

**IMPLEMENTATION OF TRIPS
AND ACCESS TO MEDICINES
FOR HIV AFTER JANUARY 2016:
STRATEGIES AND OPTIONS FOR
LEAST DEVELOPED COUNTRIES**

Background

WTO Members, at the Fourth World Trade Organization (WTO) Ministerial Conference in Doha, Qatar in 2001, agreed, in the Doha Declaration on the TRIPS Agreement and Public Health, that least-developed countries (LDC) will not be required to implement or apply the rules relating to patent protection and protection of confidential information (test data) for pharmaceuticals until 2016.ⁱ Originally, these countries were expected to fully implement the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including patent and test data protection provisions by January 2005.

The Doha Declaration was formalized by a decision of the Council for TRIPS on 27 June 2002.ⁱⁱ This decision also confirmed that LDCs retained the right to request further extensions after January 2016. The June 2002 decision was complimented by a decision of the WTO General Council waiving the obligations of LDCs to grant exclusive marketing rights (EMRs) under Article 70.9 of the TRIPS Agreement until January 2016 as well,ⁱⁱⁱ with respect to pharmaceutical patents.

The WTO legal framework contains a number of provisions regarding transition periods; these generally are intended to permit developing countries additional time to implement WTO obligations.^{iv} Article 66.1 of the TRIPS Agreement, which is the basis of the 27 June 2002 decision, is informed by special considerations in relation to LDCs. Article 66.1 in combination with the Preamble of the TRIPS Agreement^v and its objectives under Article 7,^{vi} is intended to provide maximum flexibility so that LDCs can create a sound and viable technological base, including regarding domestic pharmaceutical production. This approach to

LDCs reflects the recognition of the WTO that positive efforts are required to ensure that developing countries secure a share of the growth in international trade commensurate with the needs of their economic development.^{vii}

The TRIPS Agreement also addresses the issue of technology transfer. Article 66.2, reaffirmed in paragraph 7 of the Doha Declaration, is explicit that developed countries have responsibilities to provide incentives for promotion and encouragement of technology transfer to LDCs in order to enable them to create a sound and viable technological base to implement TRIPS. The implication is that the failure of developed countries to comply with their Article 66.2 obligations has a direct effect on whether or not LDCs can reasonably implement TRIPS^{viii}.

The issue of technical and financial assistance is clearly relevant to the transitional arrangements and the capacity and readiness of LDC and other developing countries to comply with the TRIPS Agreement. Article 67, which addresses technical and financial assistance, is placed under Part VI of TRIPS concerning transitional arrangements and states that, “in order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members.” Such assistance, among other things, needs to ensure that the balance envisaged under Article 7 of TRIPS described above, and flexibilities are an integral part of the implementation structures.

The transitional arrangements for LDCs in the TRIPS Agreement are important regarding access to antiretroviral medications, as well as for other medicines, and for the development of innovation and research and development capabilities in these countries. The transition period until 2016 in LDC for pharmaceutical and test data protection was a clear recognition of the implications of patent protection on public health, and in particular, the special needs of LDCs to have ready access to medicines, and to establish a viable technological base in the pharmaceutical sector.

The issue regarding further extension of the transition period beyond January 2016 has already been recognized. The United Kingdom and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) have called for that period to be extended. However, there are concerns that the United States Trade Representative (USTR) and the European Commission (EC) may be opposed to such an extension.^{ix}

While LDCs will continue to have recourse after January 2016 to TRIPS flexibilities (as confirmed by the Doha Declaration) to facilitate access to patented medications, there is concern that without extension of the transition period, access to antiretroviral therapy and other key medicines in LDCs will face real challenges. To date, neither the options available to LDCs to request an extension beyond 2016 nor the advocacy role that international organizations can provide in support of such an extension have not been described.

In addition, there is concern now that middle-income countries (MIC) are now fully TRIPS compliant, including those countries that currently provide LDC with a significant proportion of the active pharmaceutical ingredients and finished pharmaceutical products. While older antiretroviral medications are not patented in MIC, many of the newer antiretrovirals are on patent there. The options available to LDCs for importation of generic versions of newer antiretrovirals produced elsewhere (such as under the 30 August 2003 decision on import and export of medicines produced under a compulsory license) have not been widely used and may also not be widely understood.

