



Association of Schools of Public Health in the European Region (ASPHER) COVID-19 task force, Vaccination sub-group

Full statement on the proposal for a waiver of the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and related vaccine equity issues

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Introduction

World leaders have stated repeatedly that they support equitable and effective global vaccination against COVID-19 [Carbis Bay G7 Summit Communique, 2021], (<u>https://www.g7uk.org/wp-content/uploads/2021/06/Carbis-Bay-G7-Summit-Communique-PDF-430KB-25-pages-3.pdf</u>) [Global Health Summit, the Rome Declaration] (<u>https://global-health-summit.europa.eu/rome-declaration_en</u>).

In a global pandemic vaccine equity means that all countries should be able to immunise their populations regardless of their income, pre-existing infrastructure or economic development [UNDP COVID-19 Data Futures Platform] (<u>https://data.undp.org/vaccine-equity/</u>). The current situation, however, favours high income countries. As a result, people who live in low-and- middle- income countries are significantly less likely to have access to vaccination than those in high income countries. This is the case even for people in the highest clinical risk groups and for essential health and care workers. COVID-19 vaccines significantly reduce the burden of serious illness [Haas, 2021], death [Haas, 2021] [Alencar, 2021], symptoms [Griffin et al, 2021} and risk of transmission [Mostaghimi et al, 2021]. Where populations whose overall health is poorer, exposure risk greater because of poverty, overcrowded housing and limited social protection and where the health system is less able to respond to a surge in need for acute hospital and intensive care, that inequity is multiplied. Failure to reduce transmission through vaccination and other means increases the level of virus circulating in communities and increases the risk of that new vaccine resistant variants will emerge.

Addressing vaccine inequity

Safe, effective vaccines against SARS-CoV-2 have been available at scale since Spring 2021 and, while efforts are still underway to reduce vaccine inequity within high income countries, they have purchased sufficient supplies to offer a one, two or three dose schedule as their professional and regulatory bodies recommend.

This is not the situation in low and middle income countries who cannot pay the prices required to import vaccines at the scale and pace required to immunise their populations and who lack the means to secure supplies through other forms of commercial negotiation because they do not currently have manufacturing capacity, sources of raw materials to use as bargaining chips or a cold chain infrastructure tested to support use of mRNA vaccines

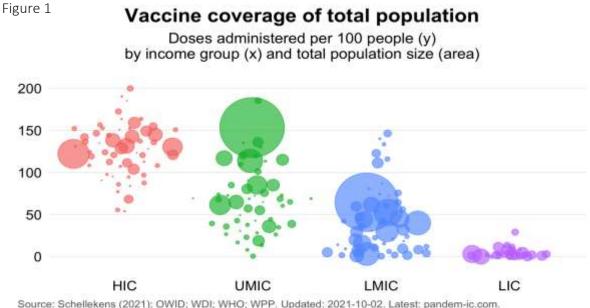


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Low-and-middle income countries should be able to rely on the global commitment to Universal Healthcare – Sustainable Development Goal 3 to secure access to sufficient vaccine at an affordable price. Addressing vaccine inequity in a global pandemic is the first step towards demonstrating that commitment is real not rhetoric. By September 2021, while Portugal had fully immunised 81% of its eligible population, in several African countries, coverage was significantly less than 2% with uptake rising slowly despite local efforts [Mathieu, E. et al (2021)]

We recognise that low- and middle-income countries also vary in the extent to which vaccines are available and accessible. Several middle income countries are struggling to afford high-income country prices and are ineligible for schemes designed to support countries with the fewest resources despite a higher proportion of their populations being at increased risk of severe disease following SARS-CoV-2 infection. Moreover, it is not just a problem of availability of vaccine doses. Effective deployment of vaccination is a significant capacity challenge that requires skilled personnel, transport and adequate storage and handling infrastructure. Vaccine inequity is also being seen within LMICs as the most affluent sections of society face fewer barriers to accessing vaccines.



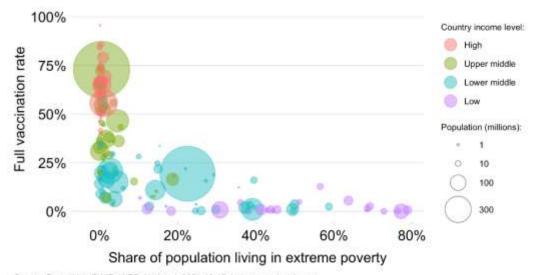
Source: Schellekens (2021); OWID; WDI; WHO; WPP. Updated: 2021-10-02. Latest: pandem-ic.com. Note: Acronyms: high (HIC), upper-middle (UMIC), lower-middle (LMIC) & low income (LIC) countries. Doses exclusive of boosters. Doses of single-dose vaccines converted into double-dose equivalents (counted twice) to achieve full vaccination threshold of 200.

