29 November 2021

Dr. Tlaleng Mofokeng
The United Nations Special Rapporteur on Physical and Mental Health
Office of the High Commissioner for Human Rights
United Nations Office at Geneva
Palais des Nations
1211 Geneva 1211
Switzerland

Re: Urgent appeal to conduct a mission to the World Trade Organization and halt violations by States of the right to physical and mental health of everyone by their opposition to the COVID-19 TRIPS waiver at the World Trade Organization

Dear Dr. Mofokeng:

On behalf of the undersigned nurses' unions from around the world, united through our international federation, Global Nurses United, and coordinated by the Progressive International, we write to you to challenge the crimes of the governments of some of the world's richest countries.

Nurses and other health care workers have been on the frontlines of the COVID-19 pandemic response, and we have witnessed the staggering numbers of deaths and the immense suffering caused by political inaction. We have directly seen the frightening toll that COVID-19 has had on our patients, our communities, and our fellow health care workers. Hundreds of thousands of nurses and other health care workers around the world have become infected and many have died.

The end of this pandemic is nowhere in sight. COVID-19 cases continue to soar in numerous parts of the world, while pharmaceutical companies and governments have failed to ensure that critical treatments and vaccines are distributed equitably in order to respond to the pandemic. High income countries have procured upwards of 7 billion confirmed vaccine doses, while low income countries have only been able to procure approximately 300 million doses. This has created what public health advocates around the world have described as "vaccine apartheid".

This unequal distribution of vaccines is not only grossly unjust for the people in low- and moderate-income countries who remain at high risk for contracting and further transmitting COVID-19, it also provides for the possibility for the development of new variants, some of which may be resistant to the current available vaccines. The development and spread of new variants poses a dire risk to all people around the world. This deadly disease has demonstrated once again that no nation stands alone in the face of a global public health crisis.

Urgent Action Appeal to the United Nations (UN) Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

There is a solution: A proposal to temporarily waive intellectual property protections for COVID-19 vaccines and treatments is currently being debated at the World Trade Organization. But instead of supporting this waiver, certain governments are protecting the profits of big pharmaceutical companies at the expense of public health.

In your letters published 19 October 2021, you determined that "States have a collective responsibility to use all available means to facilitate faster access to vaccines, including by introducing a temporary waiver of relevant intellectual property rights under the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement)".

It is now clear: Continued opposition to the TRIPS waiver is resulting in the violation of human rights of peoples across the world.

We urge you to urgently undertake a mission to the World Trade Organization to examine the facts set out in this petition and find that which we know to be true: These countries have violated our rights and the rights of our patients — and caused the loss of countless lives — of nurses and other caregivers and those we have cared for.

We, who care — we bear witness. We now testify.

Yours sincerely,

Annie Butler, Federal Secretary
Australian Nursing & Midwifery Federation
Australia

Shirley Marshal Díaz Morales, Presidente
Federação Nacional dos Enfermeiros
Brazil

Linda Silas, President
Canadian Federation of Nurses Unions
Canada

Nathalie Levesque, Interim President
Fédération interprofessionnelle de la santé du Québec
Canada

Rodrigo Manuel López García, Secretario General
Asociación Nacional de Profesionales en Enfermería (A.N.P.E.)
Costa Rica

Johnsel Diaoen, President
Curaçaose Bond Van Werknemers in Verplegende en Verzorgende Instgellingen
Curacao

Antonia Geraldino Lantigua, Secretaria General en Funciones
Sindicato Nacional de Trabajadores de Enfermeria (SINATRAE)
Dominican Republic

George Tsolas, President
Thomai Aslanoglou, General Secretary
Pan-Hellenic Federation of Nursing Staff (PASONOP)
Greece

Luis Antulio Alpirez Guzman, Secretario General
Sindicato Nacional de los Trabajadores de Salud de Guatemala
Guatemala

Josué Jeremías Orellana Muñoz, Presidente
Asociación Nacional de Enfermeras/os Auxiliares de Honduras
Honduras

Rince Joseph, National Working President
United Nurses Association
India

Karen McGowan, President
Irish Nurses and Midwives Organisation
Ireland

Ilana Cohen, President
Israeli Nurses Association
Israel

Dr. Andrea Bottega, National Secretary
Nursind
Italy

Seth Panyako, General Secretary
Kenya National Union of Nurses
Kenya

Shouts Makhumbo Galang'anda Simeza, President
National Organisation of Nurses and Midwives of Malawi
Malawi

Kerri Nuku, Kaiwhakahaere
New Zealand Nurses Organisation
New Zealand

Mg. Mirna Gallardo, Presidenta
Asociación Paraguaya de Enfermería
Paraguay

Maristela Abenojar, President
Filipino Nurses United
The Philippines

José Carlos Martins, Presidente
Sindicato dos Enfermeiros Portugueses
Portugal

Andre Gitembagara, President
Rwanda Nurses and Midwives Union
Rwanda

Cassim Lekhoati, General Secretary
The Democratic Nursing Organisation of South Africa (DENOSA)
South Africa

