

**CIVIL SOCIETY LETTER TO MEMBERS OF THE WORLD TRADE ORGANIZATION
REQUEST BY LEAST DEVELOPED COUNTRY MEMBERS FOR AN EXTENSION OF
THE TRANSITIONAL PERIOD WITH RESPECT TO PHARMACEUTICAL PRODUCTS
AND FOR WAIVERS FROM THE OBLIGATION OF ARTICLES 70.8 AND 70.9 OF THE
TRIPS AGREEMENT**

5th June 2015

Dear Members of the World Trade Organization (WTO),

As civil society organizations concerned with ensuring prompt availability of affordable medicines in Least Developed Countries (LDCs) **we call on WTO Members to unconditionally accord the LDC Group an extension of the transition period with respect to pharmaceutical products and waivers from obligations under Article 70.8 (mailbox obligation) and Article 70.9 (exclusive marketing rights) as requested in their duly motivated request to the TRIPS Council (IP/C/W/605).**

LDCs are the world's most impoverished countries with the weakest technological capacity. They are disproportionately exposed to the health risks associated with poverty (such as under-nutrition, unsafe water and poor sanitation). This situation prevails alongside multiple communicable and non-communicable disease burdens. At the end of 2013, an average of 10.7 million people living with HIV resided in LDCs, with only about 3.8 million (36%) accessing antiretroviral therapy. Health burdens from non-communicable diseases are expected to increase in LDCs. For example, the estimated percentage increase in cancer incidence by 2030 (compared with 2008) will be greater in low- (82%) and lower-middle-income countries (70%) than other countries.

Widespread poverty in LDCs means that governments struggle to provide prevention, treatment and care especially where the required pharmaceutical interventions are unaffordable. Patent protection is a key factor that can affect affordability, resulting in many important pharmaceutical products being outside the reach of LDCs.

In 2001, recognizing the special circumstances of LDCs, in particular the moral imperative to support efforts to improve public health in LDCs, WTO Members granted LDCs a specific exemption for pharmaceutical products in paragraph 7 of the Doha Declaration on TRIPS and Public Health, which later was adopted as a TRIPS Council Decision dated 27th June 2002 (IP/C/25). This decision exempts LDCs from having "to implement" or "to enforce" patents and test data obligations with regard to pharmaceutical products until 1 January 2016. The WTO General Council also granted a waiver to LDCs from its obligations under Article 70.9 of the TRIPS Agreement to grant exclusive marketing rights (EMRs).

These WTO decisions have been invaluable in enabling prompt access to affordable pharmaceutical products in LDCs. Many LDCs (at least 25 countries¹) have relied on the 2002 pharmaceutical product extension to declare patents unenforceable as well as to exempt pharmaceutical products from patent and test data obligations, thereby allowing them to import critical treatments such as medicines for their national HIV/AIDS treatment programmes, including those supported by the Global Fund to Fight HIV/AIDS, TB and Malaria and other donors (e.g. UNITAID and bilateral donors). **The widespread use of the mechanism makes it one of the most successful provisions of the Doha Declaration on TRIPS and Public Health.**

¹ See UNAIDS, Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options

We are concerned that the WTO Secretariat and some developed country WTO members are questioning the need for a pharmaceutical exemption in view of TRIPS Council decision IP/C/64 which exempts LDCs from general TRIPS compliance till 1 July 2021.

We disagree with these reservations. There are valid arguments that justify an extension of the specific 2002 pharmaceutical exemption. In 2013, WTO Members granted a mere 8 years extension to LDCs, disregarding their original request for an unconditional extension linked to graduation status (i.e. for as long as a country remained a LDC). The public health crisis in LDCs is a long-term challenge that will endure at least as long as these countries remain LDCs. The challenges in health care cannot be resolved in the remaining 6-year duration of the general extension. Requiring LDCs to rely on this short duration also creates an unpredictable environment for suppliers and procurers of affordable generic medicines. Such uncertainty for generics manufacturers, which already hesitate to register and market in LDCs, could affect the prompt availability of affordable medicines in LDCs. Moreover the 2021 general extension explicitly states that it is “without prejudice” (i.e. does not affect) a further extension of the transitional period in the 2002 pharmaceutical decision.

In addition, the 2013 general extension includes a non-obligatory aspiration of LDCs towards implementing the TRIPS Agreement. However the EU² put forward a flawed interpretation by claiming that this expression is equivalent to a no-roll-back obligation. This interpretation has been rejected by academics as well as CSOs³. This interpretation creates confusion and deters LDC governments from using the transition period to adjust their legal regimes to their particular conditions and needs. In the case of access to medicines, this confusion could be particularly devastating.