The pandem-ic.com website summarises information on vaccine equity [Schellekens P, 2021] (<u>https://pandem-ic.com/vaccine-equity-across-and-within-income-groups/</u>). Under all measurements, there is a clear and steep income gradient. While low income countries are a long way from having vaccinated the highest priority groups, lower and upper middle-income countries (excluding China) are also experiencing significant vaccine inequity. [Schellekens P, 2021] (Vaccine equity trackers <u>https://pandem-ic.com/</u>)





Figure 2 examines the relationship between country level vaccination rates, country income group and the proportion of the population living on less than \$1.9 dollars per day at 2011 purchasing power parity.



Vaccination and extreme poverty

Source: PovcalNet: OWID: WPP, Updated: 2021-10-12. Latest: pandem-ic.com. Note: Full vaccination rate excluding boosters. Extreme poverty rate: share of population living under \$1.90 a day (2011 PPP) in most recent year available since 2010. Country groups: World Bank income classification.

Current mechanisms of global vaccine delivery are welcome but not sufficient to address vaccine inequity

The WHO COVID-19 Strategic Preparedness and Response Plan [WHO, 2021] (<u>https://www.who.int/publications/i/item/WHO-WHE-2021.02</u>) sets out the following priorities for vaccination:

- Develop and implement a framework for transparent and equitable allocation of available vaccine supply globally.
- Ensure regulatory preparedness for deploying unlicensed vaccines, and reduce complexities for vaccine access and delivery in countries with reliance on emergency use listing and prequalification before introduction
- Reduce process complexities for vaccine manufacturing by developing harmonized regulatory standards, indemnification/liability, labelling, supply chain optimization and streamlined procurement mechanisms.
- Address vaccine hesitancy, misinformation and other demand-side issues impacting vaccine uptake.
- Promote technology transfer to low-income and middle-income countries with the potential capacity to accelerate global production of COVID-19 vaccines.

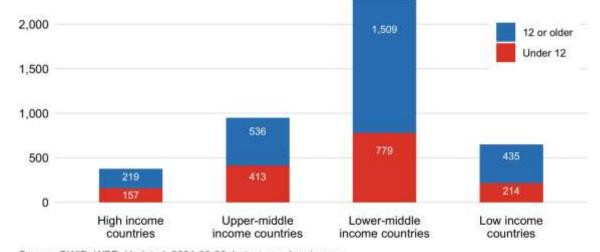


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High income countries have established bilateral deals with companies for the supply of vaccines, with the EU also negotiating as a region. For low-and- middle- income countries, the main mechanisms for vaccine delivery is through the vaccine pillar of the WHO access to covid-19 tools accelerator (ACT-A), specifically COVAX [WHO, COVAX, 2021] (https://www.who.int/initiatives/act-accelerator/covax). COVAX is the vaccines delivery pillar of the access to COVID-19 tools accelerator and key to the WHO Preparedness and Response Plan for 2021-22. The intention is that 2 billion doses of vaccine will be delivered to 98 self-financing countries and 92 of the lowest income countries. COVAX has been established with an underlying spirit of solidarity and considerable ambition for international collaboration. However, the COVAX mechanism has been disappointing because of limited active engagement with recipient countries to facilitate the detailed planning and logistics required to optimise delivery and use of vaccines received, early vaccine capture by high income countries, and manufacturer behaviour [Furneaux R, Goldhill O, 2021] (https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/).

Figure 3 illustrates the number of people who still require vaccination.



The unvaccinated population by income group Number of unvaccinated people (millions)

Source: OWID; WPP. Updated: 2021-09-30. Latest: pandem-ic.com. Note: Aggregation: World Bank income classification. Globally, 4,263 million people are currently fully unvaccinated people (2,700 million 12 or above and 1,563 million under 12). Assumes noone under 12 has been vaccinated per vaccine eligibility. Under 12 cohort approximated as <10 cohort plus 2/5 of 10-15 cohort.

Two billion doses delivered to people at the highest risk is a significant safety net, but it is clearly not enough to vaccinate the world, particularly given the requirement for two or three dose schedules. The mechanisms used to date, largely donation by high income countries and limited voluntary licensing of additional vaccine production, need to be scaled up and supplemented by other measures.





ASPHER's position

ASPHER supports the September 30 proposal to WTO for a TRIPS waiver (IP/C/W/684) [WTO, 2021]

<u>https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W684.pdf&Ope</u> <u>n=True</u>) to support delivery of the WHO strategic preparedness and response plan 2021-22 [WHO, 2021] (<u>https://www.who.int/publications/i/item/WHO-WHE-2021.02</u>).