Na Soon-ja, President
Korean Health and Medical Workers' Union
South Korea

Manuel Cascos Fernández, Presidente
SATSE
Spain

Saman Rathnapriya, President
Government Nursing Officers' Association
Sri Lanka

Yun-Sheng Lo, President
Taiwan Nurses Union
Taiwan

Justus Cherop Kiplangat, President
Uganda Nurses and Midwives Union
Uganda

Bonnie Castillo, RN, Executive Director
Deborah Burger, RN, President
Zenei Triunfo-Cortez, RN, President
Jean Ross, RN, President
National Nurses United
United States of America

Valeria Quintero, Presidenta
Sindicato Unico de Enfermería del Uruguay (SUEU)
Uruguay

Urgent Action Appeal to the United Nations (UN) Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Immediate threat to People's Right to Health Caused by Failure by the certain States and Institutions (European Union and its constituent member States, United Kingdom of Great Britain & Northern Ireland, Norway, Switzerland, and Singapore) to Support the Covid-19 Waiver Proposal at the TRIPS Council in the World Trade Organization

I. Petitioners

We are a coalition of nurses unions from 28 countries representing over 2.5 million healthcare workers, coordinated by Global Nurses United and the Progressive International.

Healthcare workers are on the frontlines of the global fight against COVID-19 — both as clinical practitioners and as leading advocates for vaccine equity. On the frontlines, COVID-19 has claimed the lives of at least 115,000 healthcare workers around the world so far, although that number is assuredly understated given the lack of accurate record-keeping by many governments around the world. The artificial scarcity of vaccines means that only two in five health and care workers are fully vaccinated on average, but the numbers are catastrophic in many parts of the world — less than one in 10 healthcare workers are fully vaccinated in the African and Western Pacific regions.

As frontline workers, we are well placed to testify against the violation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health because of the impact of a delayed Covid-19 TRIPS waiver as outlined above.

Nurse and healthcare worker unions have raised their voices for global vaccine equity repeatedly, including writing a letter to the World Trade Organization (WTO), urging that TRIPS take immediate action "to dramatically mitigate and eventually end the catastrophic death and suffering caused by the COVID-19 pandemic." We continue to raise our voices for our fellow health care workers as well as the right to health of all peoples the world over.

We share the belief that a new international health order is needed to overcome the vaccine inequity which threatens our very survival — and a concerted effort from states, institutions, companies and peoples is needed to put national resources to collective benefit, based on the principles of sovereignty, solidarity, and the universal right to life.

The following organisations are jointly submitting this petition:

1. Australia | **Australian Nursing & Midwifery Federation,** Australia's largest national union and professional nursing and midwifery organization, represents the professional, industrial and political interests of over 300,000 nurses, midwives and carers.
2. Brazil | **Federação Nacional dos Enfermeiros**, is the only national union entity that represents more than 632,000 nurses in Brazil.
3. Canada | **Canadian Federation of Nurses Unions** is the national voice for nearly 200,000 nurses and student nurses across Canada.
4. Canada | **Fédération interprofessionnelle de la santé du Québec (FIQ)** is a labour organization that represents 76 000 nurses, licensed practical nurses, respiratory therapists and clinical perfusionists who work in health institutions

throughout Quebec. It is a feminist organization with an almost 90% female membership, dedicated to defending its members and the patients in the public health network.

5. Costa Rica | **Asociación Nacional de Profesionales en Enfermería (A.N.P.E.)**, with 84 years of union life, the only professional union of nurses in the country with 3,400 members in the Costa Rican public sector.
6. Curacao | **Curaçaose Bond Van Werknemers in Verplegende en Verzorgende Instgellingen** is a trade union representing over 2,000 health care employees across Curaçao.
7. Dominican Republic | **Sindicato Nacional de Trabajadores de Enfermeria**, with more than 8,000 members, fights for the rights of Dominican nursing.
8. Greece | **Pan-Hellenic Federation of Nursing Staff (PASONOP)** has 5,000 RN and assistant nurse members nationwide working in the public health care sector.
9. Guatemala | **El Sindicato Nacional de los Trabadores de Salud de Guatemala,** with more than 30,000 members throughout the country, is the largest health union in Guatemala and has in its ranks Professionals, Technicians and Service Personnel in General.
10. Honduras | **Asociación Nacional de Enfermeras/os Auxiliares de Honduras** represents 7,300 nursing members in the Honduran health care system.
11. India | **United Nurses Association,** with over 500,000 members, is the largest trade union of nurses in India.
12. Ireland | The **Irish Nurses and Midwives Organisation**, with more than 40,000 members nationally, is the largest trade union and professional association of registered nurses and midwives in Ireland.
13. Israel | **Israeli Nurses Association** is the largest professional association of Israeli nurses with 30,000 Jewish and Arab members.
14. Italy | **Nursind**, with over 47,000 members nationwide, is the largest union of nurses in Italy.
15. Kenya | **Kenya National Union of Nurses,** representing more than 30,000 registered nurses by the Nursing Council of Kenya, is registered under the Labour Relations Act and represents nurses both in public and private hospitals.
16. Malawi | **National Organisation of Nurses and Midwives of Malawi**, with a membership of 4,000 nurses and midwives, safeguards the professional interests, and socioeconomic welfare of nurses and midwives in Malawi.
17. New Zealand | **New Zealand Nurses Organisation**, with more than 53,000 members nationwide, is the largest union and professional association of registered nurses in New Zealand.
18. Paraguay | **Asociación Paraguaya de Enfermería** is the national nurses' union of Paraguay with 2,000 members.
19. Philippines | **Filipino Nurses United**, the only national nurses labor association in the Philippines, represents 10,000 nurses in the public and private sector nationwide.
20. Portugal | **Sindicato dos Enfermeiros Portugueses,** the most representative and largest union of nurses in Portugal, represents about half of the registered nurses working in the public sector.
21. Rwanda | **Rwanda Nurses and Midwives Union,** with over 10,000 members, promotes the interests of nurses and midwives throughout Rwanda by protecting their professional image and improving their socio-economic standing.