This document seeks to:

- Analyse how LDCs have utilized the 2016 extension to facilitate the production and access to HIV and other medicines for their populations;
- Discuss what can be done to maximise the opportunities provided by the current extensions, including clarifying the options for importation of generic versions of newer ARV to LDCs;
- Describe the potential implications of LDCs having to implement the TRIPS Agreement with respect to pharmaceuticals and test data protection;
- Fill the gaps in the understanding of the process for further extension of the transition period for pharmaceutical products;
- Provide recommendations on how LDCs should proceed to seek further extensions.

Access to HIV medicines and the use of the extended transition period in LDC

A number of LDCs have changed their laws while others have declared patents on pharmaceuticals unenforceable to take advantage of the extended transition period to support access to HIV-related drugs. Some of the key legislations, policy and practice include:

LDC members in the WTO

It appears that all the LDCs in the WTO have taken advantage of the Jun2 2002 extension decision and the July 2002 decision to waive their obligations regarding exclusive marketing rights.

LDC members of the East Africa Community (EAC)^x

EAC members are working towards a coordinated approach to promote regional production of antiretrovirals and other medicines as well as to facilitate imports, as well as a common approach on TRIPS flexibilities, using the 2016 transition to the maximum to ensure wider availability of generic medicines.^{xi}

Cambodia

Cambodia has adopted specific legislative provisions regarding the 2016 transition period. The law, in Article 136, provides that patent protection for pharmaceuticals will not come into effect until the expiration of the 2016 transition period.^{xii}

Rwanda

In addition to the EAC measures described above, Rwanda is to date the only country that has notified and used the 30 August system on the import-export mechanism for

countries with insufficient or no manufacturing capacity in the pharmaceutical sector.^{xiii} Rwanda utilized the system to procure 260 000 packs of a fixed-dose combination of zidovudine, lamivudine and nevirapine from a Canadian generic manufacturer, Apotex, Inc.

Uganda

In addition to the EAC measures described above, Uganda has relied on the extended transition period to promote transfer of technology and local production of HIV and other medicines. This has resulted in the establishment of a respected local manufacturing facility for antiretrovirals and other medicines.

At least 25 LDCs have also relied on Doha paragraph 7 to allow the importation of HIV-related medicines by declaring any existing patents unenforceable to allow the importation or procurement of HIV-related generics medicines.^{xiv} This approach is based on the understanding that paragraph 7 of the Doha Declaration and the 27 June 2002 decision permits them to not “enforce rights” provided for under TRIPS with respect to pharmaceuticals and test data.

Overall, LDCs have taken laudable steps to utilize the 2016 transition to improve access to HIV-related medicines. These measures have also played a role in promoting inward technology transfer and the building of manufacturing capacities in a number of countries. Additional efforts that LDCs can expend to maximize the full the 2016 transition are described below.



USE OF THE 2016 TRANSITION TO PROMOTE LOCAL ANTIRETROVIRAL PRODUCTION IN UGANDA

In 2007, Quality Chemicals Limited, in cooperation with Cipla, set up a US\$ 38 million pharmaceutical plant in Kampala, Uganda to produce antiretrovirals drugs for the domestic market and eventually for export to the East African region and beyond. In February 2009, the plant started producing the triple-therapy combination Triomune (lamivudine, stavudine and nevirapine) and the antimalarial therapy Lumartem (artemisinin and lumefantrine). This plant has been approved for procurement of antiretroviral and malaria medicines drugs by the International Committee of the Red Cross as well as by the WHO Pre-qualification of Medicines program.

Maximizing the use of the 2016 transition to facilitate production and access to HIV medicines

Between now and the expiry in January 2016 of the current period of extended transitional arrangements for LDCs with respect to pharmaceuticals and test data, LDC, other WTO Members, the WTO Secretariat and other international organizations, and civil society, can play an important role in maximizing the opportunities for improving access to HIV-related medicines. Action is called for in the area of legislation, technology transfer, the use of the Doha Declaration paragraph 6 mechanisms, and in the area of technical assistance.

