Principles for Access to Medicines and Trade

The Trump administration is using U.S. trade power and extreme tariffs to bully other countries into binding agreements that undermine affordable and readily available access to medicines.

Trump's trade chaos demands higher drug prices outside the U.S., elevates corporate interests over health needs, promotes steep pharmaceutical tariffs that shrink global supply, undermines local capacity development, and pursues all of its demands through secret negotiations.

Countries that rush to appease U.S. demands risk agreeing to terms — including harmful intellectual property provisions and restraints on medicine price negotiation, procurement, and production — that compromise access to medicines and the right to health.

We believe trade approaches must preserve countries' abilities to:

1. **Ensure affordable prices for all.**
2. **Reject corporate bullying.**
3. **Enable plentiful supply of medicines.**
4. **Ensure the safety, efficacy, and quality of medicines.**
5. **Freely determine which international treaties are beneficial.**
6. **Adhere to transparent and accountable trade processes.**

1. Ensure affordable prices for all.

Trump wants drugmakers to raise their prices in many countries, risking treatment rationing and busting health budgets. His excuse: that this will somehow lead to lower prices for Americans. But there is no reason to think that higher prices in some countries will lead to lower prices, or "most-favored nation" pricing, in the United States. Instead, this policy threatens to fuel already high prices by giving companies with monopoly power more freedom to set excessive prices.

Medicines must be affordable for individuals and public and private payers, and sustainable for health systems.

- ➢ **To enable fairer prices, avoid measures that seek to deregulate pharmaceutical pricing.**

> ***Box 1.*** *Many countries negotiate prices and evaluate clinical and cost effectiveness to support affordability of new drugs. The United Kingdom employs such systems to help counter unreasonably high prices set by pharmaceutical companies and mitigate budgetary impacts. However, as a result of pressure from the Trump administration and the pharmaceutical industry, the U.K. has agreed to change its drug pricing standards, resulting in higher drug spending. Moreover, some drug companies are already agreeing to raise entry prices in the U.K.*

2. Reject corporate bullying.

While sustained pressure forced international trade rules to recognize the importance of safeguarding public health and access to medicines, trade agreements nonetheless frequently include intellectual property terms that go beyond internationally agreed-upon standards — including by requiring lower standards of patentability, data/marketing exclusivity (monopolies), patent term extensions, and linkage of patent and regulatory status. Trade and other political threats are frequently deployed to limit the use of compulsory licensing. This has narrowed the space available for countries to facilitate access to affordable generic medicines and to combat anti-competitive practices. In addition, the U.S. often

pursues heightened trade secret protection in trade agreements that allow companies to keep important information confidential and to hide behind non-disclosure agreements.

Countries must be free to enact and use policies that enable access to medicines without constraint of trade rules or external pressures.

- ➢ **Trade pressure should never be used to undermine or seek removal of internationally agreed policy space related to public health and intellectual property. Governments should not encourage the adoption of or agree to intellectual property commitments in trade agreements that limit the ability to protect or increase access to affordable medicines.**
- ➢ **Countries should remain free to require public disclosure of R&D and manufacturing costs, prices, supply agreements, and other publicly relevant pharmaceutical information.**

> ***Box 2.*** *Governments have the right to implement public interest safeguards in their intellectual property law and practice. India's Patents Act, for example, includes important safeguards that support affordable access to medicines by preventing the grant of poor-quality evergreening patents that lengthen monopolies on medicines. The UN Special Rapporteur on the Right to Health, recognizing the adverse impact that the WTO TRIPS Agreement and free trade agreements have had on prices and availability of medicines, recommends incorporating flexibilities like these into national laws to facilitate access to generic medicines. The Special Rapporteur further recommends that developing countries not introduce TRIPS-plus standards in their national laws and that developed countries not encourage developing countries to enter into TRIPS-plus trade agreements.*

3. Enable plentiful supply of medicines.

Following the deadly shortages of COVID-19 vaccines and treatments, there is a growing consensus toward strengthening local and regional biopharmaceutical capacities to support emergency response, address local health needs, ensure timely and adequate supply, and advance global science and research. However, trade approaches can run counter to these goals.

