

BRIEFING FOR WTO MEMBER STATES ON THE TRIPS WAIVER PROPOSAL FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

Amnesty International is calling on all World Trade Organization member states to strongly support the “Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19” (Waiver Proposal) which would help to ensure that COVID-19 medical products, including safe and effective vaccines, can be manufactured quickly and made available and affordable for all.

COVID-19 is not only a health and economic, but also a human rights crisis and cannot be overcome without true commitment to the SDG Principle to “Leave no one behind”. As often repeated this year, no one is safe until we are all safe. WTO members have the opportunity to make a coordinated global decision that can help make this a reality.

GLOBAL CONSENSUS ON THE NEED FOR INTERNATIONAL COLLABORATION ON EFFECTIVE COVID-19 HEALTH PRODUCTS

When COVID-19 was declared to be a pandemic, there was overwhelming global consensus that there was an urgent need for international collaboration to speed up product development, scale up manufacturing, expand the supply of effective COVID-19 health products and ensure everyone, everywhere is protected. The UN General Assembly has on several occasions stressed the need for intensified international cooperation and multilateral efforts to contain, mitigate and defeat the pandemic, while fully respecting human rights.¹ Such cooperation includes the exchange of information, scientific knowledge and best practices and the expansion of manufacturing capacity to meet the increasing needs for medical supplies and ensuring that these are made widely available, at an affordable price, on an equitable basis, where they are most needed and as quickly as possible.

States also have human rights obligations to provide financial and technical support to uphold the right to health, especially in the face of the international spread of disease.² This may include the sharing of research, knowledge, medical equipment and supplies.³ In addition, The UN Committee on Economic, Social and Cultural Rights has interpreted the Covenant on Economic, Social and Cultural Rights to state that: “States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.”⁴

¹ UN General Assembly Resolutions: on Global solidarity to fight the coronavirus disease 2019 (COVID-19), UN Doc A/RES/74/270, 3 April 2020, <https://undocs.org/en/A/RES/74/270>, International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19, UN Doc A/RES/74/274, 21 April 2020, <https://undocs.org/en/A/RES/74/274>, and on United response against global health threats: combating COVID-19, UN Doc A/RES/74/307, 15 September 2020, <https://undocs.org/en/A/RES/74/307>

² WHO, *International Health Regulations (2005) Third Edition*, <https://www.who.int/publications/i/item/9789241580496>

³ UN Committee on Economic, Social and Cultural Rights’ (ESCR Committee)’s Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights, paragraph 19. The duty of international assistance and cooperation also is highlighted in the International Covenant on Economic, Social and Cultural Rights (Article 2.1 and 11.1)

⁴ CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), para. 39.

Extraterritorial obligations of states as contained in international human rights law have been further clarified by the Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights (the Maastricht Principles).⁵ States are required to “elaborate, interpret and apply relevant international agreements and standards in a manner consistent with their human rights obligations” – including in relation to international trade.⁶ States are also required to “take deliberate, concrete and targeted steps, separately, and jointly through international cooperation, to create an international enabling environment conducive to the universal fulfilment of economic, social and cultural rights, including in matters relating to bilateral and multilateral trade” which is to be achieved through, “inter alia: a) elaboration, interpretation, application and regular review of multilateral and bilateral agreements as well as international standards; b) measures and policies by each State in respect of its foreign relations, including actions within international organisations, and its domestic measures and policies that can contribute to the fulfilment of economic, social and cultural rights extraterritorially”.⁷ Such steps give effect to the commitment of States to ensure that in accordance with Article 28 of the Universal Declaration of Human Rights: “Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.”

The World Health Assembly has recognized the role of extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available. It has also called on international organizations and key stakeholders to “[w]ork collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the COVID-19 response, including existing mechanisms for voluntary pooling and licensing of patents to facilitate timely, equitable and affordable access to them, consistent with the provisions of relevant international treaties including the provisions of the TRIPS agreement and the flexibilities as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health.”⁸

Despite these urgent needs and consensus on the need for international cooperation to ensure equitable access, shortage of supply continues to occur. Companies in the pharmaceutical industry around the world continue to pursue a “business-as-usual” approach to Intellectual Property (IP), which places limits on manufacturing and supply capacities. Some pharmaceutical companies have indicated that they would consider voluntary licences⁹ but it is unclear whether these would necessarily be non-exclusive and include necessary technology transfer. Others have branded mechanisms such as the COVID-19 Technology Access Pool (C-TAP)¹⁰ as “nonsense”.¹¹ Associations for the pharmaceutical industry have openly rejected initiatives calling for voluntary contributions and open sharing of COVID-19 technologies.¹²

TRIPS FLEXIBILITIES ARE NOT ENOUGH ON THEIR OWN

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 license and the special procedures under Article 31 *bis* of the agreement which facilitate the import and export of goods produced under compulsory licence.