A specific pharmaceutical exemption similar to the 2002 pharmaceutical decision will provide suppliers, procurers and donors of affordable medicines in LDCs the clarity and certainty to confidently manufacture, export and import generic medicines. Its extensive use (mentioned above) shows that it is an effective WTO mechanism for improving access to medicines in LDCs.

We are also of the view that the duration of “as long as a country remains a LDC,” requested by the LDC Group is fully justified. It is well known that the health challenges in LDCs are a long-term problem that will continue even after LDCs graduate. As such it is simply illogical and unconscionable to offer LDCs a shorter duration, requiring them to re-submit an extension request every few years.

In addition, LDCs’ request for waivers from Articles 70.8 (mailbox obligation) and 70.9 (exclusive marketing rights) are fully warranted as these obligations create further obstacles to access to affordable pharmaceutical products in LDCs. The mailbox obligation places considerable financial and administrative burdens on LDCs, which are extremely vulnerable and constrained and which are under no obligation to install patent filing systems. Additionally it may deter investment in local production, as there is a risk of pharmaceuticals being patented in the future. EMRs confers patent-like rights and monopoly, which limits the value of a pharmaceutical

² An EU release on 11 June 2013 stated: “Where least-developed countries voluntarily provide some kinds of intellectual property protection even though they are not required to do so under the TRIPS Agreement, they have committed themselves not to reduce or withdraw the current protection that they give.”

³ See <http://www.ourworldisnotforsale.org/it/signon/ngos-condemn-eu-press-release-trips-extension-ldcs>

transition period since access to pharmaceutical products could be effectively blocked for at least five years.

We reiterate that Article 66.1 of TRIPS which states “The Council for TRIPS **shall**, upon duly motivated request by a least-developed country Member, **accord** extensions of this period.” We are of the view that Article 66.1 *obliges* the TRIPS Council to approve without conditions the duly motivated request submitted by the LDCs.

It is important to recall that in 2012, the Global Commission on HIV and Law recommended that “WTO Members must indefinitely extend the exemption for LDCs from the application of TRIPS provisions in the case of pharmaceutical products and the UN and its member states must mobilise adequate resources to support LDCs to retain this policy latitude”.⁴

It is also important to also note that the LDCs’ requests has received widespread support including from international organizations (UNITAID⁵, UNDP and UNAIDS⁶), the NGO delegation to UNITAID and Communities Delegation on the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria as well as suppliers of generic medicines in LDCs (IDA Foundation).

Thus we request that all WTO Members honor their legal obligation under Article 66.1 and unconditionally accord to the LDCs their requested demands in particular:

- (a) A TRIPS Council decision extending the transitional period with respect to pharmaceutical products (that ends on 1 January 2016) for as long as the WTO Member remains a least developed country;**
- (b) A General Council decision granting a waiver to LDCs from Article 70.8 (mailbox obligation) and Article 70.9 (exclusive marketing rights) obligations for as long as the WTO member remains a least developed country.**

This will ensure continuity of the promise to LDCs struck in 2001 in the context of Paragraph 7 of the Doha Declaration on TRIPS & Public Health.

SIGNATORIES

Global Networks & Organizations

Global Tuberculosis Community Advisory Board (TB CAB)	A group of community activists from HIV and TB networks in Asia, Europe, Africa, and North and South America dedicated to increasing community involvement in TB research and access to tools to fight TB and mobilizing political will.
Peoples Health Movement	A global network of health activists, civil society

⁴ The Global Commission on HIV and Law (July 2012) available at

http://www.hivlawcommission.org/resources/report/FinalReport-Risks_Rights&Health-EN.pdf

⁵ <http://www.unitaid.eu/en/resources/press-centre/statements/1437-unitaid-urges-support-for-pharmaceuticals-exemption-for-ldcs?tmpl=component&print=1&layout=default&page=>