Timely, affordable, and equitable supply of medicines requires participation from a diversity of producers worldwide.

- ➢ **Foster broader production and research capacities, especially in low- and middle-income countries, including by enabling the sharing of intellectual property, technology, and knowledge needed to produce medical tools.**
- ➢ **Trade policies intended to support industrial policies should align with health objectives and support sustainable access to medicines everywhere. Efforts to increase domestic or regional production should prioritize health needs and should not harm global supply chains, including by avoiding disruptive and chaotic trade measures such as high tariffs on pharmaceuticals.**

> ***Box 3****. While targeted investments in domestic production, guided by health needs, can help add to supply security for essential medicines, President Trump's plan to boost domestic pharmaceutical capacity relies largely on threatening high tariffs on pharmaceutical imports. Trump's chaotic tariffs ignore more effective policies to increase domestic production and threaten broader global capacity that can support timely access to affordable medicines for all. Meanwhile, the Trump administration may pressure other countries to buy American products as part of bilateral health aid agreements which could hinder the development of local or regional manufacturing capacity in developing countries and lock in unaffordable prices for medicines.*

4. Ensure the safety, efficacy, and quality of medicines.

To help reduce regulatory burden and facilitate timely access to medicines, many regulatory authorities participate in efforts to align regulatory requirements and rely on assessments performed by other regulators. This is sensible where public agencies maintain the flexibility to balance safety, efficacy, and access in the public interest. But trade agreements can obligate countries to apply certain assessment standards or wholly accept external regulatory decisions, which can constrain agencies' ability to act in the public interest or accommodate local needs and can create avenues for dominant corporate actors to influence regulatory assessment processes in ways that inhibit each party's discretion in administering policies to regulate medicines.

Countries should preserve sovereign decision making over the regulation of medicines.

- ➢ **To fulfill the obligation to certify that medicines are safe, effective, and of good quality, national regulatory authorities must retain their autonomy, while engaging in practices — including external collaboration — that avoid unnecessary duplication, facilitate timely access, and contribute to regulatory strengthening.**
- ➢ **Trade agreements should not impinge upon space to regulate in the interest of public health.**

> ***Box 4****. The U.S.-Malaysia Agreement on Reciprocal Trade, negotiated in response to Trump's tariff threats, requires that Malaysia accept a prior marketing authorization issued by the U.S. FDA as sufficient evidence that a pharmaceutical product manufactured in the U.S. meets Malaysia's requirements for marketing authorization. The obligation raises concerns over Malaysia's freedom to determine how best to approach regulatory decisions — including when and how to rely on external regulators — to ensure products are safe and effective. Additionally, reliance on external regulatory authorities in absence of accompanying collaboration and information sharing can undermine the development of regulatory capacities in developing countries, which, in turn, can hinder efforts to strengthen local and regional production reliant on capable regulatory bodies.*

5. Freely determine which international treaties are beneficial.

Bilateral trade agreements often require or urge adoption of or compliance with international intellectual property treaties. Many of these treaties address procedures for patent applicants to simplify processes and requirements across countries. Accession to treaties may not necessarily be beneficial to developing countries, particularly treaty obligations that impose new burdens exceeding local capacity or conflicting with other domestic interests.

Governments should resist economic coercion to adopt international treaties.

- ➢ **Governments must consider whether it is in their interest to adopt international agreements, as these may impose potentially burdensome additional requirements beyond those required by a bilateral agreement.**

> ***Box 5****. Recent trade agreements under the Trump administration, require the partner country to accede to and fully implement many additional agreements. For example, the U.S.-Malaysia Agreement on Reciprocal Trade and U.S.-Cambodia Agreement on Reciprocal Trade name 13 international intellectual property agreements, including those that affect pharmaceutical patent regulation.*

6. Adhere to transparent and accountable trade processes.

The Trump administration has used its tariff chaos to force other countries into secretive trade negotiations. While civil society has long criticized free trade agreement negotiations for their lack of transparency, the current U.S. administration's trade negotiations have reached a new level of secrecy. This lack of accountability increases the risk of corporate capture, leading governments to commit to harmful provisions that could endanger health. Decisions that will shape people's health cannot be negotiated behind closed doors or dominated by corporate interests.

