

AMNESTY INTERNATIONAL

RECOMMENDATIONS TO WTO MEMBER STATES AHEAD OF THE 12TH MINISTERIAL CONFERENCE ON THE NEED FOR A COMPREHENSIVE TRIPS WAIVER FOR COVID-19 HEALTH PRODUCTS AND TECHNOLOGIES

The Covid-19 pandemic is not yet over, and the rights to health and life of millions of people around the world remain at risk now and in the future. This could be mitigated by the swift agreement of the revised proposal for a comprehensive TRIPS waiver for Covid-19 health tools as proposed by India and South Africa, yet a proposal from the WTO Secretariat would do nothing to address the barriers to equal access, and could even make compulsory licensing agreements more onerous than they are currently. This proposal should not be agreed in its current form.

Amnesty International urges all World Trade Organization (WTO) member states to continue to engage in the ongoing TRIPS waiver negotiations and agree a comprehensive and inclusive waiver that would enable equal access to all necessary Covid-19 health products and technologies.

AN ONGOING HUMAN RIGHTS CRISIS

The Covid-19 pandemic has now entered its third year. Over 11.7 billion vaccine doses have been administered, with 65.7% of the world population having received at least one dose.¹ What could have been an extraordinary feat for humanity - countries working closely together to ensure no one is left behind in vaccination efforts - is in fact the clearest and starkest indication of vaccine inequality. While almost two-thirds of the world's population have received a vaccine, only 15.9% of people in low-income countries have received their first dose.² Vaccination projections in mid-May 2022 revealed that nearly two-thirds of countries will not reach WHO's global goal of vaccinating 70% of their population by mid-2022.³

While supplies of vaccine have increased in recent months, deployment and take up remains a challenge in many countries, even as some countries are experiencing new waves of Omicron sub-variants. Ensuring equal access to Covid-19 tests and treatments is also key to preventing avoidable loss of life and long-term health problems such as long Covid. Yet access to some treatments that have come on stream in recent months remains severely unequal.⁴

Many, mainly wealthier, countries have advanced programmes delivering booster vaccine doses. This is not the reality for the majority of the world's population. The pandemic is not over. Unequal access to Covid-19 diagnostics, treatments and vaccines continues to be a reality for millions, particularly in low- and lower-middle-income countries.⁵ Short-term thinking must be replaced by long-term sustainable actions that will ensure lives are saved and the pandemic comes to an end for all.

¹ Our World in Data, ourworldindata.org/covid-vaccinations, figures correct as of 19 May 2022

² Our World in Data, ourworldindata.org/covid-vaccinations, figures correct as of 19 May 2022

³ Our World in Data, ourworldindata.org/covid-vaccination-global-projections, figures correct as of 19 May 2022

⁴ See WHO, "WHO recommends highly successful COVID-19 therapy and calls for wide geographical distribution and transparency from originator", 22 April 2022, www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator and Politico, "The Battle for Paxlovid", 19 May 2022, www.politico.com/newsletters/global-pulse/2022/05/19/the-battle-for-paxlovid-00033516

⁵ For the latest global figures of Covid-19 vaccinations by income country groups, see Our World in Data, ourworldindata.org/covid-vaccinations

STATE OBLIGATIONS TO PROVIDE INTERNATIONAL COOPERATION AND ASSISTANCE

States have an obligation to work together to respond to the pandemic. They must cooperate including by removing any potential barriers to ensure availability, accessibility, affordability, acceptability and quality of Covid-19 health products for all people.⁶ The Committee on Economic, Social and Cultural Rights (CESCR) has established that states must combat the Covid-19 pandemic in a manner consistent with human rights, which includes meeting their extraterritorial obligations to support other states fulfil their duties.⁷ In this respect states must also ensure that intellectual property rights do not prevent any countries from upholding the right to health. The CESCR noted that states “should also promote flexibilities or other adjustments in applicable intellectual property regimes to allow universal access to the benefits of scientific advances relating to Covid-19 such as diagnostics, medicines and vaccines.”⁸

As the Covid-19 pandemic continues to evolve with no end in sight, it is clear that international cooperation to address this global health and human rights crisis has largely failed, mostly due to wealthy states failing to implement their commitments to support global vaccination coverage and companies in the pharmaceutical industry prioritizing supplies to high-income countries and refusing to share intellectual property, technology, and know-how with other manufacturers.⁹

FAILURE TO AGREE A COMPREHENSIVE AND HUMAN RIGHTS COMPLIANT WAIVER

The WTO Agreement on Trade-related aspects of Intellectual Property Rights (the TRIPS agreement) enshrines the possibility of flexibilities to deal with health emergencies, including the use of compulsory licence and the special procedures under Article 31bis of the agreement which facilitate the import and export of goods produced under compulsory licence. In October 2020, India and South Africa submitted a proposal for a temporary waiver from certain provisions of the TRIPS agreement (known as the TRIPS waiver) for Covid-19 health products and technologies.¹⁰ This proposal was revised in May 2021 to address concerns expressed by some states but has not yet been agreed.¹¹

