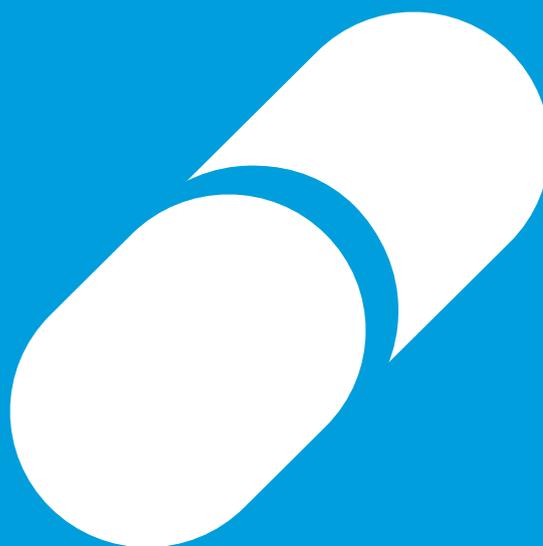


TRIPS transition period extensions for least-developed countries



Health burdens in least-developed countries – the challenge of access

In confronting disease and illness, least-developed countries (LDCs) face serious challenges on a number of fronts. LDCs are disproportionately exposed to the health risks associated with poverty (such as poor and under-nutrition, unsafe water and poor sanitation). Furthermore, low income levels mean that they also struggle to provide prevention, treatment and care, particularly where respective interventions call for high-cost medicines, diagnostics, and other health products. Patent protection is one of a number of factors which can contribute to high costs, placing many essential treatments outside the reach of LDCs.

This situation prevails alongside heavy health burdens in LDCs. In 2011, for example, an estimated 9.7 million people in LDCs were living with HIV. Of these, 4.6 million people were eligible for antiretroviral treatment in accordance with the 2010 World Health Organization HIV treatment guidelines, however only 2.5 million were receiving it.¹ While significant price reductions have been achieved for a number of ARVs, many newer, and some less toxic first-, second- and third-generation ARVs remain unaffordable for LDCs. Often these drugs are unaffordable because they remain patented, including in some LDCs.²

Low-income countries³ as a whole, bear increasing health burdens from non-communicable disease. Low- and middle-income countries together, for instance, account for over 80% of cardiovascular and diabetes deaths.⁴ While cancer incidence, notably, 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).⁵ At present, cervical cancer is the most prevalent cancer in women in low-income countries, where the incidence and mortality is greater than in high-income countries, but the generally high

cost of the patented vaccine makes this option a less affordable intervention for many LDCs at the present time.⁶

Against this challenging backdrop, it is crucial that LDCs retain the policy space which enables them to confront their health burdens with effective and affordable strategies. This Issue Brief explores one option to retain such policy space. It covers the option – available under Article 66 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) – to extend the transition period under which LDCs must become TRIPS compliant. It provides information on previous transition period arrangements; examines the potential benefits for LDCs if an extension is granted; sets out the obligations under TRIPS on other World Trade Organization (WTO) Members in respect of LDCs; covers the basics of a current proposal by LDCs for an extension of transition periods; and recommends the timely attention of all WTO Members to support the request in its current form.

Support for a proposal to grant extended transition periods – a flexibility provided for under TRIPS – is in line with the *United Nations General Assembly 2011 Political Declaration on HIV/AIDS* which urges international organizations, including UNDP and the WTO, to provide “assistance for the efforts of [developing country] Governments to increase access to HIV medicines and treatment, in accordance with the national strategies of each Government, consistent with, and including through the use of, existing flexibilities under the [TRIPS Agreement], as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health”.⁷ The UNAIDS 2011-2015 strategy endorsed by the UNAIDS Programme Coordinating Board calls on UNAIDS “to undertake concerted action to support national

governments in making use of TRIPS Agreement flexibility, and advocating for excluding legal provisions that could negatively affect access to essential medicines”.⁸ UNDP’s Strategy Note, ‘*HIV, Health and Development*’ 2012-2013 similarly calls for the “...support of public health-sensitive reforms of intellectual property legislation... that adequately address the need for affordable, accessible, safe and efficient medicines”.⁹

Background: What is TRIPS? What does it mean for access to medicines?

The TRIPS Agreement was brought into force in 1995, as part of a package of 17 agreements setting up the WTO. TRIPS introduced minimum standards for protecting and enforcing intellectual property rights to an extent previously unseen at the global level. For some countries, in respect of medicines, TRIPS meant the introduction of patents and limited forms of regulatory data protection, for others it meant extending patent protection for pharmaceutical products for the first time, and for yet for some others already granting patents, it meant extending the life of newly-granted patents.¹⁰

What are LDCs? And why do they need special consideration?