22. South Africa | **The Democratic Nursing Organisation of South Africa (DENOSA)** is a national nursing association and a representative organisation of nurses and nursing in South Africa, advancing the aspirations of nurses and advocating for their growth as both professionals and workers in the workplace, representing 82,000 nurses.
23. South Korea | **Korean Health and Medical Workers' Union**, is Korea's representative labor union for each industry in the health care sector, representing 80,000 union members, including nurses.
24. Spain | **El Sindicato de Enfermería (SATSE)**, with more than 130,000 registered nurses in Spain, is the organization with the highest union representation of all public health in their country.
25. Sri Lanka | **Government Nursing Officers' Association**, with more than 25,000 members nationwide, is the largest union of registered nurses in Sri Lanka.
26. Taiwan | **Taiwan Nurses Union**, the first nurses' union in Taiwan, kept working on issues in all aspects of nurses and their working condition with energy and sustainability in its tenth year.
27. Uganda | **Uganda Nurses and Midwives Union** is an independent, non-partisan, non-discriminatory professional union representing over 5,000 nurses and midwives in Uganda
28. United States of America | **National Nurses United**, with more than 175,000 members nationwide, is the largest union and professional association of registered nurses in the United States.
29. Uruguay | **Sindicato Unico de Enfermeria del Uruguay (SUEU)**, which represents more than 5,000 nurses, is the largest nurses' union in Uruguay.

The petition was prepared with the support and coordination of the Progressive International, Global Nurses United, and a coalition of human rights lawyers convened by the Global Network of Movement Lawyers at Movement Law Lab, with appreciation for the contributions of the ESCR-Net Secretariat, Gautam Bhatia, and Christian Pino.

II. Overview: Facts and Figures

The COVID-19 pandemic and its impacts

The health impacts of Covid-19 have been devastating. As of November 2021, over 5 million Covid-19 related deaths have been recorded worldwide, alongside more than 253 million cases. This is undoubtedly an undercount due to the lack of testing and accurate data collection in many countries.

The COVID-19 pandemic has had a major impact on public health systems - many hugely unprepared for this health emergency due to decades of underfunding. The toll on public health systems will have implications on the delivery of essential health services for years to come.

The health impacts of the pandemic go hand in hand with deep economic impacts - which have hit those with the least the hardest. Millions of jobs were lost - disproportionately impacting women - and poverty levels rose, with extreme poverty going up for the first time in 20 years.

Pharmaceutical monopolies and unequal access to COVID-19 vaccines

The development of tests, vaccines and therapeutics has been key in this global health emergency in order to prevent the spread of COVID-19 and slow down fatalities from contracting the virus. These biomedical research efforts, often benefiting from open sharing of the coronavirus genome, global cooperation and/or ample public subsidy, marked a breakthrough in the technical ability to combat the spread of infection and death.

The contribution of intellectual property barriers to inequitable and discriminatory access to vital healthcare technologies was highlighted during the human immunodeficiency virus, acquired immunodeficiency syndrome (HIV/AIDS) epidemic. In South Africa, for example, at the height of the HIV/AIDS crisis, the government passed legislation allowing generic antiretroviral imports without the permission of patent holders. A legal challenge to the legislation by the Pharmaceutical Manufacturers Association elicited widespread public condemnation and was eventually settled. The legislative action taken by the South African government and the massive public actions that followed paved the way for the Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health, otherwise known as the Doha Declaration, in November 2001. These actions ultimately pressured the pharmaceutical industry to drastically lower the prices of HIV medications, allowing for antiretroviral programmes throughout low-income countries and saving millions of lives.

For drugs repurposed for COVID-19, the pharmaceutical industry is filing patents simply to extend their market monopoly on the medicine. This is an all-too-familiar move by the pharmaceutical industry, which aims to maximise profits and artificially extend the term of monopoly on known medicines while the additional patents are not linked to any genuine innovation.

For COVID-19 vaccines, pharmaceutical companies are working to preserve their monopoly and therefore preserve high prices for their vaccines. According to the UN Secretary General's remarks in late September 2021, "73 percent [of COVID vaccines] have been [administered] in just 10 countries. High-income countries have administered 61 times more doses per inhabitant than low-income countries. Just 3 percent of Africans have been vaccinated." Recently several UN human rights special procedures mandate holders issued letters to various States and corporations "concerning the unequal access to COVID-19 vaccines...[and] also address[ing] unequal access to medicines, health technologies, diagnostics, and health therapies within and between countries which affect negatively several human rights, particularly of individuals and people living in low- and middle-income countries. Such unequal access exacerbates inequality and discrimination and impedes the realization of a democratic and equitable international order."

