Joint Civil Society Complaint to the United Nations (UN) Special Rapporteur on the Right to Health

Concerns Over the Role of the European Union, Norway, Japan and Switzerland in the World Health Organization's Pathogen Access And Benefit-Sharing System Negotiations

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Esteemed

Dr Tlaleng Mofokeng, *Special Rapporteur on the Right to Health*

Petitioners submit this complaint given renewed urgency to conclude negotiations on the WHO Pathogen Access and Benefit-Sharing (PABS) System.

Positions advanced by the European Union, Norway, Japan and Switzerland in the PABS negotiations raise serious concerns regarding compliance with the right to health, established by Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). ICESCR obligations extend beyond national borders and include duties of international cooperation, particularly with respect to access to essential medicines, vaccines, diagnostics and other health technologies.

The WHO Pandemic Agreement (PA) mandated in Article 12 the establishment of a PABS system, with operational details to be elaborated in an Annex. The purpose of the PABS system is to facilitate the rapid and timely sharing of biological materials and sequence information of pathogens with pandemic potential and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of such materials and sequence information.

The PABS system emerges from international agreed rules on access and benefit sharing under the Convention on Biological Diversity (CBD) and Nagoya Protocol, which recognises the interlinkages between access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation. The CBD also recognises the sovereign rights over genetic resources, including on digital sequence information (DSI).

The Pandemic Agreement negotiations stem from the widely documented failures of the global response to the COVID-19 pandemic, particularly the staggering inequities in access to vaccines, therapeutics and diagnostics. This is a recurring pattern in global health. Affected developing countries contribute to the development of vaccines, therapeutics and diagnostics in many ways, including by sharing pathogen materials and sequence information, yet they receive little to no benefits from the sharing of such resources. Instead, they repeatedly face delayed, inadequate and unaffordable access to the vaccines, therapeutics and diagnostics. Against this background and the promise[1] of equitable and universal access, Member States initiated negotiations on the WHO Pandemic Agreement and consequently on the PABS System.

[1] European Council. (2021, March 30). *"COVID-19 shows why united action is needed for more robust international health architecture": Op-ed article by President Charles Michel, WHO Director-General Dr Tedros Adhanom Ghebreyesus and more than 20 world leaders.* https://www.consilium.europa.eu/en/press/press-releases/2021/03/30/covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture-op-ed/

The EU, Norway, Japan and Switzerland have opposed measures aimed at ensuring legal certainty, transparency and accountability within the PABS System, including standardized access and benefit-sharing contracts, and user registration applicable to those seeking access to pathogen sequence information. They have also consistently insisted on the unrestricted right of users to seek and enforce intellectual property monopolies over products and technologies developed through access to pathogen materials and sequence information, which can hinder both further research & development and equitable access to health products.

Contradictorily, the EU, Norway, Japan and Switzerland push for legal commitments on countries to share their genetic resources and sequence information, but have consistently opposed proposals aimed at establishing enforceable accountability, traceability and benefit-sharing obligations within the PABS System. For example, they have opposed proposals requiring manufacturers to reserve a guaranteed proportion of vaccines, therapeutics and diagnostics (VTDs) for WHO to be able to prevent and respond to Public Health Emergencies of International Concern (PHEICs), which occur far more frequently than pandemics and can result in significant morbidity, mortality, social disruption and economic harm.

These countries are also opposed to proposals requiring manufacturers to grant production licences to enable rapid expansion and diversification of manufacturing capacity, particularly in developing countries. They have similarly resisted proposals for monetary benefit-sharing linked to revenues generated from the use of pathogen materials and sequence information, as well as requirements for users engaged in non-commercial activities to place resulting research and development outputs in the public domain. Such measures are essential to achieving the Pandemic Agreement's objectives of prevention, preparedness and response, and to ensuring that the benefits arising from shared pathogen samples and sequence information are distributed equitably.

Taken together, these positions risk perpetuating an extractive system in which developing countries are legally obliged to share pathogen materials and genetic sequence data for the global good, while corporations monopolise the resulting research and development and capture significant commercial benefits. At the same time, affected developing countries are left without guaranteed and equitable access to the vaccines, therapeutics and diagnostics developed from those resources. This approach exposes the contradiction of developed countries paying lip service to international cooperation, solidarity and equity, while systematically resisting measures essential to realise the right to health and ensure equitable access to life-saving medical products.

General Comment No. 14 of the Committee on Economic, Social and Cultural Rights underscores that the realization of the right to health depends upon international assistance and cooperation. The Committee affirms that States Parties must respect the enjoyment of the right to health in other countries, prevent third parties over which they can exercise influence from interfering with that right, facilitate access to essential health facilities, goods and services in other countries wherever possible, and ensure that international agreements and decisions taken within international organizations do not adversely affect the right to health. Importantly, the Comment states "States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health".

Developed country positions are also likewise difficult to reconcile with General Comment No. 17, which states that "States parties should ensure that intellectual property rights do not lead to denial or restriction of everyone's access to essential medicines necessary for the enjoyment of the right to health" and General Comment No. 24 which reaffirms that States have a duty to regulate business activities and prevent corporate conduct that undermines the enjoyment of Covenant rights.

The positions of the EU, Norway, Japan and Switzerland are also inconsistent with the parameters set out in Article 12 of the Pandemic Agreement, including that access and benefit-sharing shall be on an "equal footing," that the terms and conditions governing access and benefit-sharing shall provide legal certainty, that benefit-sharing shall be fair and equitable and that access to data should be addressed together with effective traceability measures. The Agreement is also very clear that the provisions of the PABS system should be consistent with the objectives of the CBD and Nagoya Protocol, which can be realized by having provisions consistent with internationally accepted principles and elements on access and benefit sharing.

Civil society organizations and scientists from around the world have raised concerns about inequity, biosecurity, biopiracy, the role played by Norway and the European Union in the negotiations. However, these concerns have largely been sidelined or ignored.

We respectfully request you, as the Special Rapporteur on the Right to Health, to examine this complaint and whether the positions by the European Union, Norway, Japan and Switzerland are compatible with States' obligations under the ICESCR.

Third World Network - TWN *Global*
Oxfam *Global*
AHF Global Public Health Institute *Global*
Pan African Treatment Access Movement - PATAM *Africa*
KELIN *Kenya*
People's Health Movement - PHM *Global*
Medicus Mundi International - MMI *Global*
Working Group on Access to Medicines - GTPI *Brazil*

Proyecto sobre Organización, Desarrollo, Educación e Investigación - PODER *Mexico*
Asociación Internacional para la Salud - AIS *Peru*
Brazilian Interdisciplinary Association - ABIA *Brazil*
Society for International Development - SID *Global*
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