The proposal calls for a waiver of the application, implementation, and enforcement of TRIPS provisions on copyright (Section 1), industrial designs (Section 4), patents (Section 5) and protection of undisclosed information (Section 7). The waiver proposal only focuses on categories of intellectual property that are relevant to the production, supply, and access to COVID-19 health products and technologies. The arguments and the complexities associated with utilising measures other than a TRIPS waiver when there is concentration of supply, new patents are not available for scrutiny, and the patents for production and the underlying technology are held by large and small companies, academic institutions and agencies in different jurisdictions well stated in the proposal to WTO, document IP/C/W/684 [WTO, 2021]. They are not repeated in detail here as our primary concern is immediate action to protect global public health. We consider that implementation of the TRIPS waiver should start with vaccine equity. While vaccination is presented as a distinct programme (pillar 10) within the WHO response, effective delivery will support the achievements of the others. Bringing the pandemic under control requires global vaccination and rapid attention to achieving vaccine equity.

The proposal is achievable and consistent with the initial DOHA declaration of 2001 and the provisions added when it was updated. [WTO, 2001] (https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

[WTO, 2003]. The DOHA declaration recognises that the right of countries that are members of the World Trade Organisation (WTO) to protect public health and enables them to use all of the measures available under the TRIPS Agreement to protect public health, particularly to ensure medicines for all. This includes vaccines for all. The flexibilities outlined in the DOHA agreement enable countries to require compulsory licensing, declare a national public health emergency and determine when intellectual property rights are exhausted. The DOHA declaration recognised the difficulties faced by countries without a pharmaceutical industry base and the barriers to vaccine access faced by low income countries.

ASPHER also requires that the other barriers to achieving universal COVID-19 vaccination are addressed and we set out the steps required to dismantle them below.





1. High income countries should fulfil existing commitments to deliver their fair share of vaccines to mitigate immediate vaccine inequity and buy time for sustainable change

High income countries have been stockpiling vaccines. The price they bought them at is unaffordable to low and many middle-income countries. In addition to the cost, it is not acceptable for wealthy countries to accumulate excess doses of several vaccines at a time when they have not fulfilled their existing agreements to supply to low-and-middle-income countries. As a first step, existing agreements should be honoured rapidly, and vaccines deployed to immunise health, social care, and other essential workers. Many high-income countries are only donating left-over doses that are close to their use-by date. Others have delayed fulfilling their commitments until they have completed vaccinating their own populations. Only a few countries, for example Norway, have donated in parallel with domestic use and only Germany, Norway, Canada, Kuwait and Saudi Arabia had pledged 100% or more of their fair share under the Access to COVID-19 Tools Accelerator by September 17, 2021. [WHO, 2021] https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker]. (see Appendix). High-income countries and companies need to honour and scale up their commitments with clear plans produced in partnership with those responsible for organising vaccination in the at-risk communities in low and middle income countries.

2. Donation is not enough

Even if all pledges were honoured in a timely fashion, it is not sustainable to expect that the vaccine requirements for the majority of the world's population should be met by donations from wealthy countries. Furthermore, as several high income countries hedged their bets regarding choice of vaccines or rushed to conclude national agreements to ensure rapid roll out, there is a risk of substantial waste and/or dumping expiring products on third countries and onto international programmes.

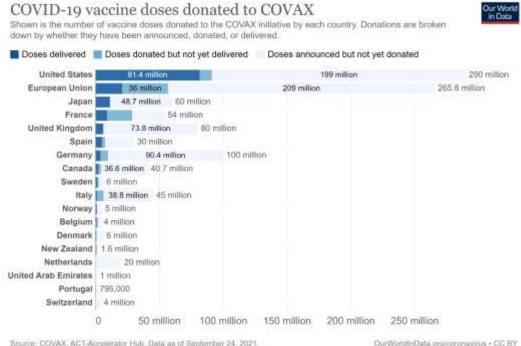
While the establishment of COVAX, the global partnership that coordinates access to vaccines, has been a remarkable achievement, it was never intended to be the only mechanism for ensuring equitable distribution of vaccines. The most optimistic forecasts indicate that COVAX will provide just enough doses to enable 37% of the eligible population in 91 lower income countries to be vaccinated by March 2022 [WHO, 2021] (<u>https://www.who.int/publications/m/item/covid-19-virtual-press-conference-transcript---14-september-2021</u>). This is the level of coverage estimated from the total commitments by the G7 and the governments, of Australia, India, South Korea and South Africa, as outlined in the Carbis bay





declaration in the statement [Carbis Bay G7 Summit Communique, 2021] (https://www.g7uk.org/wp-content/uploads/2021/06/Carbis-Bay-G7-Summit-Communique-PDF-430KB-25-pages-3.pdf). This provides for two billion doses in total, with only one billion delivered in 2022. Without additional action, the stated aim of the Rome Declaration in May 2021 'to enhance timely, global and equitable access to safe, effective and affordable COVID-19 tools (vaccines, therapeutics, diagnostics, and personal protective equipment, henceforth 'tools') is empty rhetoric.

Figure 4



Source: COVAX, ACT-Accelerator Hub. Data as of September 24, 2021. CorWorldinData.org/coronavirus - CC BY Nota: COVAX is a worldwide initiative aimed at equitable access to COVID-19 vaccines. It is directed by Gavi, CEP1, and the WHO.