As of 15 October 2021, high income countries have procured upwards of 7 billion confirmed vaccine doses, while low income countries have only been able to procure approximately 300 million doses.[1] According to a recent estimate by researchers, most

[1] Upper middle-income countries have procured approximately 2 billion doses and middle- income countries have also procured approximately 2 billion vaccine doses. See, Tab 2, 'Tracking covid-19 vaccine purchases across the

people in the poorest countries will need to wait another two years before they are vaccinated against COVID-19.

COVID-19 healthcare technology intellectual property monopolies during the pandemic have contributed to:

(i) production capacity and control being concentrated in the hands of a few high-income countries, with countries from the global south facing insufficient production, lack of diversified supplies and unaffordable prices of vaccines, therapeutics, diagnostics and other COVID-19 healthcare technologies;
(ii) making governments dependent on sole/few registered suppliers in the global market, often leading to shortages of certain vaccines, tests and therapeutics;
(iii) lack of acquisition of adequate doses of vaccines and therapeutics in many states, particularly in the global south;
(iv) the domination of the "vaccine and therapeutic market" by a few actors, principally in the global north due to high prices set by the pharmaceutical industry; and
(v) the failure to enable global licensing for mass and wide-scale distribution of vaccines, therapeutics and other COVID-19 healthcare technologies.

The direct consequences of the failure to distribute vaccines and treatments equitably to the vast majority of people of low- and moderate-income countries could be likely further transmission of COVID-19, further mass illness and large numbers of fatalities in those countries. This should be reason enough to address the crisis of global vaccine apartheid. But it does not stop there. Failure to vaccinate people in large numbers of countries around the world will allow further development of variants of concern, some of which may be resistant to existing vaccines, which in turn will spread across borders and endanger everyone.

Proposed WTO waiver of certain COVID-19-related intellectual property rights

On 2 October 2020, India and South Africa formally proposed a temporary waiver of certain Trade-Related Intellectual Property Rights (TRIPS) Agreement protections, "in relation to prevention, containment or treatment of COVID-19," inter alia "[r]ecognising the need for unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic."[2]

The temporary waiver would apply to certain IP rights on COVID-19 medical tools and technologies. It is now officially backed by 64 sponsoring governments, with around 100 countries supporting the proposal overall.

At an informal WTO TRIPS Council meeting on 14 September, supporters of the waiver expressed grave concerns over the continued non-engagement by the opponents to the waiver. For example:

globe', Duke Global Health Innovation Centre available at: https://launchandscalefaster.org/covid-19/vaccinepurchases.

[2] WTO communication, Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19, Communication from India and South Africa, 2 October 2020, available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

- South Africa: With 75% of vaccines going to 10 countries, according to a World Health Organization estimate, South Africa suggested that the European Union is able to vaccinate 60.1% of the adult population; the UK 64.4%; Switzerland 51.9%; and Africa only 3.3%.
- Australia: Australia said they back the waiver as a way to send the world a powerful message of solidarity through a positive, meaningful and consensus-driven outcome at MC12.
- China: China emphasized that the WTO has the responsibility to provide a response and a solution to the pandemic, in particular from the perspective of IP (intellectual property).
- Other developing and least-developed countries including Cuba, Bangladesh, Bolivia, Tanzania (on behalf of the African Group), Malaysia and Indonesia made strong interventions in support of the waiver proposal.

Yet the European Union and its constituent member States and the Respondent States of the United Kingdom of Great Britain & Northern Ireland, Norway, Switzerland, and Singapore have demonstrated resistance to the proposed waiver. Despite the clear public health benefits that the monopoly waiver proposal offers, a small group of nations is vigorously blocking or delaying the proposal, while also having secured the majority of available vaccines, much more than needed to vaccinate their entire populations.

- European Commission: Leaders of the European Commission, the EU's executive branch, are pushing for options, such as limiting export restrictions and encouraging voluntary licensing—half measures meant to protect patent monopolies. Two leaked documents from October 2021 detail the European Union (EU)'s positions at the World Trade Organization (WTO) which do not take the urgency of the pandemic into account. In a letter to the TRIPS council, 205 civil society organizations expressed concern about the European Commission's communication IP/C/W/6802[3] to the Council for TRIPS titled, "Urgent Trade Policy responses to the COVID-19 crisis: Intellectual Property" and a declaration on the TRIPS Agreement and Public Health in the circumstances of a pandemic (IP/C/W/681).[4] The communications presented by the European Commission to the WTO are, in our view, devoid of any useful solutions, despite this being a critical point at which the WTO should be making a decisive and concrete contribution to ensure timely, equitable global access to vaccines, treatments, diagnostics, and other COVID-19 health technologies and goods.
- United Kingdom of Great Britain & Northern Ireland: At the first Council for TRIPS meeting held on 15-16 October and 10 December 2020, the United Kingdom stated that "A waiver to the IP rights set out in the TRIPS Agreement is an extreme measure to address an unproven problem. The UK is of the view that pursuing the proposed path would be counterproductive and would undermine a regime that offers solutions to the issues at hand. Rather, we should consider how to meet the objectives of prevention, containment and treatment of COVID-19 as set out in the communication." Despite the overwhelming evidence about the usefulness of a waiver, they continued to question the relationship between intellectual property and increased availability of vaccines

