16th February, 2015

T o: H.E Amb. Christopher Onyanga Aparr
Permanent Representative,
The Permanent Mission of Uganda to the United Nations Office and other International Organizations in Geneva

Dear Sir,

Ref: Extension of Least Developed Countries' (LDC) WTO -TRIPS Pharmaceutical Transition Period

We are writing to request you, as the current leader of WTO LDC Member States, to lead LDC members of the WTO to act collectively to submit a duly motivated request to the TRIPS Council for an extension (for as long as a WTO LDC member remains a LDC) at the upcoming TRIPS Council meeting on 24th February, 2015 for the soon-to-lapse pharmaceutical transition period. We urge that this extension be without any conditions and that the TRIPS Council in addition recommend a waiver of Article 70.8 and 70.9 (mailbox provision and market exclusivity provision) to the General Council.

Article 66.1 of the TRIPS Agreement provides that the Council for TRIPS "shall, upon duly motivated request by a least-developed country Member, accord extensions". In recognition of the massive health challenges in LDCs, paragraph 7 of the Doha Declaration on TRIPS Agreement and Public Health accorded LDCs a specific extension concerning "pharmaceutical products" until 1 January 2016. This extension, affecting both patents on pharmaceutical products and data protections, was given effect through a TRIPS Council decision adopted in 2002 (IP/C/25). In addition, based on a recommendation from the TRIPS Council, a General Council decision (WT/L/478) was adopted in July 2002, waiving LDCs' obligations under Article 70.9, to provide for exclusive marketing rights during the transition period. We think that this waiver should also be extended and a waiver of Article 70.8 should be sought as recommended by the EAC[1].

This particular pharmaceutical extension was followed by two general extensions of the TRIPS-compliance transition period in 2005 (IP/C/40) and 2013 (IP/C/64). The 2005 extension decision included mandatory conditions, the most problematic being the "no-roll-back" clause, which due to LDC's persistence was substantially weakened in the most recent 2013 extension decision, which extended the general TRIPS-compliance transition period till 1 July 2021. These decisions also explicitly state that the general extensions are "without prejudice" to the TRIPS Council decision (IP/C/25) concerning pharmaceutical extension.

[1] http://eacgermany.org/wp-content/uploads/2014/10/EAC-TRIPS-Policy.pdf

Unlike the general extension decision, the 2002 pharmaceutical extension is specific with no conditions attached. The 2002 decision explicitly states that with regard to "pharmaceutical products" LDCs are not required "to implement or apply" patents (Section 5 of the TRIPS Agreement) and undisclosed information (Section 7 of the TRIPS Agreement) or to "enforce rights" provided for under those Sections until 1 January 2016. This decision is without prejudice to the right of LDCs to seek further extensions. In this regard, it is important to note that Uganda's recently amended Industrial Property Bill expressly provides for a pharmaceutical transition period, including by regulation any extension thereof. Accordingly, Uganda has already recognized this issue and its importance and it is now time to secure the needed extension.

It should be noted that there are an estimated 1.6 million people living with HIV in Uganda, which includes 150,000 children, and a rise in the prevalence of the scourge from 6.4 percent in 2005 to 7.3 percent in 2012. All these people need to access treatment. Research suggests that universal testing and access to treatment for all people living with HIV could reduce individual viral loads and therefore lower the "community viral load" thus reducing the overall potential HIV transmission risk around the world significantly. Of course, Uganda has many other pressing health needs as well with respect to both infectious and non-infectious diseases. People living with these diseases or at risk of them also need assured access to lower-cost, assured quality generics.

Pharmaceutical patents and data protections raise the costs of medicines because patent holders can exclude competition. Global studies, including the MSF, Untangling the Web of Antiretroviral Prices routinely shows that generic medicines are almost always priced lower than even the discounted prices drug companies sometimes offer to lower-income countries like Uganda. The imperatives of public health require Uganda to take the lead, both for itself and other LDCs, to make sure that LDCs can continue to source lower cost generics absent competition-blocking patents.

Uganda is also faced with domestic challenges of building a strong technological base, including in the pharmaceutical sector, and freedom from patents will allow our nascent industry to grow, producing in some cases medicines that might not even been generically produced by major generics like those in India. However, for our domestic and regional industry to grow, the industry needs for more time before the enforcement of pharmaceutical patent and data rights.