The gap between doses announced and doses delivered is clear. By mid-September 2021, approximately 16% of the pledged doses had been delivered and there was a 0.8 billion-dollar gap for vaccines alone to meet existing agreements [WHO, 2021] (update 17/9/21). (<u>https://www.who.int/initiatives/act-accelerator/funding-tracker</u>) (WHO ACT-Accelerator Prioritized Strategy & Budget for 2021. 2021 <u>https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for-2021</u>).

Current efforts will not deliver global vaccine equity and will not even be enough to make a significant dent in avoidable COVID-19 related mortality, particularly since there are ongoing delays in pledges delivering vaccines to low-middleincome countries. Other forms of multilateral agreement designed to scale up production and distribution are essential for the effective management of a global pandemic. Again, the Carbis bay declaration promises manufacturing capacity in





all continents but there is no clarity regarding scale, scope, and pace [Carbis Bay G7 Summit Communique, 2021] (<u>https://www.g7uk.org/wp-content/uploads/2021/06/Carbis-Bay-G7-Summit-Communique-PDF-430KB-25-pages-3.pdf</u>). There are simple, practical measures to improve equity of vaccine distribution and address the need to strengthen staffing and infrastructure. Others have described them in more detail, and we summarise these below. Governments and companies could easily start to adopt these before COP 26, demonstrating immediate global solidarity and corporate social responsibility. ([Yamey, 2021] [Hassan, Yamey, Abassi, 2021].

3. Ensure that arrangements are built on equity of esteem

National and local teams in low- and middle-income countries have considerable experience in the successful delivery of mass vaccination and vaccination trials in challenging circumstances. They have also overcome recent Ebola outbreaks under extraordinarily difficult circumstances. Attention to the 4 Rs framework–reciprocity, relatability, relationships, respect, including equitable access to trustworthy information regarding the illness, immunisation and the role of the vaccine is essential. [Dada, 2021]. The commercial protectionism from major pharmaceutical companies (and some countries) [Dutfield, 2021] [Maxmen 2021] [Sell, 2006] [Torres, 2020] has combined with neo colonial and paternalistic approaches to create a narrative that suggests poor countries cannot produce vaccines in line with international quality standards, yet India is the largest producer of vaccine in the world.

4. Expand production capacity

Pandemic vaccination efforts are unlikely to remain a global one-time effort suitable for ad-hoc measures and coalitions of charitable donations. Currently the UNICEF vaccine market dashboard [UNICEF, 2021] (<u>https://www.unicef.org/supply/covid-19-vaccine-market-dashboard</u>) indicates that there are 3.6 billion doses of vaccines that already have regulatory approval available for use in 2021, increasing to 22.2 billion in 2022. There is sufficient capacity for immediate distribution but a more sustainable, scalable and geographically distributed global supply chain is required.

This requires consideration of how production of vaccines is organised for the remainder of the pandemic, building on immediate concerns regarding equitable vaccine distribution to put in place what will be required to address future pandemics. Any future strategy must address prioritisation processes and production capacity. WHO has taken a strong stand against use of a third dose of vaccine in healthy populations while vaccine production remains artificially





constrained. Others have questioned the ethics of promoting a third round of vaccination in high income countries before additional evidence is available regarding the necessity of a third to dose in the general population and until production capacity is sufficient to ensure a sustainable global supply chain that can respond rapidly to the emergence of new variants or surges.

The challenge of production capacity has already been debated internationally during previous reviews of pandemic preparedness. The DOHA declaration allows for increasing vaccine production by various means and it is part of the Access to COVID Tools Accelerator framework. [DOHA 2001, 2003] [WHO, 2021]. Innovative technologies will enable approaches similar to those used for sharing materials to enable rapid mass production as part of influenza management if the existing vaccine production sites increase capacity and it is also expanded and maintained in additional countries. This issue is at the core of the debate on technology adoption and transfer. This includes the role of mRNA-based vaccines.

Support from high income countries for scaled up manufacturing, capacity building and investment across the supply chain would demonstrate a real commitment to sustainable public health measures that address the wider determinants of health such as secure, skilled employment and associated infrastructure.

5. Remove unwarranted export restrictions Several countries, currently including the US, China, Japan, and South Korea have vaccine and/ or essential raw material export restrictions in place. India originally had a 'vaccine friendship scheme' but paused it as Indian society opened rapidly and it then became overwhelmed with the Delta variant.

Public health rather than commercial criteria should guide the balance between vaccine retention to manage surges and outbreaks and maintaining the pace of vaccine production across countries so that there is minimal disruption to the vaccination programmes in Low- and Middle-Income Countries.