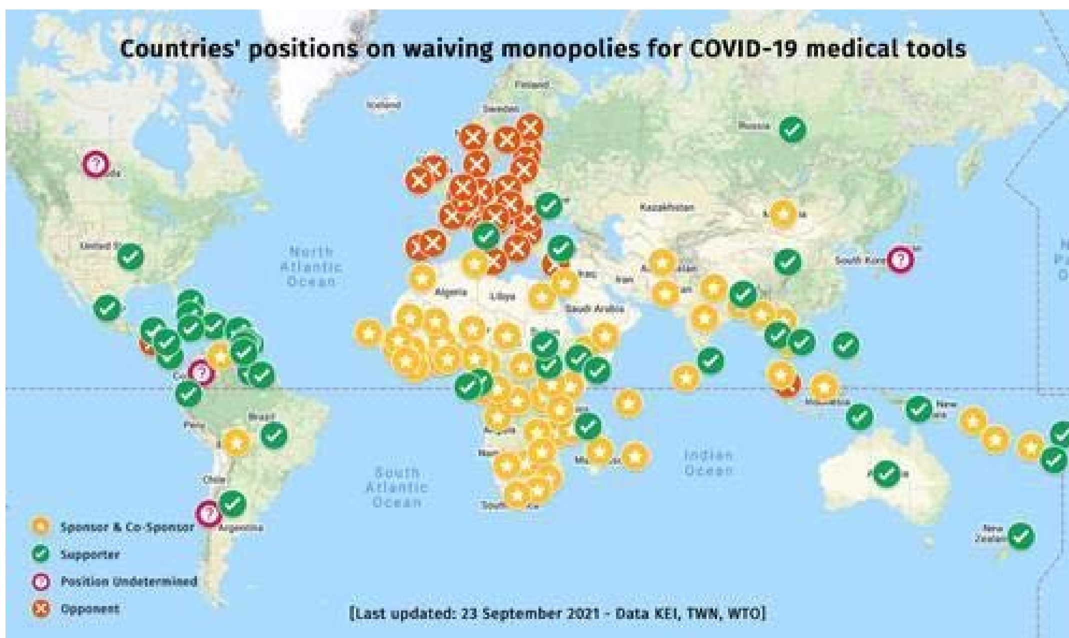
[3] IP/C/W/680 (wto.org)

[4] IP/C/W/681 (wto.org)

at a meeting of the Council for TRIPS held on 23 February 2021, by stating "we encourage Members to identify where idle capacity exists that can be utilised to address manufacturing demands, how IP is related to supply shortages, and how the proposed Waiver would be an immediate solution to identified production shortage…"

- Norway: In response to a letter from civil society, the Prime Minister of Norway stated the following: "we remain unconvinced that this waiver will result in increased production capacity within a relevant timeframe. We are also mindful of the fact that [intellectual property rights] IPRs incentivize innovation — both during the COVID-19 pandemic and especially with health crises we may encounter in the future"
- Switzerland: In their statement at the Council for TRIPS held on 23 February 2021, they clearly stated their opposition: "In the view of Switzerland, the proposed TRIPS Waiver would not facilitate global access to COVID-19 vaccines. On the contrary, we consider suspending large parts of the TRIPS Agreement would be counterproductive. It would undermine the efforts currently ongoing, to scale up manufacturing to achieve such global access."
- Singapore: In a statement made during the Council for TRIPS held on 23 February 2021, they said "[I]t is not clear that waiving IP rights will provide a "silver bullet" to solve the challenges surrounding the complex issue of equitable and timely access to vaccines. There are still significant challenges in producing or ramping up production of vaccines in many countries, but these challenges have more to do with limited healthcare infrastructure, domestic regulatory deficiencies and supply chain blockages rather than IP rights."

The graphic below demonstrates the divide between support and opposition from countries in the world (last updated 23 September 2021):



Failure of existing mechanisms

COVAX

Efforts to encourage international cooperation to support a more equitable global response have proven unsuccessful, largely owing to high-income countries' low-participation in cooperative initiatives. COVAX is a multi-institutional effort bringing WHO together with Gavi, the Vaccine Alliance, and CEPI as a pillar of the Access to COVID-19 Tools (ACT) "to promote the fair and equitable allocation of COVID-19 vaccines that are procured or distributed to countries participating in the scheme" in a spirit of global solidarity.

However, wealthy countries have not stepped up early enough - just 14 percent of the 1.8 billion doses pledged by global north/high-income countries have arrived in low- and middle-income countries so far.

While this charitable endeavour can be commended, COVAX has not delivered the global vaccine equity we direly need, because it was not designed to drastically increase global manufacturing and distribution.