It is a catastrophe that negotiations around the TRIPS waiver have been delayed, halted or opposed by a few countries, including the European Union, Switzerland and the United Kingdom, despite the support of over 100 WTO member states¹² to expand access to much-needed Covid-19 health products.¹³ Since the TRIPS waiver was first proposed almost 20 months ago, there have been nearly 5.2 million confirmed deaths,¹⁴ although the World Health Organization has estimated the true number of excess deaths associated with the Covid-19 pandemic to be almost 15 million.¹⁵

The delay in agreeing to a waiver has fueled the continuing gross inequality in Covid-19 vaccination rates between countries and is likely to repeat this inequality in access to life-saving treatments that are being developed or have been developed. This could lead to thousands more preventable deaths. Wealthy countries that still try to justify their action in preventing global access to vaccines, tests, and treatments that they provide to their own populations are not just acting

⁶ Amnesty International, *A Fair Shot: Ensuring Universal Access to Covid-19 Diagnostics, Treatments and Vaccines* (Index: POL 30/3409/2020), 8 December 2020, www.amnesty.org/en/documents/pol30/3409/2020/en/. This Amnesty International policy briefing outlines state obligations in relation to Covid-19 diagnostics, treatments and vaccines, which must be applied to their own populations as well as people in other countries.

⁷ CESCR, *Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights*, E/C.12/2020/1, 17 April 2020, para 20

⁸ CESCR, *Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights*, E/C.12/2020/1, 17 April 2020, para 21

⁹ Amnesty International, *Money Calls the Shots: Pharma's response to the Covid-19 vaccine crisis* (Index: POL 40/5140/2022), 14 February 2022, www.amnesty.org/en/documents/pol40/5140/2022/en/

¹⁰ World Trade Organization (WTO), Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19*, Revised Decision Text, 2 October 2020, WTO Doc: IP/C/W/669

¹¹ WTO, *Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19: Revised decision text*, 25 May 2021, WTO Doc: IP/C/W/669/Rev.1

¹² As of 20 May, the waiver proposal had 65 co-sponsors and the support of over 100 WTO member states.

¹³ See MSF's map showing which countries support or oppose the Covid-19 IP waiver at WTO, [msf.org.uk/article/does-your-government-support-measures-increase-access-covid-19-vaccines-and-medical-tools](https://www.msf.org.uk/article/does-your-government-support-measures-increase-access-covid-19-vaccines-and-medical-tools)

¹⁴ Our World in Data, ourworldindata.org/covid-deaths, Cumulative number of confirmed deaths reported from 2 October 2020 to 18 May 2022

¹⁵ WHO, *14.9 million excess deaths associated with the COVID-19 pandemic in 2020 and 2021*, 5 May 2022, www.who.int/news/item/05-05-2022-14.9-million-excess-deaths-were-associated-with-the-covid-19-pandemic-in-2020-and-2021

immorally but also breaching their legal obligations to support other states to realize the rights to health, equality, life and science.¹⁶

THE 'COVID-19 TRIPS' PROPOSAL AND ITS LIMITATIONS

The new proposal *Covid-19 TRIPS* put forward by the World Trade Organization (WTO) Secretariat on 3 May 2022, after informal discussions with the EU, India, South Africa and USA, in its current form is not a human rights compliant or even adequate response to the magnitude of the health crisis the world must tackle together.¹⁷

The shortcomings outlined below demonstrate how this new proposal is nowhere near enough to ensure the expanded supply and technology transfer that is needed for equal access to Covid-19 health products and technologies in order to protect the rights to life and health across the globe.¹⁸

Excludes vitally needed medicines and tests

The new proposal is limited to vaccines only and excludes vitally needed medicines and diagnostic tests for at least six months. With the pandemic still raging throughout the world, and with low rates of vaccination in many low- and middle-income countries, an expanded supply of these is urgently needed. Without diagnostic tests, doctors cannot decide if a patient would benefit from a treatment, and without access to adequate supplies of treatment, they cannot treat Covid-19 patients who could benefit. The six-month delay risks adding to the human rights catastrophe of the Covid-19 pandemic.

Even though some voluntary licences for certain treatments such as Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332, administered in combination with low dose ritonavir have been agreed,¹⁹ many countries are excluded and are at the mercy of high prices set by the pharmaceutical companies producing these products.²⁰ Amnesty International has documented how pharmaceutical companies have consistently put profits over people during the pandemic.²¹

Key IP Barriers not addressed

Additionally, although it partially addresses some patent-related issues, the proposal fails to address barriers to technology transfer, including access to the confidential information, data, trade secrets, and manufacturing know-how that countries and companies need in order to rapidly expand vaccine manufacturing capacity.

Limiting a waiver to patents alone will not help achieve expanded access to COVID-19 health products. Instead, as has already been seen with the Technology Transfer Hub, vaccine developers are having to reverse engineer vaccines in order to develop commercial scale products that still need to get regulatory approval. The refusal of major vaccine producers like Pfizer and Moderna to share their mRNA vaccine technologies with WHO's mRNA hub or other independent producers is adding months, if not years, of delay to the production of needed vaccines.

