

To:

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Board Members of Gavi, the Vaccine Alliance

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Dear Members of the Gavi Board,

As the world grapples with the COVID-19 pandemic, there is an urgent need for the development and delivery of effective and safe vaccines that are affordable and available to all countries and vulnerable populations equitably and in a timely manner. We, the undersigned civil society organisations and individuals, write to express our deep concerns around whether such access to future COVID-19 vaccines will be guaranteed.

As civil society, we are closely following potential COVID-19 vaccine developments and the initiatives underway to try and improve access, namely the COVID-19 Vaccine Global Access (COVAX) pillar of the Access to COVID-19 Tools (ACT) Accelerator and the Gavi-led COVAX Facility (as well as the COVAX Advance Market Commitment (AMC)). We need approaches that work to reach all people and ensure that the first vaccines developed will go to those who need them most, rather than to the countries that use their wealth to get to the front of the line. Recent developments, however, including Gavi's 'Preliminary Technical Design' (11 June) of the COVAX Facility, have deepened our concerns.

The COVAX Facility and COVAX AMC are market-based initiatives intended to incentivise the pharmaceutical industry to produce volumes of potential COVID-19 vaccines for future needs and to secure doses. This initiative reflects the reality that Gavi and governments have not delivered on a previous promise of designating COVID-19 vaccines as 'global public goods'. In a "business as usual" approach to intellectual property, 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 monopolise future

COVID-19 vaccines and decide who does and does not get access. It is worthwhile to note that on top of the more than US\$4.5 billion of public and philanthropic funding already given to companies for COVID-19 vaccine research and development (R&D), Gavi is now designing a fund to award further money to pharmaceutical corporations. 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. Moreover, companies' lack of transparency on the cost of R&D and manufacturing makes the effort to assess claims of a 'no profit' price nearly impossible.

While we appreciate the need for urgent and swift solutions, we caution against rushing into a flawed strategy that risks compromising future access. The COVAX Facility Preliminary Technical Design document worryingly reinforces tiered pricing, which has not been proven to improve access but instead is a well-known industry pricing strategy, and an unequal structure of access based on countries' wealth (i.e. countries that self-finance their vaccines versus Gavi-supported countries). Additionally, the secrecy surrounding Gavi's recent announcement of a US\$750 million deal with AstraZeneca for 300 million doses of their potential vaccine seems to reverse Gavi's original promise to ensure transparency and secure vaccines 'at cost'.

In the wake of the COVAX Facility's launch, and building on the lessons learned from Gavi's pneumococcal vaccine AMC, we highlight seven urgent recommendations that should be incorporated into the next phase of the Facility's design:

1. **Vaccines must be allocated based upon public health criteria for all countries:** Gavi's Preliminary Technical Design document presents a strikingly unequal and inequitable picture of how the forthcoming WHO-developed equitable allocation framework will be applied within the COVAX Facility, and how potential COVID-19 vaccines will be allocated among countries based on their financial capacities, not public health needs. While wealthier, self-financed countries are encouraged to use the forthcoming World Health Organization (WHO)-developed Global Equitable Allocation Framework, they are not required to abide by it, whereas poorer donor-dependent countries are obliged to abide by it. Additionally, it seems that there are different proposals for allocating future COVID-19 vaccines based upon a country's wealth: self-financing countries will seemingly have a different allocation formula applied (to cover a set proportion of their population (e.g. ~20%)), while donor-dependent countries will only receive enough vaccine to vaccinate their most vulnerable populations based on national demand. Gavi must urgently revisit this decision and ensure that future COVID-19 vaccines are allocated based on public health criteria for all countries; not just those who are dependent on donors.
2. **Transparency must be fundamental to the COVAX Facility:** Gavi claimed it would ensure transparency when it first announced the possibility of a COVID-19 vaccine AMC on 1 May; however, to date there has been no transparency around the COVAX Facility's design nor the first deal with AstraZeneca. In order to assess the prices set, Gavi must require that any agreement with pharmaceutical companies mandates transparency around all costs of development and production. Gavi must also publish any agreements and contracts made with industry. As Gavi is receiving taxpayer money to finance these deals, transparency is essential for public scrutiny.