While there is no ‘threshold’ definition of a LDC, the WTO recognizes LDCs as countries which have been designated as such by the United Nations.¹¹ They comprise more than 880 million people (about 12% of the world’s population), but account for less than 2% of world GDP and about 1% of global trade in goods.¹² As such, due concessions to this

group in respect of their patent obligations – while holding great potential to maximize their ability to fulfill basic health and access goals – would have very minor implications for world trade volumes.

Least-developed countries around the world

AFRICA:

Angola, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, São Tomé and Príncipe, Senegal, Sierra Leone, Somalia, South Sudan, Sudan, Togo, Uganda, United Republic of Tanzania and Zambia.

ASIA-PACIFIC:

Afghanistan, Bangladesh, Bhutan, Cambodia, Kiribati, Lao People’s Democratic Republic, Myanmar, Nepal, Samoa, Solomon Islands, Timor-Leste, Tuvalu, Vanuatu and Yemen.

LATIN AMERICA AND THE CARIBBEAN:

Haiti

Source: UN-OHRLLS

Even though the TRIPS Agreement marked a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important policy options, flexibilities and safeguards.¹³ **One of these flexibilities was that least-developed members were granted an initial ten-year transition period to become TRIPS compliant and were eligible for further extensions of the transition periods upon proper motivation.** These transition periods were accorded “...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”.¹⁴

History of transition periods and previous extensions

While the initial period for transition to full compliance for LDCs was until 1 January 2006, TRIPS provides that the TRIPS Council¹⁵ “shall, upon duly motivated request by a least-developed country Member, accord extensions of this period”.¹⁶

Accordingly, there have been two subsequent extensions relevant to medicines since the commencement of TRIPS. The first extension was granted by the TRIPS Council in 2002. This extension provided that LDCs would not be obliged to implement or enforce patent and test data obligations with respect to pharmaceutical products until 1 January 2016.¹⁷ This decision formalized agreement that had been reached prior to the TRIPS Council in paragraph 7 of the 2001 Declaration on the TRIPS Agreement and Public Health (the ‘Doha Declaration’) – the seminal clarification by the TRIPS Council about the rights of Members to interpret and implement TRIPS to protect public health and promote access to medicines.¹⁸

The second extension, approved by the TRIPS Council in 2005, provided that LDCs would not have to apply the provisions of TRIPS (in general, not just as they apply to pharmaceuticals) other than Articles 3, 4 and 5, until 1 July 2013.¹⁹ This fixed term extension came with a ‘no-rollback’ clause, which essentially prevents LDCs from rolling back (i.e. providing a reduced degree of IP protection) once its laws contain provisions that move towards becoming TRIPS compliant.

A new request (submitted by Haiti on behalf of the LDC group in November 2012, and currently before the TRIPS Council) seeks to effectively extend the period of this 2013 general exception.²⁰ A key difference between the previous extensions and the LDC Group proposal is that if granted, the exemption would remain in force for as long as the LDC

is considered an LDC. A second difference is that the LDC proposal would not impose any conditions on the grant of the extension in terms of preserving existing levels of intellectual property protection.

Importance of extension periods for LDCs

Like many WTO flexibilities, the primary benefit of an extended transition period lies in the preservation of policy space for LDCs – conserving the autonomy of LDCs to determine appropriate development, innovation, and technological promotion policies, according to local circumstances and priorities.

A well-designed intellectual property system must balance the private rights of inventors with the public needs of society. International intellectual property rules reflect this premise: the stated *Objectives* of TRIPS comprises the assertion that “...**the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.²¹

The Article 66 provisions, affording the possibility of extended transition periods to develop a sound and viable technology base, are thus a continuation of these *Objectives*. In line with Article 66, and in view of the interconnectedness between sectors and forms of intellectual property in a well-operating technology base, the current LDC Group proposal suggests a blanket extension of transition periods for LDCs – across all forms of intellectual property, and across sectors. Without the requirement of providing intellectual property protections, LDCs are free to follow the historic path of copying and adaptation to develop their technological capacities, at the same

time strengthening their human, administrative, financial and other capacities as provided in Article 66.1.