Legislative change

In order to maximize the opportunities provided by the 2016 transition, LDCs need to make the necessary legislative changes in their patents laws. Although many LDCs have not yet fully implemented the TRIPS Agreement, all WTO member-LDCs have a patent or industrial property law, which permits patents on pharmaceuticals. While non-enforcement declarations are considered to permit the procurement of medicines there is no legal certainty for LDCs that such declarations are fully protected. Lack of legal certainty can have a chilling effect on procurement agencies and generic companies interested in investing in local/regional production.

Importantly, the transition period for general TRIPS implementation for LDCs is July 2013 (prior to the end of the pharmaceutical and test data transition). Although there are efforts to further extend this general TRIPS implementation period, granting of such an extension is not guaranteed. LDCs have come under pressure to implement these other aspects of TRIPS, and if implemented, there must be a specific exclusion of

pharmaceuticals and test data in the law, otherwise the overall TRIPS requirements will prevail over the January 2016 transition date.

The language in the legislation in Cambodia can be a model for other LDCs to address this situation. Legislation could, for example, specify that the sections/articles in the law relating to patentable subject matter do not apply to pharmaceutical products or undisclosed test data until 2016 or such other time that might be specified to ensure legal certainty and better facilitate actions that are needed to produce and/or import generic HIV-related medicines.

Technology transfer and building of technological base

Technology transfer, as already noted, is an integral component of the transitional arrangements for LDCs under the TRIPS Agreement. The LDC transition period was meant to address the administrative, technical and financial constraints faced by LDCs which can be dealt with through technical assistance and to allow *maximum flexibility* for LDCs to build a sound and viable technological base, including in the pharmaceutical sector. There is a direct linkage between the fulfillment of developed country obligations to provide incentives to promote and encourage technology transfer to LDCs, including in the pharmaceutical sector (under Article 66.2 of TRIPS), and the termination or extension of the transitional arrangements for LDCs (under Article 66.1). Available evidence suggests that developed countries have not, to date, tangibly met their obligations under Article 66.2.^{xv} They will need to augment their efforts to implement their Article 66.2 obligations fully.

Use of the 30 August 2003 Compulsory License Import-Export mechanism

There is limited pharmaceutical manufacturing capacity in most WTO-member LDCs, and even fewer WHO prequalified antiretrovirals from LDCs; therefore manufacturers in LDC cannot supply most of the key donor funded antiretroviral procurement programmes, including the Global Fund. For the foreseeable future LDCs will continue to rely heavily on imports from MICs and developed countries to meet their antiretroviral needs.

The 30 August 2003 WTO General Council Decision regarding the problem of countries with insufficient or no manufacturing capacity in the pharmaceutical sector can be an important part of the efforts to maximise the impact of the LDCs 2016 transition. This decision permits antiretroviral export by a country that is TRIPS compliant, by waiving their obligation (under Article 31(f) of the TRIPS Agreement) that the majority of products produced under a compulsory license is used only for a domestic market,

and also waiving their obligation (under Article 31(h)) that payment of adequate compensation to the patent holder is required when a compulsory license is issued. This decision can be used to facilitate the continued production by key MIC, such as India, of generic antiretrovirals (and other medicines) for supply to LDCs.

Provided that LDCs make the legislative changes discussed above, middle and upper income countries in the WTO can help LDCs maximise the opportunities under the 2016 transition by putting in place the legal mechanisms that will allow them to use the 30th August decision. So far, only Canada^{xvi}, countries in the European Community^{xvii}, and India^{xviii} have put in place the system to allow the functioning of the 30 August 2003 decision. Even then the approach taken by Canada has been criticized as being complex and overly burdensome^{xix}. The approach by India (under Section 92A of the Indian Patent Act) could provide a model for a legal framework.

The impact of this legislation in India is that LDCs only have to notify the Controller of Patents in India that they do not grant or enforce patents on pharmaceuticals and that they require supplies from India.