Ten years ago on the 14th of November while at Doha, WTO member states agreed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. The Doha declaration is a reaffirmation of members' rights to exploit the

flexibilities as provided under the TRIPS agreement. Uganda is a least developed country with very limited technological capacity to support the pharmaceutical needs of its population.
In order to make possible access to affordable medicines as well as to develop and sustain local pharmaceutical production for national use and for export, it is critical to exclude pharmaceutical products from patent protection. We believe that a good trade policy can be a powerful instrument but much of its potential to improve health, reduce poverty and stimulate development is being lost. The World Trade Organization's agreement covering intellectual property, including patents, has received much international public attention. The Trade-related aspects of intellectual property rights (TRIPS) agreement was purportedly intended to reward innovation and transfer technology. However after more than a decade, innovation in truly novel pharmaceuticals is in decline while the promise of technology transfer to developing countries unfulfilled. Most worryingly, the TRIPS Agreement has priced essential drugs beyond the reach of millions of people who need them.

The 2002 specific pharmaceutical decision has proven to be invaluable to policy makers at the national and regional level. This decision has been relied on as the legal basis to amend national patent laws to exclude pharmaceutical products, from patenting. Numerous LDCs have relied on the Doha Declaration paragraph 7 and 2002 pharmaceutical decision to allow the importation/procurement of HIV related generic medicines by declaring any existing patents unenforceable.[2]

In addition, multiple international, regional and sub-regional initiatives acknowledge the importance of governments incorporating in patent legislations and fully utilizing TRIPS flexibilities to facilitate access to affordable medicines. The African Union Roadmap on Shared Responsibility and

Global Solidarity for the AIDS, Tuberculosis and Malaria Response in Africa; the Pharmaceutical Manufacturing Plan for Africa (PMPA), the EAC East African Community Regional Pharmaceutical Manufacturing Plan of Action for 2012–2016 are some of the initiatives that are specifically supportive of extending the pharmaceutical exemption beyond 2016 as they consider the exemption to be essential to addressing the public health challenges as well to build a sound and viable technological base in the pharmaceutical sector.

We are of the view that a specific pharmaceutical extension is important and necessary to provide LDCs the certainty needed to exempt pharmaceutical products from patenting as well as to not enforce existing pharmaceutical patents. Such an extension will also provide longer-term predictability and continuity as it would cover a period beyond 1 July 2021 for most LDCs.

[2] UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016 : Strategies and Options for least Developed Countries*, UNAIDS Technical Brief 2011, p.4, http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf

The 2002 pharmaceutical extension decision will expire on 1 January 2016.Thus we are of the view that urgent action should be taken by LDCs to submit as a group a "duly-motivated request" to the TRIPS Council meeting on 24th February, 2015 for an extension of the transition period for as long as an LDC Member State remains a LDC, without conditions, and that it should further motivate waivers of Articles 70.8 and 70.9 to the General Council, also for as long as an LDC Member State remains an LDC.

We are as such looking forward to working with you to address our concerns as articulated above.

Sincerely,

1. Action Group for Health Human Rights & HIV/AIDS (AGHA Uganda)
2. Center for Health, Human Rights and Development (CEHURD)
3. Center for Information Policy in Africa
4. Centre for Participatory Research and Development (CEPARD)
5. Coalition for Health Promotion and Social Development (HEPS Uganda)
6. Community Health And Information Network(CHAIN)
7. Community Initiative for Sexual Reproductive Health and Rights (CISRHR)
8. East African Health Platform (EAHP)
9. Eastern Africa National Networks of AIDS Service Organizations (EANNASO)
10. Global Access Project (Health Gap)
11. Global Coalition of Women against AIDS in Uganda (GCOWAU)
12. Human Rights Awareness and Promotion Forum (HRAPF)
13. Irene Namyalo Ugandan science Reporter
14. Lungujja Community Health caring Organization (LUCOHECO)
15. National Care Centre
16. National Community of Women Living with HIV/AIDS in Uganda (NACWOLA)
17. National Forum of PLHA Networks in Uganda (NAFOPHANU)
18. Southern and Eastern African Trade Information and Negotiations Institute (SEATINI)
19. The Institute of Public Policy and Research (IPPR) –Uganda
20. The Positive Men's Union (POMU)'
21. The Uganda Association of Women Lawyers, FIDA-Uganda
22. The Uganda Network on Law, Ethics & HIV/AIDS (UGANET)
23. The Uhuru Institute
24. Uganda Alliance Of Patients' Organizations(UAPO)
25. Uganda Harm Reduction Network (UHRN)
26. Uganda Health and Science Press Association (UHSPA-Uganda).
27. Women's Organization Network for Human Rights Advocacy (WONETHA)
28. Mariam Foundation

29. Health Rights Action Group (HAG)