⁶ http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/may/20150521_PS_WTO_LD_C

	organizations and academics in approximately 70 countries.
International Grail Global Justice Network	International social and cultural women's movement in 20 countries in all continents.
International-Lawyers.Org	Works on international cases and matters of global justice in international forums such as the United Nations and the African Union or African Commission on Human and Peoples' Rights.
International Treatment Preparedness Coalition Global	A global movement of people living with HIV, treatment activists and their supporters dedicated to treatment access for all in need.
International Trade Union Confederation (ITUC)	ITUC represents 174 million workers in 156 countries and territories and has 315 national affiliates.
LDC Watch	A global alliance of national, regional and international civil society organisations (CSOs), networks and movements based in the LDCs and supported by civil society from development partner countries.
Oxfam	A global movement of people who share the belief that, in a world rich in resources, poverty isn't inevitable. It's an injustice, which can, and must, be overcome.
PLUS Coalition Internationale Sida	An international coalition fighting AIDS in Africa, Europe and North America
Médecins Sans Frontières - Access Campaign	Medical humanitarian organisation advocating for access and innovation to drugs, diagnostics and vaccines
NGO Delegation to UNITAID Board	Member of UNITAID Executive Board
Society for International Development (SID)	An international NGO with global network in more than 80 countries
Therapeutic Solidarity and Initiatives for Health (Solthis)	An international medical association dedicated to patients living with HIV / AIDS in developing countries. Headquartered in France.
Third World Network	An international network of organisations and individuals.
Universities Allied for Essential Medicines	A worldwide student organization with chapters at over 40 research universities.

Inter-regional and Regional Networks

ACP Civil Society Forum	Represents organizations in Africa, the Caribbean and the Pacific Islands
The Arab NGO Network for Development (ANND)	A regional network working in 11 Arab countries with 7 national networks (with an extended membership of 200 CSOs) and 23 NGO members. Executive bureau is based in Lebanon.
ARCADE	Senegal
Asia Pacific network of people living with HIV (APN+).	A network of member organizations in 30 Asia-Pacific countries
East African Health Platform (EAHP)	An advocacy forum of private sector organizations, civil society organizations, faith based organizations (FBOs) and other interest groups working on health in East Africa.

Eastern Africa National Networks of AIDS Service Organization (EANNASO)	A regional network of 8 national networks of AIDS Service Organizations in 7 countries (Burundi, Ethiopia, Kenya, Rwanda, Sudan, Tanzania mainland, Zanzibar and Uganda). Based in Arusha, Tanzania.
Food and Trade Network for East Africa (FATNEA)	Works with farmer organisations, NGOs and other civil society groups in East Africa.
Health Action International Europe	HAI Europe is an independent, European network, working to increase access to medicines and improve their rational use.
Health GAP	US, Kenya, Uganda
International Treatment Preparedness Coalition MENA	Middle East & North Africa
Information Group on Latin America (IGLA)	Europe, Latin America and the Caribbean
Pan African Treatment Access Movement (PATAM)	Works to scale up HIV/AIDS treatment, care and support.
Pacific Network on Globalisation (PANG)	A Pacific regional network promoting economic self-determination and justice in the Pacific Islands.
SADC Council of NGOs	A regional umbrella organisation of NGOs in the 15 member States of the SADC region based in Botswana
South Asia Alliance For Poverty Eradication (SAAPE)	An alliance of journalists, academics, trade unionists, human rights activists, NGOs and other civil society actors to fight against poverty and injustice in South Asia.
Women in Development Europe (WIDE+)	A Europe-based network of gender and feminist specialists, women's rights advocates, activists, researchers and women's rights and development organizations.

National Organizations

Sanayee Development Organization	Afghanistan
FAECYS - Federation of Commerce and Services Workers	Argentina
Attac France	France
Australian Fair Trade and Investment Network	Australia
Gonoshasthaya Kendra	Bangladesh
Bangladesh Network of People Living with HIV (BNP+)	Bangladesh
Equity and Justice Working Group Bangladesh (EquityBD)	Bangladesh
Community Development Library (CDL)	Bangladesh
Nabodhara	Bangladesh
CNCD-11.11.11 (Centre national de coopération au développement)	Belgium
Forum des Organisations de Producteurs Agricoles du Burundi (FOPABU)	Burundi
Service to Humanity for Integration, Neighbourliness and Equity	Burundi
Brazilian Interdisciplinary AIDS Association - ABIA	Brazil
Gestos - Soropositividade, Comunicação e Gênero	Brazil
GTPI/Rebrip - Working group on intellectual property of the Brazilian network for people's integration	Brazil
Save the Earth	Cambodia
Vithey Chivit (VC), Cambodia	Cambodia