Trade policy and trade negotiations must be transparent, participatory, and accountable to the public to ensure that any agreement reflects democratic input and advances the public interest.

- ➢ **Before governments share texts of their proposals in negotiations, those texts should be published in an on-the-record public comment process, and all consolidated texts after any negotiating round should also be made public so that citizens and civil society experts can influence the contents before a renegotiated text is finalized.**

Pro-corporate, pro-monopoly models reinforced by the current trade order and exploited by the powerful are failing the world. Health must be a guarantee, not a bargaining chip.

Signed,

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ABAC/ONG Burkina Faso
Acción Internacional para la Salud Perú
ACHA-AFRICA
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Asia Pacific Research Network (APRN)
Asociación Santa Micaela
Association for Proper Internet Governance
Association of Democratic Doctors (Verein demokratischer Ärzt*innen)
Association of Women of Southern Europe
Australian Fair Trade and Investment Network
AVAC
Bekwarra hepatitis B support & advocacy initiative
BFLA
Both ENDS
Brazilian Interdisciplinary AIDS Association
BUKO Pharma-Kampagne, Germany
Canadian Centre for Policy Alternatives
Cancer Alliance, South Africa
CARAM Asia
Center for Economic and Policy Research
Centre for Health and Development Initiative Africa (CHDIA)

Centre for Human Rights and Rehabilitation (CHRR)
Coalition des organismes communautaires quebecois de lutte contre le sida (COCQ-SIDA)
COALITION OF WOMEN LIVING WITH HIV AND AIDS
Communications Workers of America (CWA)
Dr Uzo Adirieje Foundation (DUZAFOUND)
European Trade Justice Coalition
Florida Physicians for Social Responsibility
Friends of Vulnerable Village Children Uganda - FVVC-Ug
Fundacion Huesped
Fundación IFARMA
GeneEthics
Georgetown University Center for Global Health Policy & Politics
Girl Rescue Foundation (GRF)
Global Exchange
Global Health Council
Global humanitarian Progress GHP Corp
Global Justice Now (UK)
Good Health Community Programmes
Health Action International
Human Rights Defenders Coalition (HRDC)
ICHANGE
Indonesia for Global Justice (IGJ)
Institute for Policy Studies - Global Economy Project
IRESCO
JARRIDD International
Just Futures Collaborative
Just Treatment
Kamukunji Paralegal Trust (KAPLET)
Kimirina
LHL International Tuberculosis Foundation
Mainline
MARSAL
Medical IMPACT
Medicinas para la Gente Capitulo Latinoamerica
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National Forum of People Living with HIV and AIDS Networks Uganda (NAFOPHANU)
Naturefriends Greece
NETWORK Lobby for Catholic Social Justice
Nigerian Women Agro Allied Farmers Association.
Open Markets Institute
Partners In Health
People's Health Movement - North America
Pharmaceutical Accountability Foundation
PowerShift e.V.
PrEP4All
Prescrire
Public Eye
Public Health Association of Australia
Public Services International (PSI)

Resilient40
Salud por Derecho
Salud y Farmacos
Sinatsisa Lubombo Women and girls Empowerment organization
Social Security Works
Southern and Eastern Africa Trade Information and Negotiations Institute (SEATINI)
Spark Street Advisors
St. Hemmingways CBO
T1International
The Society for Children Orphaned By AIDS Inc. (SOCOBA)
The United Methodist Church - General Board of Church and Society
Third World Network
Trade Justice Education Fund
Trade Justice Movement
Trade Justice Network Canada
Trade Justice New York Metro
Traditional, Complementary and Integrative Healthcare Coalition
Transform Trade
Treatment Action Group
Union Congolaise des Organisations des PvVIH
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