6. Optimise the options within TRIPS as part of the pandemic response plan

The DOHA declaration [DOHA 2001, 2003] and existing World Trade Organisationstatements[WIPO, 2021]<u>https://www.wipo.int/covid-19/en/news/2021/news 0002.html</u>][WTO, 2021]make clear that there areoptions within TRIPS for compulsory licensing and exceptions, but these are clearlyinadequate and ineffective means of delivering vaccine equity. However,countries and companies that have tried to obtain compulsory licenses in line withthe public health provisions within TRIPS have been blocked – see Bolivia, Biolyse





andCanada[Bruce,2021](https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-
Scathing-On-Obstacles-To-Compulsory-Licensing)2021]

Despite the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) statement about the five steps to urgently address COVID-19 vaccine equity in May 2021 [IFPMA 2021] (<u>https://www.ifpma.org/resource-centre/five-steps-to-urgently-advance-covid-19-vaccine-equity/</u>) and their statement [IFPMA, 2021] (<u>https://www.ifpma.org/covid19/</u>), that there are enough doses of vaccine for everyone to be doubly vaccinated, vaccine supply is artificially constrained and thus not reaching low-and-middle-income countries in a timely way. This enables some producers to monopolise the market, controlling the volume of production and the supply chain to countries. Not all COVID-19 vaccine-producing companies are members of IFPMA.

Compulsory licensing, technology transfer and secondments of expert people and resources can all be arranged, complete with non-disclosure agreements for protection of trade secrets, when a global company has an urgent medicines or technology research barrier to be overcome in a high income country. If they cannot be delivered rapidly in a pandemic, then these mechanisms are not fit for purpose and need to be overhauled urgently.

7. Agree an immediate TRIPS waiver

As leaders of Schools of Public Health in the WHO European Region and topic experts we are dismayed at EU and UK opposition to a TRIPS waiver. The EU and UK parliaments are the major obstacles to vaccine equity. Support for an immediate TRIPS waiver for this pandemic and development of a pathway for TRIPS waivers for future pandemics is essential and would provide some evidence that high income countries were willing to act to address the current vaccine inequity and market failure.

The precedent has already been set by withdrawal of the case by 40 pharmaceutical companies when South Africa enforced compulsory licensing provisions to enable local production of anti-HIV medicines [Dhar, Gopakumar 2020] (<u>https://artnet.unescap.org</u>), use of flexibilities by Rwanda for the import of anti-HIV medicines, the three previous TRIPS waivers since 1995 and the DOHA agreement which allows for significant flexibility on public health grounds, not just for countries but for formal global partnerships, like GAVI, that are established to meet collective goals.





There are no robust legal arguments against a TRIPS waiver. The EU and UK are holding onto the belief that a TRIPS waiver is not required and the market is working, in the face of all evidence to the contrary.

8. Consequences of failure to agree a TRIPs waiver

Optimising all alternative approaches to increasing supply and access to vaccine that do not require a TRIPS waiver (donation, improved distribution, concessions regarding licensing and acceptance of vaccine) will not produce vaccine coverage equivalent to high income countries until at least the end of 2022. [WHO, 2021] (ACT-A commitment tracker – <u>https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker</u> and Appendix)

9. Delays in achieving adequate global coverage will prolong the pandemic for all countries and increase the risk of new, high consequence variants.

Prolonging the pandemic means that all countries will experience additional educational, social, and economic disruption and harms and that those with fewest resources will continue to be penalised. Global experience of virus information sharing from the Global Initiative on Sharing All Influenza Data (GISAID) (<u>www.gisaid.org</u>) indicates that intellectual property rights protection driven arguments can have negative consequences for global pandemic preparedness measures [Nature, 2016] [Elbe, 2017]. GISAID has expanded to include SARS-CoV-2 and, while access to data has improved, greater transparency and more comprehensive coverage of virus and sequencing data is essential for ongoing vaccine development and monitoring ongoing effectiveness against emerging variants of SARS-CoV-2, with ongoing gaps in the availability of essential data reported [Yu, 2021].

Prolonging the pandemic means an avoidable extension to current disruption to global supply chains for all countries and all industries, directly through COVID-19 and related illnesses, lack of capacity to deal with prevention and treatment of other conditions and diversion of resources that would otherwise be used to support investment by and in sustainable social and economic development in low and middle income countries.

10. Why a TRIPS waiver is important and reasonable: public funding and participation has been significant

The development of mRNA vaccines is a result of decades of research and development, much of it funded by, or in partnership with, Governments and health services. This includes: the EU programme in place since 2009 [European

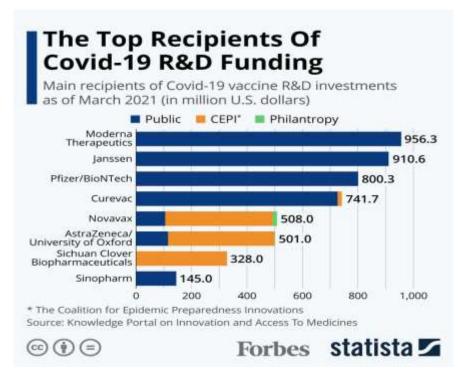




Commission, 2021] <u>https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation/vaccines_en</u>), UK Research and Innovation Vaccine Manufacturing Innovation Centre [UKRI, 2021] (<u>https://www.vmicuk.com/vmic-facility</u>), the future vaccine manufacturing hub (EPSRC, grant number: EP/R013764/1) the NIH Vaccine Research Centre established in 1977 [NIH, 2021] (<u>https://www.niaid.nih.gov/about/vrc</u>,

<u>https://www.niaid.nih.gov/sites/default/files/NIAID-VRC-Brochure.pdf</u> provide examples of some of the long established centres with Canadian Institutes of Health Research (CIHR) producing a helpful timeline summarising research milestones [CIHR, 2021] (<u>https://cihr-irsc.gc.ca/e/52424.html</u>).