First, the "insufficient inclusion and meaningful engagement" of low- and middle-income countries in COVAX's high-level discussions and decision-making was a serious design flaw. Further, COVAX chose to concentrate manufacturing in a single facility in India, which set back the timeline on developing global manufacturing capacity. Additionally, there have been transparency issues with the COVAX program, with no agreements between COVAX and vaccine companies made available for public scrutiny. As a result, critical information, such as manufacturing and delivery schedules, are not publicly available.

C-TAP

Respondents have not engaged in the WHO-organised COVID-19 Technology Access Pool (C-TAP), a voluntary mechanism for the open sharing of knowledge, intellectual property and data on COVID healthcare technologies. The pharmaceutical corporations based in the Respondent States that hold intellectual property monopolies over such technologies have also failed to participate in C-TAP.

To date, the EU has not brought any major pharmaceutical company operating within the EU to join the WHO's Covid-19 Technology Access Pool (C-TAP), a platform launched over a year ago to enable the voluntary sharing of IP, data, and knowledge with qualified manufacturers. No company has voluntarily joined this initiative either. Only a few EU member states have endorsed the C-TAP Solidarity Call to Action. While the Spanish National Research Council has reportedly promised that it will provide its diagnostic tests under a nonexclusive license to C-TAP, to date, no company marketing vaccines has agreed to join the WHO Covid-19 mRNA Technology Transfer Hub.

Compulsory Licensing

At the meeting of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) on 15-16 October 2020, WTO members discussed how best to use the global

intellectual property (IP) system to tackle the COVID-19 pandemic. Proponents of the proposed waiver argued that many countries — especially developing countries — may face institutional and legal difficulties when using TRIPS flexibilities, including the special compulsory licensing mechanism provided for in Article 31bis, which they saw as a cumbersome process for the import and export of pharmaceutical products.

In the case of patents alone, the patent system contains flexibilities such as opposition systems and compulsory licenses. However, challenging each and every patent application or grant everywhere they may exist is not a practical or sustainable option. In communication dated 30 October 2021, the co-sponsors of the waiver detailed the inadequacies and difficulties in relying on Article 31 and 31bis of the TRIPS Agreement to scale up manufacturing. This is exacerbated when dealing with a complex global web of patent holding. For instance, in the case of mRNA vaccines larger companies involved in product development may have a patent portfolio, but the patent portfolio to the underlying technology is held by numerous other academic laboratories or small biotech companies.

Even where compulsory licenses are issued for patents, pharmaceutical companies may bring legal cases against them, and continue to lobby for trade-based measures against governments that use them.

Submission

It is our submission that Respondents' resistance to the comprehensive TRIPS waiver (and its implementation) since it was originally proposed one year ago will cost hundreds of thousands if not millions of lives by significantly setting back what progress could have been made in increasing global supply and equitable access to vaccines and other COVID-19 healthcare technologies. Médecins Sans Frontières has described in detail both the potential for mRNA technology to be applied in numerous life-saving scenarios and the ability for production capacity to be quickly scaled up in regions like Africa where there is currently an overreliance on importation. Public Citizen published a report outlining a process using computational modelling to show how global supply of mRNA vaccines could significantly increase in just one year through the establishment of regional hubs.

Had the Respondents supported the temporary TRIPS waiver request or its implementation and enforcement, and not delayed negotiations to remove IP barriers and share technology, precious time (and therefore lives) could have been saved in building up regional capacity across the global south.

We appeal to you to (i) consider this matter under the Urgent Appeal procedure, (ii) issue Allegation Letters to the Respondents, compelling them to take specific actions that can address this matter with alacrity, and (iii) undertake a WTO mission to investigate the decision-making process on the TRIPS waiver.

III. Urgency of Appeal

The present global pandemic gives rise to a scenario in which the rights of both persons within Respondent States, with high vaccination rates, and in low- and middle- income countries, with low vaccination rates, are jeopardized by the inequitable international

response to COVID-19. As the virus mutates, new variants emerge and spread more quickly through unvaccinated populations than populations with high vaccination rates; thus, widespread and international vaccination efforts are key to effectively addressing the pandemic in the long-term and doing so in compliance with human rights obligations.

Over a year of advocacy efforts later, we make this appeal to the Special Rapporteur to urgently undertake a mission to the World Trade Organization and make a determination that the Respondents actions to impede the TRIPS waiver constitute a continuing breach of their obligations to guarantee the right to physical and mental health of everyone.

We believe it is imperative to act urgently in anticipation of upcoming talks before the World Trade Organization Ministerial Conference at the end of November 2021.

IV. Legal Obligations

As noted by General Comment No. 14 (2000), on Article 12 of the International Covenant on Economic, Social, and Cultural Rights, "health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity."[5]

In addition, international law also places a positive obligation upon States to ensure the existence of conditions that guarantee security, health, and hygiene *at work* and *of workers*.[6] For pandemics, in particular, workers - who come into frequent contact with one another, often in closely-packed physical spaces - are at specific risk with respect to their basic right to health.