IMPLEMENTATION OF THE 30 AUGUST 2003 DECISION IN INDIA

(1) Compulsory licence shall be available for manufacture and export of export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of patented pharmaceutical products from India.

(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

Technical assistance

The effective use of the 2016 transition period, as well as the use of other TRIPS flexibilities, requires technical, administrative, financial and technical expertise and capacities that are often not readily available in LDCs. Significant external technical and other resources will be required for LDCs to fully benefit from the flexibility provided by the 2016 transition period. Capacity building and technical assistance will therefore be crucial between now and 2016.

UN agencies and other international organizations, including the Joint United Nations Programme on HIV/AIDS

(UNAIDS), the United Nations Conference on Trade and Development (UNCTAD), United Nations Development Program (UNDP), the World Health Organization (WHO) and the World Bank that have previously played a key role in providing technical assistance on public health and IP will need to continue and enhance their activities. The work of UNDP, in cooperation with WHO and UNAIDS, in providing policy and technical support to LDC countries reforming their intellectual property legislations to incorporate public health-related TRIPS flexibilities will need to be continued. The role of developed countries to provide financial and other assistance as envisaged under Article 67 of the TRIPS Agreement needs to be enhanced, as well.

The potential implications of failure to renew the LDCs transition for pharmaceuticals beyond 2016

If the transitional arrangements for LDCs with respect to pharmaceuticals and test data ends in January 2016, there will be a significantly more complex situation regarding the availability and pricing of HIV-related medicines compared to the situation that obtained in 2001 when the Doha Declaration was adopted. Middle income countries such as India which have historically been major suppliers of generic antiretroviral medications to low- and middle-income countries (LMICs) have introduced product patent regime for pharmaceuticals and test data protection since 2005, which means their manufacturers can no longer automatically be able to produce generic versions of newer, now patented antiretroviral medications, without receiving voluntary licenses from the patent holder or compulsory licenses from the relevant national authorities. At the present time, there are few WHO prequalified generic manufacturers of antiretroviral therapy that are located in LDCs.

While the treatment situation has obviously improved since the Doha Declaration, the need remains great. In addition, there are particularly complex challenges for LDCs with respect to second and third line HIV treatment. According to Medecins Sans Frontieres (MSF), the lowest price currently available in the global market for a second-line regimen recommended by the new WHO guidelines is currently priced at US\$ 442 - more than three times the most affordable of the improved first-line regimens.^{xx} The price of third line treatment could be as high as 19 times more than that price. The patent status and prices of new diagnostics is also likely to be an issue. There is a real danger that if the LDCs do not get a further extension, the progress that has been made to improve access to HIV-related medicines in these countries will be reversed.

Extending the LDCs transition period beyond 2016 – Strategies and options

The June 2002 decision formalizing the extension of the LDCs transitional arrangements to January 2016 with respect to pharmaceuticals and test data is explicit that LDCs retained their right, under Article 66.1, to request extensions of the transitional period. However some WTO members have indicated their opposition to any further extensions of the transition period and have taken the position that LDCs implement the relevant provisions by January 2016. It is important to clarify the legal and practical parameters that should guide the dialogue regarding whether, and in what form, further transition periods should be granted to LDCs.

Article 66.1 is explicit that the TRIPS Council has an obligation to grant extensions to the transition period if it receives a duly motivated request from an LDC. The use of the mandatory *shall* means that the TRIPS Agreement is clear that further extension must be granted by the Council once it has received a duly motivated request. As *extensions* (plural) is utilized in Article 66.1, there is no limit to the number of extensions that can be granted to LDCs. The TRIPS Agreement does not ordain any particular procedure or format to request for extension. Therefore, it will be sufficient if the request complies with the general rules of procedure and the practice of the Council for TRIPS for formal communication. LDCs can make the request individually or as a group, since it is accepted practice for WTO Members to make joint communications to the TRIPS Council or other bodies.