Figure 4 shows who has received the most funding and the source. This highlights the importance of non-company investment, particularly public funding [McCarthy, 2021].



The argument that if you take patents away there will be no drugs ever made again as the incentive is removed is therefore not valid.

There would also have been no vaccine to sell without the participation of the members of the public and patients who volunteered to participate in the research, including vaccine research, required to help bring the global COVID-19 pandemic under control. Much of that research: data sources, methods, results, code is required to be available on an open data basis and, at minimum, to expert advisers and regulators. Experience from previous pandemics is that intellectual





property and trade secret arrangements can delay or limit the global sharing of data necessary to deploy tools like vaccines that are necessary to optimise the pandemic response. As stated in the September 30th proposal to WTO [WTO, 2021], a TRIPS waiver allows companies the world over the freedom to operate and to produce covered COVID-19 health products and to use health technologies without the fear of infringing another party's IP rights and the attendant threat of litigation. Furthermore, adoption of a TRIPS waiver acts as an important political, moral and economic lever towards encouraging solutions aimed at global IP/C/W/684 - 2 - equitable access to COVID-19 health products and technologies including vaccines, therapeutics and diagnostics, which is in the wider interest of the global public. This outcome is also consistent with the Covenant on Economic, Social and Cultural Rights, especially Article 12 which recognizes the "human right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and obligating the taking of steps to fully realize this right, including "those necessary for ... the prevention, treatment and control of epidemics, endemics, ... and other diseases" (IP/C/W/684).

11. Negotiate fair compensation for the research carried out to develop the vaccine in a way that does not undermine future efforts to develop and improve vaccine products

A TRIPS waiver does not make the vaccine free because companies can still receive fair payment. Research undertaken to develop the vaccine should be acknowledged and compensated, in a way that does not undermine future efforts to develop and improve vaccine products. Companies' ability to set prices unaffordable to large parts of the world, however, fuels the vaccine hesitancy argument that pharmaceutical companies are less interested in a safe, effective vaccine that will help bring the pandemic under control than in optimising shortterm profits. A TRIPS waiver supports companies and governments by neutralising that argument.

A TRIPS waiver is a global response to a global pandemic. While patents are national rights, countries without an existing ability to manufacture vaccines have to purchase the vaccines or the rights to make them in so the application of TRIPS in other countries is relevant. Since attempts to secure licenses under TRIPS have failed, it is clear that a TRIPS waiver is necessary.

12. A TRIPS waiver is an essential step on the way to new, more effective multilateral partnerships, not a permanent solution

The TRIPS waiver is an emergency response. It should be put in place immediately. It will need to be in place for the next three to five years, and then reviewed on a rolling basis. It will be required to address deficiencies in current vaccine





agreements, to improve their implementation and to respond rapidly to the evolution of the pandemic. We should anticipate that further surges in transmission will have a global impact. Our own health cannot be divorced from the risks associated with the emergence of new variants, particularly those that originate in countries with low coverage of vaccination.

An initial timescale of three to five years would enable countries and companies to build on the recommendations of the Pan European Commission on Health and Sustainable Development WHO Commission (Monti Commission) [WHO Europe, 2021] and related analyses [Jit et al, 2021] including testing new models of networked multilateral governance for innovation [Ekström AE]. These approaches provide an opportunity for investment in a broader range of countries, reducing the reliance and thus vulnerability of global supply chain on a few high-income countries. This work can then prepare the ground for the new pandemic preparedness treaty, so that it is not rushed but sustainable, implementable and core to the work of WHO.

13. Change the future intellectual property environment for all current and future SARS-CoV-2 vaccines in the new pandemic preparedness treaty set under the WHO.

The treaty has not yet been developed so is not ready for deployment this winter against the global pandemic. It is, however, an opportunity to rectify the mistakes made by high income countries, companies, and global bodies through an overarching commitment to ensure equity is at the heart of pandemic preparedness and that vaccines are recognised as а public good. (https://www.salute.gov.it/imgs/C 17 pagineAree 5459 8 file.pdf, [G20 Italia, 2021) [G20 Rome Declaration 5-6 Sept 2021] https://global-healthsummit.europa.eu/rome-declaration en).

Pandemic Treaty negotiations should provide a means to agree the framework for decision making, principles and criteria that must be fulfilled when addressing the interfaces between trade, intellectual property rights and pandemic preparedness. This must encompass trade secrets, export controls, protection of data, and equitable access not only to vaccines, but diagnostics, pandemic products, medicines, knowledge, data, and technology transfer.

