The Trans-Pacific Partnership: Trading Away Access to Affordable Medicines

Brief to the House of Commons
Standing Committee on International Trade

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The Canadian HIV/AIDS Legal Network promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally, through research and analysis, advocacy and litigation, public education and community mobilization.

Le Réseau juridique canadien VIH/sida fait valoir les droits humains des personnes vivant avec le VIH/sida et vulnérables à l'épidémie, au Canada et dans le monde, à l'aide de recherches et d'analyses, de plaidoyer, d'actions en contentieux, d'éducation du public et de mobilisation communautaire.

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INTRODUCTION

The Canadian HIV/AIDS Legal Network (the "Legal Network") welcomes this opportunity to provide submissions to the House of Commons Standing Committee on International Trade on the subject of the Trans-Pacific Partnership (TPP).

The Legal Network works for the human rights of people living with HIV and of communities particularly affected by HIV, both in Canada and internationally. We are also a member of the Global Treatment Access Group (GTAG), a working group bringing together various Canadian organizations advocating for greater access to medicines, and other aspects of the human right to the highest attainable standard of health, in developing countries.

We are deeply concerned that the TPP threatens to undermine the protection and promotion of a range of human rights. In practice, the intellectual property chapter will undermine the ability of some of the world's poorest to access lower-cost medicines. Under the TPP, individuals, public health systems and insurance providers will have to spend more to purchase drugs. Many of the world's poorest will not be able to afford them, and may suffer ill-health or death as a result. If adopted in its current form, the TPP would end up being, in the words of Médecins Sans Frontières, "the most harmful trade agreement ever for access to medicines."[1]

As it currently stands, the provisions of the TPP go far beyond existing international agreements in their impact on access to medicines ─ including the WTO *Agreement on Trade-Related Aspects of Intellectual Property* (TRIPS). These provisions, which have been characterized as "TRIPS-plus," limit and undermine countries' ability to use the safeguards and flexibilities that were included in the TRIPS Agreement to protect the public interest, such as "promoting access to medicines for all" (as agreed unanimously by WTO Members in their 2001 "Doha Declaration").[2]

During the 2015 federal election, the Liberal Party declared that "it must keep its word and defend Canadian interests during [TPP] negotiations." These interests clearly include access to affordable medicines domestically. Canadians already pay some of the highest drug prices in the world and spending on pharmaceutical products is one of the three largest elements of our overall health care spending, year after year.[3] Meanwhile, in the absence of a national, universal pharmacare plan, studies demonstrate that a significant percentage of Canadians experience the cost of medication as a barrier to proper health

[1] Médecins Sans Frontières, online: http://www.msf.ca/en/issues/access-essential-medicines-campaign.

[2] WTO Ministerial Council, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2, 14 November 2001, online: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[3] Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 to 2015* (Ottawa: CIHI, 2015), online: https://www.cihi.ca/en/spending-and-health-workforce/spending/national-health-expenditure-trends.

care—and provisions in the TPP will further complicate the already challenging task of developing universal, equitable pharmacare coverage across the country.[4]

But "Canadian interests" also include a commitment to ending the tragic global gap in access to medicines, particularly burdensome for developing countries facing multiple major public health challenges—including, but not limited to, HIV.[5] By locking in "TRIPS-plus" provisions, the TPP would thus set back commitments Canada has already made to promote global health—not just for Canadians and the 800 million people living here and in the other TPP member states—but for countless other countries, since the TPP is being billed as a model for future trade agreements across the globe. Developing countries will suffer the greatest harms from this constant ratcheting-up of more stringent intellectual property provisions unnecessarily benefiting patent-holding pharmaceutical companies.

We set out below a number of specific concerns about how provisions in the TPP will undermine equitable access to affordable medicines, particularly:

(i) the stricter rules on intellectual property protection;

(ii) the deal's impact on drug formulary prices and weakening of controls on drug company marketing; and

(iii) the expanded rules for corporations to sue governments for regulating in the public interest under the investor-state dispute settlement clause.