What constitutes a “*duly motivated*” request needs to be clarified. There is no specific definition of the phrase in the TRIPS Agreement. The lack of specific definition in the Agreement suggests that the phrase has

no special meaning other than as understood in ordinary English, where “duly” means *in the proper manner or time* while “*motivate*” means to give a reason or justify; in other words, a *duly motivated* request therefore is one that is properly presented and justified. The request will need to comply with the general rules of procedure of the Council for TRIPS and the practice for presenting formal communication. In order to answer the question as to whether LDCs are *justified* to request for additional extensions after 1 January 2016, a number of parameters (set out in Article 66.1) need to be considered and certain questions answered. The parameters should be utilized to make the case for the extension of the transition period; the strategy should be to collect, analyze and communicate information regarding these parameters and the answers to key questions. These parameters and questions are:

Purpose

What is the purpose or objective of the transitional arrangements for LDCs? Has that purpose been met?

Economic, financial and administrative situation

Article 66.1 justifies the special transitional arrangements for LDCs on the basis that these countries have special needs and requirements and, in particular, because of their economic, financial and administrative constraints. Have LDCs overcome these constraints? Has the technical assistance provided to these countries to address the financial and administrative constraints for setting up IP systems, including under the Agreement between the WTO and WIPO, addressed the underlying economic situation in the countries?

Soundness and viability of technological base

Exempting LDCs from the application of the TRIPS Agreement for a longer period and the provision for extensions to this period is intended to provide these countries with flexibility to create a viable technological base, including a sound and viable technological base in the pharmaceutical sector. While it is not intended that countries must become self-sufficient in the pharmaceutical sector, at the minimum they should have in place basic capacities and infrastructure to support various key pharmaceutical sector activities. The question then is, have LDCs created a sound and viable technological base in the pharmaceutical sector? Considering the limited number of WHO pre-qualified or US FDA approved manufacturers in LDCs it is clear that such a technological base does not yet exist in the LDCs.

Fulfillment of obligations by other WTO Members

The LDC transition period is, as already noted, directly linked to the obligations of

developed country members “to provide incentives to enterprises and institutions in their territories” for the purpose of promoting and encouraging technology transfer to LDCs. Have developed countries fulfilled their obligations under Article 66.2 generally and in the pharmaceutical sector in particular? What is the evidence that these countries have fulfilled their obligations in this regard? If developed countries have not fulfilled their Article 66.2 obligations can they oppose the granting of flexibility to the poorest and weakest in the WTO?

Technical assistance and capacity building to overcome financial and administrative constraints is also an important part of the transitional arrangements for LDCs. Has such assistance been sufficiently provided to these countries? In particular, have these countries received the relevant assistance to prevent abuse of intellectual property rights and to ensure the achievement of the objectives and principles of the TRIPS Agreement as set out in Articles 7 and 8?

Conclusion

Least developed countries have used the 2016 transition period and have demonstrated the value of the flexibility provided by the extension. There remains opportunity to further enhance the benefits of this transition period through the end of the period in 2016. Least developed, as well as other developing and developed countries, the WTO Secretariat and other international organizations as well as civil society, can all play a role in maximizing opportunities to improve access to HIV-related medicines in least developed countries during this period.

By January 2016, the patenting situation of HIV-related medicines, particularly second and third-line treatments, as well as

diagnostics, will be even more complex than it was in 2001 when the Doha Declaration was adopted. Therefore LDCs will continue to need maximum flexibility beyond January 2016 with respect to their TRIPS obligations in order to address their public health needs. There are clear parameters and rationale for granting LDCs further extension before full pharmaceutical patenting is required. The case for extension should be made clearly and in timely manner by LDCs with the support of other WTO Members and international organizations, such as UNAIDS. It is key that a coherent legal, political and practical case is presented, complying with TRIPS procedures, in order to ensure success.

ⁱ See paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN (01)/DEC/W/2 dated 20 November 2001.

ⁱⁱ Article 66.1, which falls under the part on transitional arrangements under TRIPS, provides that in view of the special needs and requirements LDC Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, for a period of 10 years from 1 January 1995. It also provides that the Council for TRIPS shall, upon duly motivated request by an LDC Member, accord extensions of this period. The 27 June 2002 decision (WTO document IP/C/25) provides that LDC Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016. It further provides that the decision is made without prejudice to the right of LDC Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.