For the production of antiretroviral therapy and other essential medicines, the potential of an exemption is a particularly important opportunity. A number of LDCs, such as Uganda, Cambodia and Rwanda have made use of existing extended transition periods to develop legislation and subsequent manufacturing of HIV-related medicines.²² These successes provide useful examples of what is achievable in the absence of full TRIPS compliance. If the transition period for LDCs is not extended, the sustainability of these existing local generic production facilities – and the future capacity of other LDCs to follow their example – becomes less certain.

The ability of LDCs to manufacture their own medicines is particularly important in the face of declining certainty that LDCs will be able to continue importing cheap generic medicines. Historically important suppliers of LDC markets, often middle-income countries such as India, have had to apply pharmaceutical product patents since 2005. This means their manufacturers can no longer automatically produce generic versions of newer, now patented, medications without receiving voluntary licenses from the patent holder or applying for compulsory licenses.²³

Also contributing to the urgent need to maintain and increase the affordability of ARVs through importation or local manufacture in LDCs is the growing insecurity of international funding of the global AIDS response. The onset of the global economic crisis saw international assistance flatten; declining in 2010, and increasing marginally in 2011, but at a level only on par with 2008 levels of funding.²⁴

The combination of these current and upcoming pressures puts in to question the ability of LDCs to meet the already large task of procuring and providing affordable medicines to their populations. The freedom for LDCs to independently manufacture affordable essential medicines (without the conventional restrictions brought about by patent protection), or to import them without the need to first apply for a compulsory license, should therefore be an important consideration for LDCs as they consider options for accessing low cost treatments into the future.²⁵

What are WTO Members obligations in respect of proposals for extension?

The TRIPS Agreement places obligations on all WTO Members to make special consideration for the needs of LDCs, both in a general way (under the Preamble²⁶ and stated Objectives, as discussed above), as well as in very specific ways.

In respect of extensions of the LDC transition periods, TRIPS offers little margin for interpretation for this approval process, providing that the TRIPS Council “shall, upon duly motivated request²⁷ by an LDC Member, accord extensions of this period”.²⁸ Furthermore, TRIPS contains no legal basis for attaching conditions to such an extension.

The ‘LDC Group proposal’

While LDCs currently can choose to be exempt from the requirement to apply the bulk of TRIPS provisions, this exemption is set to expire on 1 July 2013. LDCs are currently seeking to have this period extended. At the 5 November 2012 WTO TRIPS Council meeting, Haiti, on behalf of LDCs, submitted a proposal requesting an extension of the transitional period, under Article 66.1 of the TRIPS Agreement.²⁹ If this proposal is adopted in its current form, it would effectively also extend the waiver issued to LDCs with regard to pharmaceutical-related provisions (due to expire in 2016).

As reasons for the proposed extension, the LDC Group proposal cites little change in the development position of LDCs since the last extension, and refers to the potential technology transfer and development benefits of deferring full TRIPS implementation. In view of the impossibility of determining when individual LDCs will be able to overcome the constraints that prevent them from creating a viable technological base the proposal suggests that LDCs should not be required to apply the bulk of TRIPS provisions until they cease to be a LDC. The proposal also attaches draft text of a decision for adoption by the next Council of TRIPS meeting. Notably, this draft decision does not incorporate the ‘no-roll back’ provision that prevented LDCs from abandoning existing national levels of IP protection under previous extensions, and would remain in place so long as a LDC remains classified as a LDC.

Conclusion

The present LDC Group proposal is set to be discussed at the next TRIPS Council meeting, scheduled for 5-6 March 2013. The potential benefits for LDCs in deferring compliance are broad: from the direct public health benefits of being able to manufacture and provide inexpensive essential medicines, to the flow on effects to the wider economy of a more sophisticated technology base which is encouraged through freer transfers of technology. Furthermore, TRIPS is clear about the obligation to accord extensions following duly motivated requests. This proposal should therefore be given close and immediate attention by all WTO Members, especially LDCs.

In addition, strong support for extended transition periods for LDCs has been made by the *Global Commission on HIV and the Law*, in its recommendation that “WTO Members must indefinitely extend the exemption for LDCs from the application of TRIPS provisions in the case of pharmaceutical products”.³⁰ The heavy disease burden on LDCs, including for HIV, Hepatitis C and TB, provides an urgent and compelling case for the international community to take all measures possible to protect and extend the health of the people living in these countries.