A few countries, including Canada, Germany and Hungary¹³, have revised their national laws to make it easier and quicker for governments to use any patented medical technologies when needed during the pandemic, alerting the need to address IP barriers.

⁵ The Maastricht Principles constitute an international expert opinion, clarifying human rights law on Extraterritorial Obligations. The Maastricht Principles were issued on 28 September 2011 by 40 international law experts from all regions of the world, including current and former members of international human rights treaty bodies, regional human rights bodies, as well as former and current Special Rapporteurs of the United Nations Human Rights Council. The Maastricht Principles do not purport to establish new elements of human rights law. Rather, the Maastricht Principles clarify extraterritorial obligations of States on the basis of standing international law. The Principles and their commentary which sets out the legal authority for each principle are available at: <http://eprints.lse.ac.uk/47404/>

⁶ Principle 17 of the Maastricht Principles. The commentary to this principle cites the jurisprudence of the CESCR, as well as decisions by the European and Inter-American Court of Human Rights which affirmed the principle that states cannot ignore their human rights treaty obligations by concluding treaties that could contradict those human rights treaty obligations.

⁷ Principle 29 of the Maastricht Principles. The commentary to this principle grounds it in Article 55 and 56 of the UN Charter, Article 28 of the Universal Declaration of Human Rights and the obligation of states, as confirmed by the UN CESCR, that steps taken towards the full realization of the relevant rights in the Covenant “should be deliberate, concrete and targeted as clearly as possible towards meeting the obligations recognized in the Covenant.” *General Comment No. 3, para. 2.*

⁸ World Health Assembly Resolution on COVID-19 response, UN Doc. WHA73.1, 19 May 2020, https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf

⁹ Bill & Melinda Gates Foundation, *Life Science Companies and the Bill & Melinda Gates Foundation: Commitments to Expanded Global Access for COVID-19 Diagnostics, Therapeutics, and Vaccines – Joint Statement*, 30 September 2020, <https://www.gatesfoundation.org/Media-Center/Press-Releases/2020/09/Commitments-to-Expanded-Global-Access-for-COVID-19-Diagnostics-Therapeutics-and-Vaccines>

¹⁰ The COVID-19 Technology Access Pool (C-TAP) will compile, in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>

¹¹ The Telegraph, *WHO patent pool for potential COVID-19 products is ‘nonsense’, pharma leaders claim*, 29 May 2020, <https://www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/>

¹² International Federation of Pharmaceutical Manufacturers and Associations, *IFPMA Statement on the “Solidarity Call to Action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data”*, 28 May 2020, <https://www.ifpma.org/resource-centre/ifpma-statement-on-the-solidarity-call-to-action-to-realize-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/>

¹³ WTO, *Mapping pathways to coherence on public health, intellectual property and trade*, 21 October 2020, p 80, www.wto.org/english/news_e/news20_e/health_21oct20_e.pdf

However, when countries lack immediate manufacturing capacity for any of the essential parts for a product, including raw materials, components or packaging materials, removing IP barriers on one product in one country alone will not be sufficient. Therefore, a country-by-country and product-by-product¹⁴ approach of using the TRIPS flexibilities remains limited in addressing IP challenges in this pandemic.

The Waiver Proposal, submitted by India and South Africa, and co-sponsored by Kenya and Eswatini in October 2020 came at this critical moment. It envisages a temporary and complementary policy space within the TRIPS framework that could empower governments to take more automatic and expedited actions when accessing the IP-protected technologies that could save the lives of millions of people. Many developing countries demonstrated strong support when the proposal was first presented at the TRIPS Council on 15 October 2020. More than 300 civil society organisations globally¹⁵ and a number of international organisations including WHO¹⁶, UNAIDS¹⁷, the South Centre¹⁸, and other international organisations including UNITAID¹⁹, and Drugs for Neglected Diseases *initiative*²⁰ have expressed their strong support for the move. A group of UN Special Procedures have also welcomed the proposal.²¹ The proposal will be further discussed at TRIPS Council meetings on 20 November and 10 December 2020, which are expected to result in a report to the WTO General Council which is scheduled to meet on 17 December 2020.

OPPOSITION TO THE WAIVER PROPOSAL UNDERMINES MUCH NEEDED GLOBAL SOLIDARITY

At the TRIPS Council meeting on 15-16 October 2020, several states, including Argentina, Bangladesh, Chad, Chile, China, Columbia, Costa Rica, Ecuador, El Salvador, Indonesia, Jamaica, Egypt, Mozambique, Nepal, Nicaragua, Nigeria, Pakistan, Philippines, Sri Lanka, Tanzania, Thailand, Turkey and Venezuela expressed full or general support for the Waiver Proposal, with some asking for further information.²² However, a group of mostly wealthy countries, including Australia, Brazil, Canada, Japan, Norway, USA and the United Kingdom as well as the EU, instead of realising global solidarity by prioritising public health and joining the support for the Waiver Proposal, opposed the proposal, blocking a consensus decision at that meeting.