This includes ensuring that pandemic treaty will be set under an adequately resourced and empowered WHO [Gostin, 2021] and that the treaty will ensure that WHO guidance and public health and health system resilience priorities will precede/underpin decisions taken by international bodies who have technical competence in other areas, but whose decisions can have a significant impact on the global scale of avoidable pandemic related illness and death.





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Appendices

Glossary

Carbis bay statement

We reiterate our endorsement of the G20 Rome Declaration and the statement agreed by our Foreign and Development Ministers on equitable access. We will work together and with others, leveraging the full spectrum of the capability and capacity we can each deploy to support the global vaccination effort, through finance for and sharing of doses, science, ensuring accessibility through voluntary licensing, manufacturing and ensuring availability through exports, opening supply chains, and supporting final mile delivery (Carbis Bay declaration)

<u>GAVI</u>

The Global Vaccine Alliance, GAVI, is a public/private/third sector partnership, initially designed to reduce morbidity and mortality from vaccine preventable childhood diseases by funding and overseeing the scale up of access to vaccines and delivery of (mostly) childhood immunisation programmes. The Vaccine Alliance's stated mission is to save children's lives and protect people's health by increasing equitable use of vaccines in lower-income countries

GISAID

GISAID is the Global Initiative on Sharing All Influenza Data. It promotes rapid and open access to epidemic and pandemic virus data <u>www.gisaid.org</u>

COVID-19 Vaccines Global Access (COVAX)

COVAX is a worldwide initiative aimed at equitable access to COVID-19 vaccines directed by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO). COVAX coordinates international resources to enable low-to-middle-income countries equitable access to COVID-19 tests, therapies, and vaccines.

IFPA

The International Federation of Pharmaceutical Manufacturers and Associations represents research-based biopharmaceutical companies, and regional and national associations across the globe. (<u>https://www.ifpma.org/who-we-are/ifpma-in-brief/</u>)

Pandem-ic

Pandem-ic analyzes the COVID-19 pandemic through the lens of the World Bank's income classification of countries. Its purpose is to highlight the uneven impact of COVID-19 on developing countries and draw attention to the need for equitable solutions in this interconnected world.

<u>UNDP</u>

The COVID-19 Data Futures Platform is a project of the United Nations Development Programme (UNDP). UNDP works to eradicate poverty while protecting the planet. We help countries develop strong policies, skills, partnerships and institutions so they can sustain their progress.





Contributions of public donors as a share of their fair share against ACT-A 2020-21 funding need

as of Sep 17

Total pledge / Total ask 48%			
	in USD billion	in USD billion	in %
	Contribution		Pledge/ Benchmark
Country	benchmark	Pledge (public)	(%)
Germany	2.01	2.63	131%
Norway	0.39	0.49	126%
Canada	1.01	1.10	109%
Kuwait	0.08	0.08	106%
Saudi Arabia	0.30	0.31	105%
Sweden	0.39	0.31	78%
United Kingdom	1.61	1.11	69%
Italy	0.77	0.49	64%
United States	9.80	6.21	63%
Switzerland	0.69	0.41	59%
Japan	2.40	1.21	51%





Iceland	0.02	0.01	51%
Spain	0.52	0.20	39%
New Zealand	0.10	0.03	29%
France	1.22	0.34	28%
Republic of Korea	0.78	0.21	27%
Netherlands	0.65	0.16	25%
Australia	0.76	0.13	17%
Finland	0.14	0.02	14%
Denmark	0.28	0.02	9%
Qatar	0.14	0.01	7%
Serbia	0.02	0.00	7%
Luxembourg	0.08	0.00	5%
Greece	0.08	0.00	5%
Croatia	0.02	0.00	4%
Austria	0.24	0.01	4%
Belgium	0.32	0.01	3%
Oman	0.03	0.00	3%
China	3.51	0.10	3%
Singapore	0.28	0.01	2%





Portugal	0.08	0.00	2%
Malta	0.01	0.00	2%
Estonia	0.01	0.00	1%
Ireland	0.33	0.00	1%
Hungary	0.06	0.00	1%
Colombia	0.08	0.00	1%
Lithuania	0.02	0.00	1%
Czech Republic	0.11	0.00	0%
Poland	0.23	0.00	0%
Indonesia	0.25	0.00	0%
Slovak Republic	0.05	0.00	0%
Romania	0.07	0.00	0%
Mexico	0.41	0.00	0%
Thailand	0.19	0.00	0%
Panama	0.02	0.00	0%
Mauritius	0.01	0.00	0%
India	0.62	0.00	0%
Brazil	0.50	0.00	0%
Russian Federation	0.50	0.00	0%





