing to inequity includes:

- Side-lining and marginalization of WHO’s decision-making processes especially the voices of LMICs in decision-making; lack of transparency and the absence of accountability mechanism.
- WHO’s reliance on donor voluntary funds especially its reliance on the funding by the Gates Foundation;
- Conflict of interests esp, WHO’s relationship with Gates and the pharmaceutical industry;
- Influence of developed countries esp. EU and the US over WHO’s senior management;
- Fragmentation of pandemic response under ACT-A.
- The absence of a fair and equitable framework adopted by the World Health Assembly for potentially pandemic pathogens similar to the PIP Framework;
- The absence of any conditionalities on the industry that has benefitted from public funding to commit to equitable allocation, the lifting of intellectual property monopolies and the sharing of technology and knowledge.
- The absence of agreement that during a health emergency, intellectual property monopolies will not be applicable.
- The requirements of the WTO-TRIPS Agreement especially its Article 31bis mechanism, and the two decades of pressure that has been placed on developing countries by developed countries and the pharmaceutical industry discouraging the use of TRIPS flexibilities and creating legal obstacles to establishing local manufacturing capacity.¹⁶

¹⁴ ibid

¹⁵ ibid

¹⁶ <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>

- High concentration and monopoly in the production of medical products, its materials and components. The world's top 10 exporting economies supplied about three-quarters of world trade of COVID-19-critical products.¹⁷ Concentration of production and supply extends to raw materials and components for manufacturing. For e.g. “in the case of single use bioreactor bags, are not only in short supply because of exceptionally high pandemic demand, but also because there's been a classic monopoly rollup of the bioprocess supplies industry. That consolidation is fortified by extensive intellectual property barriers that prevent new entrants from manufacturing these now crucial bioreactor bags and filters.”¹⁸
 - The reliance on voluntary approaches to scale up and diversify manufacturing and supply.
 - The absence of regulatory pathway for the approval for vaccines “similar” to originator vaccines¹⁹
 - The absence of expedited regulatory pathway for the approval of biosimilars²⁰
 - Significant delays in WHO prequalification of diagnostics, therapeutics and vaccines.
- The impact of these elements are discussed above in Part I.

III. Addressing these inequities and improving the global health emergency ecosystem

- a) How should the global health emergency ecosystem be reformed to improve equity?**
- b) What are key measures that should be implemented to ensure future global responses to health emergencies are fairer, more equitable and more effective?**

These are some possible measures for a better pandemic response:

- To set up a fair and equitable framework through an intergovernmental process, and the World Health Assembly for potentially pandemic pathogens similar to the PIP Framework with pharmaceutical companies expected to take on legally binding commitments to provide access as well as to issue global licenses for manufacturing.
- Transparent and accountable decision-making processes that involves WHO Members (especially developing and least developed countries) and civil society.
- A policy on conflict of interests where donors such as Gates and the pharmaceutical companies and others with a vested commercial interests are kept at arm's length with no opportunity to influence decision-making processes.
- No outsourcing of WHO's responsibility to other international agencies such as GAVI.
- Ensuring sustainable financing for WHO esp. increasing Member States assessed contributions and reducing reliance on voluntary funding.
- WHO to ensure that initiatives affecting WHO Member states goes through WHO's decision-making processes i.e. the Executive Board and the World Health Assembly.
- Ensure that the provision of public funding to industry is subject to conditions that ensures equitable and affordable access globally such as licensing of the technology to all manufacturers esp in developing countries on competitive terms and conditions, and ensuring pricing that is affordable.

¹⁷ https://www.wto.org/english/tratop_e/covid19_e/medical_goods_update_jun21_e.pdf

¹⁸ <https://mattstoller.substack.com/p/why-are-there-shortages-of-plastic>

¹⁹ <https://www.twm.my/title2/wto.info/2021/ti210616.htm>

²⁰ <https://healthpolicy-watch.news/access-to-affordable-biologics-in-the-context-of-covid-19-will-who-step-up-to-its-responsibility/>

- Ensuring that all intellectual property monopolies esp patents, trade secrets, industrial design and copyright are waived globally to scale up and diversify manufacturing and supply and reduce prices (as more suppliers enter the market), for a temporary period of time e.g. 5 years.
- Ensuring that requirements of the WTO-TRIPS Agreement esp its Article 31bis mechanism are simplified so that there is sufficient freedom to manufacture, use, import and export medical products. Statutory licenses should be encouraged to address public health needs.
- Developing countries should also be encouraged to optimally utilize TRIPS flexibilities and developed countries should not put pressure on developing countries discouraging the use of such flexibilities.
- To promote diversification in the production and supply of medical products, its materials and components. Each region/sub-region should be reasonably self-sufficient with respect to production and supply.
- The business model of the pharmaceutical industry has to be changed. Its obscene focus on profits is at the expense of many lives around the world. We need to move away from the “secret, restrictive voluntary” model of licensing to an equitable transparent global licensing of manufacturing. Without diversifying production and supply, health emergencies cannot be addressed.
- Establish simplified regulatory pathway for the approval for vaccines “similar” to originator vaccines
- Simplify regulatory pathway for the approval of biosimilars
- Fast-track WHO’s prequalification of diagnostics, therapeutics and vaccines needed during a health emergency.
- Create an international mechanism of cooperation for the sharing of regulatory dossiers with manufacturers around the world to facilitate manufacturing as well as to expedite regulatory approval of follow-on vaccines and biosimilars. This will also avoid duplication of clinical trials and facilitate R&D into better vaccines and treatments.