Positive-Generation	Cameroon
Treatment Access Watch Africa	Cameroon
Coalition 15%	Cameroon
Cameroon Movement for UHC	Cameroon
Cameroon TB Group	Cameroon
Mouvement camerounais pour le plaidoyer à l'accès aux traitements (MOCPAT)	Cameroon
3ID	Cameroon
ASSOAL	Cameroon
Réseau des animateurs pour l'éducation des communautés (RASAEC)	Cameroon
RNUH	Cameroon
Social Development Foundation	Cameroon
Universal Health Coverage Platform Cameroon	Cameroon
The Canadian HIV/AIDS Legal Network	Canada
La Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-SIDA)	Canada
Canadian Union of Postal Workers	Canada
The Council of Canadians	Canada
Action Research Group for the Integral Development,	Democratic Republic Congo
Recherche et Action pour un Développement Multisectoriel (RADEM)	Democratic Republic of the Congo
Red de Ambientalistas Comunitarios de El Salvador (RACDES)	El Salvador
AIDES	France
ATTAC	France
Consumer Council of Fiji	Fiji
BUKO Pharma-Kampagne	Germany
Health Access Network	Ghana
Association des Jeunes Filles Pour la Promotion de l'Espace Francophone	Guinee
IT for Change	India
Initiative for Health & Equity in Society	India
Diverse Women for Diversity	India
All India Drug Action Network	India
EMPOWER	India
Gram Bharati Samiti	India
Presentation Justice Network	Ireland
Fairwatch	Italy
Consumer Protection Association	Lesotho
Policy Analysis and Research Institute of Lesotho (PARIL)	Lesotho
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)	Malaysia
GLOBE	Mauritania
Organisation Faîtière des organisations de la Société Civile	Mauritania
Sindicato Único Nacional de Trabajadores de Nacional Financiera (SUNTNAFIN)	Mexico
Collectif pour le droit à la santé au Maroc	Morocco
L'ALCS, association de lutte contre le sida	Morocco
Réseau Euromed Maroc	Morocco
Prevention Information et Lutte contre le Sida (PILS)	Mauritius

Myanmar Positive Group (MPG- National PLHIV Network)	Myanmar
National NGO Network (3N)	Myanmar
Pyi Gyi Khin	Myanmar
Future Light	Myanmar
All Nepal Peasants Federation (ANPFa)	Nepal
LEADERS Nepal	Nepal
Rural Reconstruction Nepal (RRN)	Nepal
Association Nigerienne des Scouts de l'Environnement	Niger
ONG GOULBI du Niger	Niger
Le Reseau Des ONGs De Developpement et Associations De Defense Des Droits De L'Homme Et De La Democratie (RODADDHD)	Niger
Labour,Health and Human Rights Development Centre	Nigeria
Aids Fonds	Netherlands
BOTH ENDS	Netherlands
STOP AIDS NOW!	Netherlands
Wemos Foundation	Netherlands
Baluchistan Rural Development & Research Society	Pakistan
Initiatives for Dialogue and Empowerment through Alternative Legal Services (IDEALS)	Philippines
Seres (con) viver com o VIH	Portugal
Platform of the Guinean Civil Society Organizations to Support Health and Vaccination	Republic of Guinea
Romanian Association Against AIDS	Romania
South Durban Community Environmental Alliance	South Africa
Union Universal Desarrollo Solidario	Spain
Centre for Development Alternatives	Sri Lanka
National Fisheries Solidarity Movement [NAFSO]	Sri Lanka
ADETRA Association	Switzerland
Groupe sida Genève	Switzerland
Berne Declaration	Switzerland
Health Innovation in Practice	Switzerland
YOLSE, Santé Publique et Innovation	Switzerland
Governance Links Tanzania	Tanzania
FTA Watch	Thailand
Worldview	The Gambia
Ligue Des Consommateurs Du Togo (LCT)	Togo
Centre for Health Human Rights and Development (CEHURD)	Uganda
Community Health And Information Network (CHAIN)	Uganda
Uganda Network of AIDS Service Organizations(UNASO)	Uganda
Coalition for Health Promotion and Social Development (HEPS Uganda)	Uganda
Uganda Coalition for Access to Essential Medicines (UCAEM)	Uganda
Mariam Foundation	Uganda
SEATINI	Uganda
Health Poverty Action	UK
National Justice & Peace Network	UK
RESULTS	UK
StopAids	UK
Salamander Trust	UK
Traidraft Exchange	UK

Initiative for Medicines, Access & Knowledge (I-MAK), Inc.	USA
Knowledge Ecology International	USA
Public Citizen	USA
Student Global AIDS Campaign	USA
SEATINI	Zimbabwe
Training and Research Support Centre	Zimbabwe