States opposed to the Waiver Proposal suggested that IP is not a barrier in relation to COVID-19 medicines and technologies, ignoring the hard evidence that restrictive licensing practices have already caused a shortage of supply in several countries, including in Europe.

Many states have pledged important financial contributions to the Access to COVID-19 Tools Accelerator and its vaccine pillar, the COVAX Facility, for the purchase of potential COVID-19 vaccines. However, only limited quantities of COVID-19 vaccines can be reserved from developers because high-income countries, including the USA, the UK and EU member states, have engaged in “vaccine nationalism”, bypassing these global mechanisms to secure a vast share of global vaccine supplies to the detriment of the majority of the global population living in low-and-middle income countries.

Some states have pointed to the potential use of the TRIPS flexibilities, even though some of them have opted out from this article. However, some of these states also discourage other states from making use of these flexibilities, for example through Free Trade Agreements.²³

THE WAIVER PROPOSAL IS TEMPORARY

¹⁴ There may be multiple patents for a given product, for example covering the manufacturing process as well as the product itself. Public Citizen has mapped the patent landscape for two potential vaccines. See <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/> and <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>

¹⁵ Civil society letter supporting proposal by India and South Africa on waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19, https://twm.my/announcement/signonletter/CSOLetter_SupportingWaiverFinal.pdf

¹⁶ WHO, *WHO Director-General's opening remarks at the World Health Assembly - 9 November 2020*, <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-world-health-assembly--9-november-2020>

¹⁷ UNAIDS, *UNAIDS supports a temporary WTO waiver from certain obligations of the TRIPS Agreement in relation to the prevention, containment and treatment of COVID-19*, 15 October 2020, https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201015_waiver-obligations-trips-agreement-covid19

¹⁸ South Centre, *Proposal by India and South Africa to waive certain provisions of the WTO TRIPS agreement to support the global COVID-19 pandemic response*, <https://www.southcentre.int/wp-content/uploads/2020/11/Note-on-India-SA-proposal-waiver-TRIPS.pdf>

¹⁹ Unitaid, *Unitaid supports call for intellectual property waivers and action for access to COVID-19 products*, 13 October 2020, <https://unitaid.org/news-blog/unitaid-supports-call-for-intellectual-property-waivers-and-action-for-access-to-covid-19-products/#en>

²⁰ Drugs for Neglected Diseases *initiative*, *DNDi statement on India and South Africa request to WTO to waive IP rules for COVID-19 health tools*, 12 October 2020 <https://dndi.org/statements/2020/dndi-statement-india-south-africa-request-wto-waive-ip-rules-covid-19-health-tools/>

²¹ OHCHR, *No one is secure until all of us are secure: UN experts decry COVID vaccine hoarding*, 9 November 2020, <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26486&LangID=E>

²² *TRIPS Council to resume discussions next week on TRIPS waiver*. D. Ravi Kanth, published in SUNS #9233, 16 November 2020, <https://www.twm.my/title2/wto.info/2020/ti201114.htm>

²³ Pedro Roffe and Christopher Spennemann, *The impact of FTAs on public health policies and TRIPS flexibilities*, *International Journal of Intellectual Property Management*, January 2006, https://www.researchgate.net/publication/228675662_The_impact_of_FTAs_on_public_health_policies_and_TRIPS_flexibilities

The Waiver Proposal does not overhaul the TRIPS Agreement, but provides a time-limited suspension to certain specific provisions during the current global crisis. WTO member states can support the Waiver Proposal and stand in solidarity with the rest of the world without applying or using the waiver itself, if they wish. Therefore, the strong opposition to the Waiver Proposal by some WTO member states essentially denies other countries the additional legal flexibility to produce or import life-saving medical tools when needed – thereby impacting on the right to health and to life of individuals in those countries, particularly the most vulnerable. As such, their opposition is a regrettable disservice to the international community’s professed commitment to respect for human rights, which includes the obligation to engage in international cooperation to create an international enabling environment conducive to the universal fulfilment of economic, social and cultural rights.

RECOMMENDATION TO ALL MEMBER STATES OF THE WORLD TRADE ORGANIZATION

- Express strong support for the “Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19” as submitted by India and South Africa, and co-sponsored by Kenya and Eswatini, at the TRIPS Council meetings on 20 November and 10 December and at the WTO General Council meeting on 17 December.