3. **Prices must be set ‘at-cost’:** There should be no profit turned on the back of this global pandemic. Yet, Gavi’s recent Preliminary Technical Design document surprisingly states its plan to accommodate a tiered pricing approach over time, providing the opportunity for pharmaceutical companies to further profiteer from this global health crisis. In light of the significant taxpayer money already invested in COVID-19 vaccine R&D, Gavi’s COVAX Facility must insist that it pay no more than the at-cost price for future doses of COVID-19 vaccines. While AstraZeneca claims a ‘no profit’ price in its agreement with Gavi, there is no transparency with which to verify this information. It is worthwhile to note that while Gavi typically negotiates prices ~90% less than industrialised countries, this agreement is only 37% less than that of the United States, one of the wealthiest countries in the world.
4. **No risky advance payments without clear conditions:** Figures received by civil society show that Gavi estimates it will need US\$10.3 billion for risky investments (R&D investments, manufacturing scale up and building inventory) and up to US\$15.7 billion for volume guarantees. Gavi has seemingly not outlined any conditions or criteria for these risky investments, including the advance funds awarded to AstraZeneca: What happens if AstraZeneca’s product is not ultimately successful or if AstraZeneca is unable to meet the volumes stipulated? Why has AstraZeneca been selected first? The lack of conditions and criteria, and transparency around them, is worrying. Gavi must not engage in risky advance payments to private pharmaceutical corporations without clear and transparent criteria and without conditions set for each manufacturer that receives funds.
5. **Operate in line with WHO’s Solidarity Call to Action for equitable global access to COVID-19 health technologies:** Gavi’s COVAX Facility must require that manufacturers receiving its funds share their intellectual property, technologies, know-how and data in such a way that guarantees the non-exclusive right to use, produce and supply for all competent entities worldwide, so that the world is given the best chance to rapidly scale up manufacturing of successful COVID-19 vaccines. Requirements regarding open-licensing and technology transfer by companies must be inherent in the COVAX Facility. Additionally, Gavi should clearly state its support for measures and solutions (including the COVID-19 Technology Access Pool (C-TAP)) that aim to overcome intellectual property barriers that limit the number of manufacturers, and ultimately, limit access.
6. **Non-governmental purchasers must be included:** While Gavi’s COVAX Facility only focuses on governments as future purchasers of COVID-19 vaccines under the deals it brokers, non-governmental, humanitarian and civil society organisations are also key actors for the delivery of future COVID-19 vaccines, particularly to the most vulnerable populations who are often not reached by government services. In the past, Gavi’s agreements with industry have not included humanitarian organisations and non-governmental organisations as possible purchasers, resulting in examples where these actors were left paying double the Gavi price to purchase the same vaccine for use in a Gavi-eligible countries. The COVAX Facility must therefore require that these non-governmental actors can purchase the COVID-19 vaccines at the lowest global price and directly from the companies.
7. **Accountability is critical:** The Gavi Secretariat must be more accountable to the Alliance partners for the development of the COVAX Facility and the agreements it pursues. In addition, as a key implementing partner of the WHO ACT-Accelerator process, and with its proposal to house a ‘global’ facility (i.e. beyond Gavi’s geographical competency), Gavi should recognise its broader accountability to all WHO

Member States. It is concerning that the first phase of the COVAX Facility's design, in addition to the significant agreement brokered with AstraZeneca for US\$750 million, seemed to be done outside of the Gavi governance structure. Also, it seems that developing countries – to which Gavi is mainly responsible in its core work – have not had adequate input into the design of the Facility. It is unclear if Gavi is founding a new organisational structure or remains accountable to its Board and governance committees for the COVAX Facility and its funds. Civil society wishes to be meaningfully involved in the design of the Facility.

Short-sighted nationalism is unacceptable in the face of this pandemic where equitable allocation of future COVID-19 vaccine doses among countries and global solidarity should be paramount. We therefore support the concept of a global mechanism as a necessary counter to nationalist stockpiling measures, and as a means to protect public health and accomplish true equity in accessing future COVID-19 vaccines. However, a global mechanism needs to ensure that all countries are bound by it and that the underlying inequality in access to health care is addressed by prioritising the protection of the most vulnerable populations living in resource-limited settings. We wish to underscore that civil society strongly supports a WHO-led global allocation framework to arbitrate the potentially scarce COVID-19 vaccine supply based on both existing and future manufacturing capacity, and we will call on all governments and companies to abide by it. To achieve this, the problematic approach proposed in the Preliminary Technical Design document needs to be critically scrutinised at the upcoming Gavi Board meeting.

We thank you, Board Members, for your attention to our above-listed concerns and we hope that you work to ensure that these recommendations are rapidly incorporated into the COVAX Facility's design.

We invite you to engage with the below civil society organisations and individuals and we welcome the opportunity to discuss with you how we can work together to ensure that future COVID-19 vaccines are accessible to all and truly global public goods.

Sincerely,

1. Access to Medicines Ireland
2. Action against AIDS, Germany
3. Afrihealth Optonet Association [CSOs]
4. Association des Femmes de l'Europe Meridionale (AFEM)
5. BARAC UK
6. BUKO Pharma-Kampagne
7. Carmen Capriles, Bolivia
8. Centre for Community-Driven Research (CCDR)
9. Changemaker Norway
10. Corporación Innovarte, Chile
11. Dr. Mohga Kamal-Yanni, Consultant in global health and access to medicines
12. Dr. Uzo Adirieje Foundation (DUZAFUND)
13. Ecologistas en Acción, Spain
14. Fondation Eboko, France
15. Foundation for Integrative AIDS Research (FIAR), USA

16. Fundación IFARMA, Colombia
17. Global Health Advocates France
18. Global Justice Now
19. Health Action International (HAI)
20. Health Education Literacy Programme, Pakistan
21. Health Global Access Project (International)
22. Ibn Sina Academy of Medieval Medicine and Sciences, India
23. ITPC.LATCA
24. Just Treatment
25. Knowledge Ecology International (KEI)
26. Lawyers Collective
27. Médecins Sans Frontières Access Campaign
28. Misión Salud, Colombia
29. Nelson Mandela TB HIV Community Information & Resource Centre Kisumu, Kenya
30. Oxfam
31. Positively UK
32. Public Citizen
33. Public Eye, Switzerland
34. Reacción Climática, Bolivia
35. RESULTS Korea
36. Salud por Derecho, Spain
37. Salud y Fármacos
38. SECTION27, South Africa
39. SELACC - Secretariado Latinoamericano y del Caribe de Cáritas
40. Srividhya Ragavan, Professor of Law, Texas A&M School of Law
41. STOPAIDS
42. Sukaar Welfare Organization, Pakistan
43. Universities Allied for Essential Medicines (UAEM)
44. World Vision Deutschland e.V.
45. Yolse, Santé Publique et Innovation