The General Comment further notes that the right to health requires the *availability* of public health facilities, goods, and services (which includes essential drugs), *accessibility* (which specifically includes *economic* accessibility), *acceptability*, and *quality*.[7] Corresponding State obligations include making available "relevant technologies, using and improving epidemiological surveillance and data collection on a disaggregated basis, the implementation or enhancement of immunization programmes and other strategies of infectious disease control."[8] Furthermore, these facilities must be provided in a *non-discriminatory* manner. In particular, there may be no discrimination in the provision of essential health services on grounds of *national or social* origin.[9]

The General Comment makes it clear that State obligations include the obligations to respect, protect, and fulfill the right to health. In particular, "the obligation to fulfil requires States to adopt appropriate legislative, administrative, budgetary, judicial,

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[5] General Comment No. 14 (2000), E/C.12/2000/4 (August 2000), para 1.

[6] CASO EMPLEADOS DE LA FÁBRICA DE FUEGOS EN SANTO ANTÔNIO DE JESUS Y SUS FAMILIARES VS. BRASIL, SENTENCIA DE 15 DE JULIO DE 2020, Corte Interamericana de Derecho Humanos, para 155.

[7] Ibid., para 12.

[8] Ibid., para 16.

[9] Ibid., para 18.

promotional and other measures towards the full realization of the right to health."[10] This is to be read alongside the Alma Ata Declaration, which requires international cooperation to achieve the right, and notes that "the existing gross inequality in the health status of the people particularly between developed and developing countries as well as within countries is politically, socially and economically unacceptable and is, therefore, of common concern to all countries."[11] Specifically and categorically, the General Comment notes that "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."[12]

The General Comment clarifies that "violations of the right to health can occur through the direct action of States or other *entities insufficiently regulated by States*."[13] Thus, violation through *omission* is specifically recognised by the General Comment, and "include[s] the failure to take appropriate steps towards the full realization of everyone's right."[14] This, in turn, includes situations involving "the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations."[15]

It has been specifically recognised that Article 12 of the ICESCR - as interpreted by General Comment No. 14 - has a specific bearing on the Covid-19 Pandemic, and the acts and omissions of States parties in relation thereto, including the failure or refusal to permit the granting of a temporary TRIPS waiver. On 17th April 2020, the Committee on Economic, Social, and Cultural Rights ["CESCR"] issued a "Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights." Specifically, the CESCR noted that "States parties are under an obligation to take measures to prevent, or at least to mitigate"[16] the impacts of Covid-19. The Committee went on to categorically observe that "States parties should also use their voting powers in international financial institutions to alleviate the financial burden of developing countries in combating the pandemic, with measures such as granting these countries different mechanisms of debt relief. States parties 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.[17]

Later in 2020, a statement by nine United Nations Human Rights Experts noted that "the existing TRIPS regime … may have an adverse impact on prices and availability of

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[10] Ibid., para 33.

[11] Declaration of Alma-Ata International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978.

[12] General Comment No. 14 (2000), supra, para 39.

[13] Ibid., para 48.

[14] Ibid., para 49.

[15] Ibid., para 50.

[16] CESCR, Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights, E/C.12/2020/1 (17 April 2020).

[17] Ibid., para 21.

medicines"[18], and that "international cooperation and assistance between developed and developing countries are crucial in ensuring that all relevant health technologies, intellectual property data and know-how on COVID-19 vaccines and treatment are widely shared as a global public good."[19] For this reason, the statement went on to specifically observe that "in order to protect the right to health, States should use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding flexibilities to protect public health and provide access to medicines for all. This through, inter alia, granting compulsory licences as recognized in the Doha Declaration on the TRIPS Agreement and Public Health and following the a [sic] commitment made in the Sustainable Development Goals (SDG3)."[20]

The CESCR released another statement in December 2020, when it became clear that COVID-19 vaccines were on the horizon. In this statement, the CESCR explicitly linked vaccination with Article 12 of the ICESCR - as interpreted in General Comment 14 - to note that "every person has a right to the enjoyment of the highest attainable standard of physical and mental health, which includes access to immunization programmes against the major infectious diseases. Every person also has a right to enjoy the benefits of scientific progress[21], which includes access to all the best available applications of scientific progress necessary to enjoy the highest attainable standard of health. Both rights imply that every person has a right to have access to a vaccine for COVID-19 that is safe, effective and based on the application of the best scientific developments."[22]

Given, however, that the intellectual property in the vaccines are predominantly held by private firms, the CESCR went on to note that "States parties consequently have a duty to prevent intellectual property and patent legal regimes from undermining the enjoyment of economic, social and cultural rights."[23] This included an obligation to make full use of existing TRIPS flexibilities, such as compulsory licensing - but the CESCR also observed that, given the scale and seriousness of the pandemic, internal TRIPS flexibilities were unlikely to prove sufficient. The CESCR thus observed that the temporary waiver of TRIPS provisions "supported by a number of special procedures of the Human Rights Council, should be considered and implemented in order to facilitate the prevention, containment and treatment of COVID-19 through the global affordability of vaccines."[24]

Subsequently, in April 2021, the CESCR took note of the inequitable distribution of the COVID-19 vaccine. The CESCR observed that intellectual property rules were serving as barriers to equitable distribution, and that existing TRIPS flexibilities - such as compulsory licensing - had proven insufficient because of the time taken to grant and receive compulsory licenses. The CESCR therefore noted that "the current restrictions imposed by the intellectual property rules in the TRIPS Agreement make it very difficult

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[18] Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world, available at https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E

[19] Ibid.