Narrow geographical limitations

The new proposal restricts the use of the waiver to only "eligible countries", which would leave out many other countries already far behind in their vaccination efforts and consequently key groups in those countries who have been disproportionately impacted by the pandemic. These include groups protected under the Convention on the Elimination of

¹⁶ International Commission of Jurists, *Global jurists call for waiver of global intellectual property rights for COVID-19 vaccines and therapeutics*, 8 November 2021, www.icj.org/global-jurists-call-for-waiver-of-global-intellectual-property-rights-for-covid-19-vaccines-and-therapeutics/

¹⁷ WTO, Council for Trade Related Aspects of Intellectual Property Rights, *Covid-19 TRIPS*, IP/C/W/688, 3 May 2022, docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W/688.pdf&Open=True

¹⁸ See MSF, *MSF Comments on the Reported Draft Text of the TRIPS Waiver Negotiation*, March 2022, msfaccess.org/sites/default/files/2022-03/COVID19_TechBrief_MSF-AC_Waiver-Quad-text_briefing-doc_ENG_March2022.pdf and *Comments on the Patent Listing Requirements in the Draft Text of the TRIPS Waiver Negotiation*, March 2022, msfaccess.org/sites/default/files/2022-03/COVID19_TechNote_Patent-listing_ENG_March2022.pdf

¹⁹ Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries, November 16, 2021, www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing

²⁰ Médecins sans Frontiers, *MSF responds to Medicines Patent Pool deal with 35 manufacturers to produce COVID-19 treatment nirmatrelvir/ritonavir*,

17 March 2022, msf-access-campaign.prezly.com/msf-responds-to-medicines-patent-pool-deal-with-35-manufacturers-to-produce-covid-19-treatment-nirmatrelvirritonavir

²¹ Amnesty International, *A double dose of inequality: Pharma companies and the Covid-19 vaccines crisis* (Index: POL 40/4621/2021), 22 September 2021, www.amnesty.org/en/documents/pol40/4621/2021/en/ and Amnesty International, *Money Calls the Shots* (Index: POL 40/5140/2022), 14 February 2022, www.amnesty.org/en/documents/pol40/5140/2022/en/

Racial Discrimination, in particular persons of African or Asian descent, those belonging to national or ethnic minorities including non-citizens, Roma communities and Indigenous Peoples in significant part attributed to consequences of the historic racial injustices of slavery and colonialism that remain largely unaccounted for today.²²

Unduly onerous new reporting requirements

The new proposal includes requirements that go beyond what is required by the current TRIPS Agreement when compulsory licences are issued. These include the obligation to list all patents on vaccine components and final products, and to report multiple details to the WTO, even in circumstances where Article 31 bis of the TRIPS Agreement would not otherwise require such notice.

As there are 280 components of mRNA vaccines, sourced from 19 countries, the first obligation would be time consuming and onerous. It would require a listing of each patented component as well as of the final vaccine, covering the patent landscape not only in the country where the exclusion applies, but in all countries of production and export of components used in the vaccine.

As new patents can be filed on existing vaccines or components at any time, the compulsory licensing applications would need continuous monitoring and amendment to comply with these mandatory conditions as envisioned in the text. This is a far more onerous requirement than currently required under the TRIPS Agreement and would make it very difficult for any compulsory licences to be issued and used to produce vaccines.

Not fit for purpose

These are just a few of the various shortcomings rendering this new proposal nowhere near good enough to ensure the expanded supply and technology transfer that is needed for equal access to Covid-19 health tools in order to protect the rights to life and health globally.²³

THE NEED FOR A COMPREHENSIVE TRIPS WAIVER AND ACTION TO ENSURE TECHNOLOGY TRANSFER

The Covid-19 TRIPS proposal in its current form, or any similar proposals that may limit a waiver in scope, geographically and/or require additional requirements not in the TRIPS agreement, would be inadequate and out of line with states' human rights obligations. As such, the proposal could actually be a significant step backwards, setting a concerning precedent for any future response to a global health emergency.

Any comprehensive waiver must be complemented by actions by pharmaceutical companies, in line with their human rights responsibilities, to share their knowledge and technology to support a wider and more autonomous production of tests, treatments, and vaccines to ensure a timely delivery to those who need them the most around the world.

RECOMMENDATIONS

Amnesty International urges all WTO member states to:

- continue to engage in the ongoing TRIPS waiver negotiations and support a comprehensive and inclusive agreement that would enable equal access to all Covid-19 health products and technologies that are necessary for the world to overcome a disease that has killed millions of people and created the gravest public health crisis of our time.

Amnesty International also urges all states to:

- put all possible measures and policies in place, including legislation, to prevent pharmaceutical companies from impeding broader access to life-saving health tools, especially in times of crisis.

²² CERD, Statement 2, 106th session, 11-29 April 2022, tbineternet.ohchr.org/_layouts/15/treatybodyexternal/Download.aspx?symbolNo=INT%2fCERD%2fSWA%2f9548&Lang=en, paras 1-2