ⁱⁱⁱ The decision is contained in WTO document W/L/478.

^{iv} There are also transitional periods for developed countries, some as long as ten years, as in the case of the Textile Agreement. For a detailed discussion of the transition periods under the TRIPS Agreement including the negotiating history of Article 66.1 see UNCTAD & ICTSD, (2005) *Resource Book on TRIPS and Development*, Cambridge University Press, New York, Part 6, Chapter 33.

^v Para 6 of the Preamble to the TRIPS Agreement recognises the special needs of LDCs, which necessitate maximum flexibility in the domestic implementation of laws, and regulations in these countries with a view to enabling them establish a sound and viable technological base.

^{vi} Article 7 of TRIPS provides 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.”*

^{vii} See paragraph 3 of the Preamble to the Agreement.

^{viii} Article 66.2 presumes that without technology transfer from developed countries LDCs will have limited or no source of technology to build a viable technological base.

^{ix} For a discussion on some of the controversy see e.g. Love J., on the Knowledge Ecology International Blog at <http://keionline.org/node/1154>. The IFPMA statement supporting the extension is available at http://www.ifpma.org/fileadmin/content/Innovation/IP%20and%20Access/Release_TRIPS_%20extension_10Feb2011.pdf.

^x The EAC Countries are Burundi, Kenya, Rwanda, Tanzania and Uganda. Of these, Burundi, Rwanda, Tanzania and Uganda are LDCs.

^{xi} The Protocol has been developed with the support of German’s GIZ project. Information on this project and the various inter-related activities is available at <http://www.eacgermany.org/index.php/eac-giz-programme/trips-and-pharmaceutical-production>.

^{xii} The Cambodian law can be downloaded from WIPO Lex at <http://www.wipo.int/wipolex/en/details.jsp?id=5781>.

^{xiii} For a discussion on this case see UNAIDS, WHO and UNDP (2011). The Rwanda notification to the WTO is contained in WTO document IP/N/RWA/1.

^{xiv} Based on ‘t Hoen E., (2009) *The Global Politics of Pharmaceutical Monopoly Power*, AMB Publishers, Diemen. Angola, Benin, Burkina Faso, Burundi, Central African Republic, Cambodia, Chad, Democratic Republic of Congo, Djibouti, Gambia, Guinea, Guinea-Bissau, Haiti, Lesotho, Malawi, Mali, Mozambique, Myanmar, Niger, Senegal, Rwanda, Tanzania, Togo, Uganda and Zambia.

^{xv} For analysis of how developed countries have performed see e.g., Foray D., (2009) “Technology Transfer in the TRIPS Age: The Need for New Types of partnerships between Least Developed and Most Advanced Economies” *Issue Paper No. 23*, ICTSD, Geneva and Moon S., (2008) “Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? – An Analysis of Country Submissions to TRIPS Council (1999-2007)”, *Policy Brief Number 2*, UNCTAD and ICTSD, Geneva.

^{xvi} Canada implemented the 30 August 2003 decision through amendments to its Patent Act in 2005. The Patent Act as amended is available at <http://laws-lois.justice.gc.ca/PDF/P-4.pdf>.

^{xvii} See Regulation (EC) No 816/2006 of the European Parliament and the Council of 17 May 2006 on Compulsory Licensing of Patents relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, Official Journal of the European Union L 157/1.

^{xviii} See the Patent (Amendment) Act of 2005 available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

^{xix} For criticism of the Canada legislation see e.g., Cohen-Kohler J.C., Esmail L.C., and A.P. Cosio “Canada’s Implementation of the Paragraph 6 Decision: Is it Sustainable public Policy” *Globalization and Health* available at <http://www.globalizationandhealth.com/content/3/1/12>. Also see Canadian HIV/AIDS Legal Network at <http://www.aidslaw.ca/EN/camr/index.htm>.

^{xx} See MSF’s Untangling the web of Antiretroviral price reductions at <http://utw.msfaccess.org/background/challenges>.

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