[20] Ibid.

[21] ICESCR in Article 15(1)(b)

[22] CESCR, "Statement on universal and equitable access to vaccines for the coronavirus disease (COVID-19)", E/C.12/2020/2 (15 December 2020).

[23] Ibid.

[24] Ibid.

to achieve the international cooperation needed for the massive scale up in production and distribution of vaccines to the levels that are now technically possible and urgently required to achieve herd immunity as soon as possible."[25] Thus, in the view of the Committee, "all mechanisms, including voluntary licensing, technology pools, use of TRIPS flexibilities and waivers of certain intellectual property provisions or market exclusivities should be explored carefully and utilized. All these different initiatives have different characteristics and could be implemented in different and complementary ways as there are also existing challenges for the implementation of each of them. That is why they should be explored simultaneously according to the different needs of countries and their ability to implement them at the national and international levels. Thus, the waiver of certain provisions of the TRIPS Agreement is an essential element of these complementary strategies."[26]

On the basis of the above, this petition notes: *first*, that the right to health is an *erga omnes* right that forms part of the ICESCR; *secondly*, that the right to health obligates States parties to take positive action in order to fulfill the content of the right, including - and especially - in cases involving immunisation against infectious diseases; *thirdly*, that in the specific context of the COVID-19 pandemic, these obligations include the obligation to provide free and urgent - or at the very least, affordable - vaccines to all, as public goods; *fourthly*, that the rules of the intellectual property regime act as barriers to the full implementation of the right to health; and that *finally*, and therefore, failure to support the TRIPS waiver in the aid of public health constitutes a continuing breach of State obligations to prevent - or at least, mitigate - the COVID-19 pandemic.

We note that as recently as last week, the International Commission of Jurists has published an Expert Legal Opinion calling upon States to respect their human rights obligations to not impede the proposed COVID-19 TRIPS waiver.[27] At the time of writing, this Opinion has been endorsed by more than 100 jurists across the globe. We are entirely in agreement with the contents of the Opinion.

V. Impact and Remedies

Respondents have actively opposed or resisted the TRIPS waiver request initially made by South Africa and India in October 2020. Respondents are instead proposing half measures that betray their privileging of the intellectual property monopolies of a handful of corporations over the lives, health and livelihood of people in the global south.

Experts at the leading science journal Nature, Médecins Sans Frontières (MSF) Access Campaign, the Third World Network, along with the TRIPS waiver proposal sponsors, have presented numerous examples of how enforcement of IP rules have blocked, delayed, or limited production of chemical reagents for Covid-19 tests, ventilator valves, Covid-19 treatments, and elements of Covid-19 vaccines. IP constraints have led to shortages of vaccines and key raw materials like bioreactor bags and filters. Rather

[25] CESCR, "Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property", E/C.12/2021/1 (23 April 2021).

[26] Ibid.

[27] ICJ, "Human Rights Obligations of States Not to Impede the Proposed COVID-19 TRIPS Waiver", available at https://www.icj.org/wp-content/uploads/2021/11/Human-Rights-Obligations-States-Proposed-COVID-19-TRIPS-Waiver.pdf, accessed on 11th November 2021.

than manufacturers being held back by an inherent lack of manufacturing and technological capability, studies have shown that transnational claims to IP impede new manufacturers from entering and competing in the market. The same dynamics are playing out today with COVID-19 — as we, as nurses and health care workers, see their devastating impact on our patients everyday.

With the urgent need to spur action by the Respondents, we urge the Special Rapporteur to:

(i) Undertake a mission to the World Trade Organization to investigate the facts set out in this petition and (ii) make a determination that the Respondents actions to impede the TRIPS waiver constitute a continuing breach of their obligations to guarantee the right to physical and mental health of everyone. Key elements of the mission involve:

a. **Visit to the WTO Secretariat and the TRIPS council, including consultations with ambassadors to the WTO from India, South Africa, and the Respondent States;**
b. **Interviews with officials at the World Health Organization and COVAX (co-led by Gavi and the Coalition for Epidemic Preparedness Innovations (CEPI));**
c. **Country visits to the Respondent States, and meetings with parliamentarians and executives of pharmaceutical companies in their jurisdiction; and**
d. **Consultations with civil society organizations, families of COVID-19 victims, and healthcare workers; and**
e. **Press-conference after the mission with the findings.**

If you have any questions or would like to discuss this further, please contact:

Kenneth Zinn, Coordinator
Global Nurses United
kzinn@nationalnursesunited.org
8455 Colesville Road, Suite 1100
Silver Spring, Maryland 20910 USA
Tel: +1 202 297 4976

Varsha Gandikota, Member of the Cabinet
Progressive International
varsha.gandikota@progressive.international
Rue de la Servette 96
Genève, 1202 Switzerland
Tel: +1 475 201 8995