End notes

- 1 Global Report: UNAIDS Report on the Global AIDS Epidemic, 2012. http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_with_annexes_en.pdf
- 2 For more detailed information about patent and price status of key ARVs in individual countries, see the Medicines Patent Pool *Medicines Patent Status Database* <http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/> and MSF’s ‘Untangling the Web of Antiretroviral Price Reductions 2012’ http://d2pd3b5abq75bb.cloudfront.net/2012/11/27/10/34/06/884/MSF_Access_UTW_15th_Edition_2012_updatedOct2012.pdf
- 3 ‘Low-income’ is a category of economies identified by the World Bank, as having a GNI per capita of \$1,025 or less <http://data.worldbank.org/about/country-classifications/country-and-lending-groups#IDA>. This list of low-income countries is similar to the WTO’s list of LDCs, with a few differences, since LDCs are classified according to indicators in addition to income – see footnote 8.
- 4 WHO, *Global Status Report on Noncommunicable Diseases 2010* http://whqlibdoc.who.int/publications/2011/9789240686458_eng.pdf
- 5 *Ibid.*
- 6 *Ibid.*

- 7 Paragraph 72, UN General Assembly Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS 8 July 2011 http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/06/20110610_UN_A-RES-65-277_en.pdf
- 8 UNAIDS Getting to Zero: 2011-2015 Strategy http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2010/jc2034_unaids_strategy_en.pdf.
- 9 UNDP's Strategy Note, 'HIV, Health and Development' 2012-2013 <http://www.undp.org/content/dam/undp/library/hivaids/English/HIV%20Strategy%20Document%20-%20New.pdf>
- 10 Implementation of TRIPS-related intellectual property rights has implications for health and social wellbeing other than access to medicines. Patents can block access to green technologies and climate control and mitigation technologies, the absence of which can adversely affect health. IP protections for seeds and plant varieties can negatively impact small farmers' livelihoods and food security thereby negatively impacting nutritional status and health. Access to education resources that might otherwise be copyright protected and unaffordable is vital to health literacy and thus health status.
- 11 For criteria used by the UN Development Policy and Analysis Division to identify LDCs, see http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_definitions.shtml. There are currently 48 least-developed countries on the UN list, 33 of which to date have become WTO members http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm
- 12 'About LDCs', United Nations Office of the High Representative for the least-developed countries, Landlocked Developing Countries and the Small Island Developing States (UN-OHRLS) <http://www.unohrlls.org/en/ldc/25/>
- 13 For an overview of TRIPS public health flexibilities, see UNAIDS/WHO/UNDP Policy Brief, 'Using TRIPS flexibilities to improve access to HIV treatment' http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf
- 14 Article 66(1) TRIPS.
- 15 The Council for TRIPS is the body, open to all members of the WTO, that is responsible for administering the TRIPS Agreement, in particular monitoring the operation of the Agreement http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm
- 16 Article 66(1) TRIPS.
- 17 WTO document IP/C/25 http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm
- 18 The Doha Declaration provided that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
- 19 WTO document IP/C/40 http://www.wto.int/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf
- 20 WTO document IP/C/W/583 http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipcw583_e.pdf
- 21 Article 7 TRIPS.
- 22 See UNAIDS technical brief, *Implementation of TRIPS and access to medicines for HIV after January 2016: Strategies and options for least-developed countries*, http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf
- 23 For a discussion of the challenges for future sustainability of access to generic medicines, relating to the changing patent environments in traditional suppliers, see UNAIDS technical brief, *ibid*.
- 24 Kaiser Family Foundation/UNAIDS report, *Financing the Response to AIDS in Low- and Middle- Income Countries: International Assistance from Donor Governments in 2011* <http://www.kff.org/hivaids/upload/7347-08.pdf>
- 25 For an outline of options for pharmaceutical manufacturing in LDCs, see http://unctad.org/en/docs/diaepcb2011d5_en.pdf
- 26 The Preamble includes a statement "Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base". See http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf
- 27 TRIPS provides no further guidance on the terms 'duly motivated' or 'request'. UNAIDS suggests that a plain English reading is therefore intended for an interpretation of 'duly motivated' and that for an action to constitute a 'request', it would therefore be sufficient if the request complies with the general rules of procedure of the TRIPS Council. See *ibid*.
- 28 Article 66(1) TRIPS.
- 29 See WTO document IP/C/W/583 www.wto.org/tw/SmartKMS/fileviewer?id=129266
- 30 The *Global Commission on HIV and the Law* was convened on behalf of the UNAIDS family by UNDP. The independent Commission comprised a panel of eminent persons who interrogated, reported and made recommendations on the relationship between legal responses, human rights and HIV (2012) <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>.



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