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
Date

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 healthrisks 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 countries[1]) 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 for least Developed Countries, UNAIDS Technical Brief 2011.

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 along 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 EU[2] 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 CSOs[3]. This interpretation creates confusion and deters LDCs' 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.[4]

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. EMRs confers patent-like rights and monopoly, which limits the value of a pharmaceutical transition period since access to pharmaceutical products could be effectively blocked for at least five years.

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[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

[4] The Global Commission on HIV and Law (July 2012) available at http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf

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 also note that the LDCs' requests has received widespread support including from international organizations (UNITAID[5], UNDP and UNAIDS[6]), 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.

[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_LDC