



23 February 2015

(15-1052)

Page: 1/2

**Council for Trade-Related Aspects of  
Intellectual Property Rights**

Original: English

**REQUEST FOR AN EXTENSION OF THE TRANSITIONAL PERIOD UNDER ARTICLE 66.1 OF  
THE TRIPS AGREEMENT FOR LEAST DEVELOPED COUNTRY MEMBERS WITH RESPECT TO  
PHARMACEUTICAL PRODUCTS AND FOR WAIVERS FROM THE OBLIGATION OF  
ARTICLES 70.8 AND 70.9 OF THE TRIPS AGREEMENT**

*Communication from Bangladesh on behalf of the LDC Group*

The following communication, dated 20 February 2015, is being circulated at the request of the delegation of Bangladesh on behalf of the least developed country Members.

1. The least developed country (LDCs) Members of the WTO represent the poorest and weakest segment of the international community. The economies of least developed country Members are extremely vulnerable, with large segments of their population living in poverty. They bear high burdens of infectious and non-infectious diseases and face numerous challenges in confronting disease and illness. LDCs are disproportionately exposed to the health risks associated with poverty (such as poor and under-nutrition, unsafe water and poor sanitation). Further low-income levels mean that they also struggle to provide their population with prevention, treatment and care. Patent protection contributes to high costs, placing many critical treatments outside the reach of LDCs.

2. In 2011, some 9.7 million of the 34 million people living with HIV worldwide, live in LDCs.<sup>1</sup> Of the people living with HIV in LDCs, 4.6 million were eligible for antiretroviral (ARV) treatment in accordance with the 2010 World Health Organization HIV treatment guidelines, however only 2.5 million were receiving it.<sup>2</sup> While the ARV treatment situation may have somewhat improved since the 2001 Declaration on TRIPS and Public Health (WT/MIN(01)/DEC/2), the need remains significantly great. There are particularly complex challenges for LDCs with respect to second line HIV treatment which is more than double the price of the first line regime, and third line HIV treatment which could be as much as 15 times the price of first line treatment.<sup>3</sup>

3. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has expressed concern that "without extension of the transition period, access to antiretroviral therapy and other key medicines in LDCs will face real challenges"<sup>4</sup> and with "a real danger ...progress that has been made to improve access to HIV-related medicines in these countries will be reversed".

4. LDCs also bear increasing health burdens from non-communicable disease. For example, cancer incidence is expected to rise 82% from 2008 to 2030 in low-income countries (compared to 58% in upper-middle and 40% in high-income countries).<sup>5</sup>

5. Resolution A/HRC/23/L.10/Rev.1 of 11 June 2013 adopted by the UN Human Rights Council on access to medicines in the context of the right of everyone to the enjoyment of the highest

<sup>1</sup> UNAIDS, UNDP, "TRIPS transition period extensions for least-developed countries", Issue Brief, 2013.

<sup>2</sup> UNAIDS, UNDP, "TRIPS transition period extensions for least-developed countries", Issue Brief, 2013.

<sup>3</sup> Medecins San Frontieres Access Campaign (2013). "Untangling the Web of Antiretroviral Price Reductions", 16<sup>th</sup> Edition.

<sup>4</sup> UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016 : Strategies and Options for least Developed Countries*, UNAIDS Technical Brief 2011,

<sup>5</sup> WHO, "Global Status Report on Noncommunicable Diseases", 2010

attainable standard of physical and mental health urges States to promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights which provide flexibility for that purpose.

6. Against this context, it is imperative for LDCs to retain maximum policy space to enable them to confront their health burdens with effective and affordable strategies.

7. Article 66.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") accorded least developed country Members a ten-year exemption from most obligations under the TRIPS Agreement in view of the "special needs and requirements of least developed country Members, their economic, financial and administrative constraints and their need for flexibility to create a viable technological base".

8. This exemption was due to expire on 1 January 2006. On June 2002, TRIPS Council decision IP/C/25 extended the transition period until 1 January 2016 in relation to patents and test data protection related to pharmaceutical products pursuant to the instructions of the Ministerial Conference in paragraph 7 of the Declaration on TRIPS and Public Health (WT/MIN(01)/DEC/2). The Decision was adopted "without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.

9. On the recommendation of the TRIPS Council, the General Council also granted to the LDCs a waiver from obligation under Article 70.9, till 1 January 2016, in accordance with Article IX of the Marrakesh Agreement Establishing the World Trade Organization (WT/L/478).

10. The 2002 TRIPS Council Decision (IP/C/25) supplemented by the General Council waiver (WT/L/478) has facilitated access to affordable medicines in LDCs. However LDC Members of the WTO continue to face massive health challenges from communicable and non-communicable diseases. In addition to the socio-economic and financial constraints, LDCs also lack adequate technological base and local pharmaceutical manufacturing capacity. These special needs and circumstances of LDCs, and the vulnerability of LDCs confirm the need for a renewed transition period for as long as these constraints remain.

11. Article 66.1 provides that the Council for TRIPS "*shall*, upon duly motivated request by a least developed country Member, *accord* extensions of this period."

12. Least developed country Members of the WTO hereby submit a duly motivated request for an extension of the transitional period (that ends on 1 January 2016) for as long as the WTO Member remains a least developed country.

13. Least developed country Members also request that the TRIPS Council recommend to the General Council a waiver for LDCs from obligations under Articles 70.8 and 70.9 of TRIPS for as long as the WTO Member remains a least developed country.

---