Turkey	0.28	0.00	0%
United Arab Emirates	0.27	0.00	0%
Israel	0.17	0.00	0%
Malaysia	0.15	0.00	0%
Argentina	0.15	0.00	0%
Iran, Islamic Rep.	0.11	0.00	0%
South Africa	0.11	0.00	0%
Chile	0.10	0.00	0%
Iraq	0.06	0.00	0%
Peru	0.06	0.00	0%
Kazakhstan	0.06	0.00	0%
Algeria	0.05	0.00	0%
Ecuador	0.03	0.00	0%
Dominican Republic	0.02	0.00	0%
Bulgaria	0.02	0.00	0%
Slovenia	0.02	0.00	0%
Belarus	0.02	0.00	0%
Lebanon	0.02	0.00	0%
Uruguay	0.02	0.00	0%





Costa Rica	0.02	0.00	0%
Bahrain	0.02	0.00	0%
Azerbaijan	0.02	0.00	0%
Tunisia	0.01	0.00	0%
Libya	0.01	0.00	0%
Turkmenistan	0.01	0.00	0%
Cyprus	0.01	0.00	0%
Paraguay	0.01	0.00	0%
Latvia	0.01	0.00	0%
Trinidad and Tobago	0.01	0.00	0%
Brunei Darussalam	0.01	0.00	0%
Bosnia and Herzegovina	0.01	0.00	0%
Botswana	0.01	0.00	0%
Georgia	0.01	0.00	0%
Bahamas, The	0.01	0.00	0%
Jamaica	0.01	0.00	0%
Gabon	0.01	0.00	0%
Equatorial Guinea	0.01	0.00	0%
Namibia	0.00	0.00	0%





North Macedonia	0.00	0.00	0%
Mongolia	0.00	0.00	0%
Albania	0.00	0.00	0%
Armenia	0.00	0.00	0%

European Commission	0	0.59
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Contributions of public donors as a share of their fair share against ACT-A 2020-21 funding need as of Sep 17

in L	JSD billion	in USD billion	in %
	ntribution		Diadaa (Daaraharanda (
Country - be Germany	enchmark - 2.01	Pledge (public) - 2.63	Pledge/ Benchmark (131
Norway	0.39	0.49	126
Canada Kuwait	<u>1.01</u> 0.08	1.10 0.08	109 106
audi Arabia	0.30	0.31	105
Sweden	0.39	0.31	78
Jnited Kingdom taly	1.61 0.77	<u>1.11</u> 0.49	69 64
Jnited States	9.80	6.21	63
Switzerland	0.69	0.41	59
apan celand	2.40	<u>1.21</u> 0.01	51 51
Spain	0.52	0.20	39
New Zealand France	0.10	0.03	29 28
Republic of Korea	0.78	0.21	27
Netherlands	0.65	0.16	25
Australia Finland	0.76	0.13	17
Denmark	0.28	0.02	9
Qatar	0.14	0.01	7
Serbia .uxembourg	0.02	0.00	7
Greece	0.08	0.00	5
Croatia	0.02	0.00	4
Austria Belgium	0.24	0.01	4
Dman	0.03	0.00	3
China	3.51	0.10	3
Singapore Portugal	0.28	0.01	2
Valta	0.01	0.00	2
stonia	0.01	0.00	1
reland lungary	0.33	0.00	1
Colombia	0.08	0.00	1
ithuania	0.02	0.00	
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ndonesia	0.25	0.00	C
ilovak Republic	0.05	0.00	C
Romania Mexico	0.07	0.00	C
Thailand	0.19	0.00	C
Panama Mauritius	0.02	0.00	C
ndia	0.62	0.00	C
Brazil	0.50	0.00	C
Russian Federation	0.50	0.00	C
Jnited Arab Emirates	0.28	0.00	((
srael	0.17	0.00	0
Malaysia Argentina	0.15	0.00	C
ran, Islamic Rep.	0.13	0.00	((
outh Africa	0.11	0.00	C
Chile rag	0.10	0.00	с С
Peru	0.06	0.00	
(azakhstan	0.06	0.00	C
Algeria Cuador	0.05 0.03	0.00	с С
Dominican Republic	0.03	0.00	((
Bulgaria	0.02	0.00	C
llovenia Belarus	0.02	0.00	C
ebanon	0.02	0.00	C
Jruguay Sosta Rica	0.02	0.00	0
Costa Rica Bahrain	0.02	0.00	C
Azerbaijan	0.02	0.00	C
unisia ibya	0.01	0.00	C
ibya urkmenistan	0.01	0.00	C
yprus	0.01	0.00	C
Paraguay atvia	0.01	0.00	C
rinidad and Tobago	0.01	0.00 0.00	
Brunei Darussalam	0.01	0.00	C
Bosnia and Herzegovina Botswana	0.01	0.00	C
Georgia	0.01	0.00	((
Bahamas, The	0.01	0.00	C
amaica Gabon	0.01	0.00	C
quatorial Guinea	0.01	0.00	(
Namibia	0.00	0.00	C
North Macedonia Mongolia	0.00	0.00	C C
Albania	0.00	0.00	C
Armenia	0.00	0.00	C