STRICTER RULES ON INTELLECTUAL PROPERTY

The TPP's chapter on intellectual property would strengthen and prolong the private monopoly rights enjoyed by pharmaceutical companies in various ways, impeding and delaying the competition that brings medicine prices down, by means of:

- Expanding the scope of patenting: Patents of 20 years (at least) must be available for new uses of known drugs and new methods or processes of using a known

[4] M. Dutt, *Affordable Access to Medicines: A Prescription for Canada* (Ottawa: Canadian Doctors for Medicare & Canadian Centre for Policy Alternatives, 2014), online: www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2014/12/Affordable_Access_to_Medicines.pdf.

[5] This commitment was reflected in the widespread support—including from 80% of Canadians polled—for legislative proposals in front of the last Parliament (e.g., Bill C-398) that were aimed at fixing the flaws in Canada's Access to Medicines Regime (CAMR).Such fixes remain needed if the regime is ever to deliver on Parliament's previous unanimous pledge (more than a decade ago) to support developing countries in getting more affordable, generic medicines—rather than remaining moribund, with only one licence issued under the system, authorizing a limited quantity of just one medicine (for treating HIV) to one country (Rwanda). See: Canadian HIV/AIDS Legal Network, *Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers* (Toronto: Legal Network, 2012), online: http://www.aidslaw.ca/site/wp-content/uploads/2013/04/CAMR_QA_Oct2012-ENG.pdf.

drug, even if there is no therapeutic benefit for patients—making it easier for companies to "evergreen" their patents to extend their market monopolies.

- Patent term extensions: The TPP would also require countries to extend drug companies' patent terms by years to "compensate" them for delays in the process of getting their patent approved or getting approval to market their drug.

- Patent "linkage": TPP countries must create laws that give patented drug companies an opportunity to get an order blocking generic drugs from being approved for marketing if the patent-holding company alleges the generic drug would infringe its patent. The US and Canada already have such systems in place. The Canadian regulations are regularly abused by patented drug companies to obtain automatic injunctions blocking competitors from the marketplace for years based on mere allegations, and have been described by the Supreme Court of Canada as "draconian."[6]

- Data and market exclusivity periods: The TPP will require countries to grant new and longer periods (for some countries) of "data exclusivity" over information about a drug's safety and efficacy that is submitted to drug regulators in order to get approval to sell the drug. By blocking the use of this information to assess the quality of subsequent, generic versions of that drug, data exclusivity rules are another way, separate from the patent status of a drug, to delay the entry of generic competitors into the market and thereby maintain a monopoly in the market. Related to this, and particularly noteworthy in the TPP, are the controversial new rules on biologic medicines—i.e., those made from biological sources or processes (as opposed to being chemically synthesized like conventional drugs), such as vaccines, blood products and gene therapies. The category of biologics includes new treatments for cancer and various immune conditions, and includes some of the most expensive pharmaceuticals on the market. The TPP would require countries to give 8 years of "effective market protection" (i.e., monopoly) to makers of biologic drugs, whether through the application of data exclusivity rules, or these rules in combination with undefined "other measures," before any more affordable, follow-on "biosimilar" drugs (akin to generic versions of conventional drugs) could be allowed to compete in the market.

- New, harsher enforcement: TPP countries must ensure they provide for civil, administrative and criminal procedures for the enforcement of drug companies' intellectual property rights. This includes powers for customs officers to detain shipments, including of items in transit to other countries simply based on a "suspicion" of trademark infringement—provisions that have already previously been abused in Europe to interfere with the shipment of legitimate generic medicines between developing countries. It also would allow courts to award

[6] *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, at para. 33

damages for an infringement based on the "suggested retail price"—i.e., the price suggested by the patented drug company, with an obvious consequence of inflating damages.

The provisions in the TPP's intellectual property chapter will thus delay, impede or chill competition in the marketplace, which is a critical factor in bringing down the prices of medicines—as has been shown vividly by the global experience with antiretroviral drugs needed to treat millions of people with HIV.[7] Such delays come at the expense of millions of people who cannot afford medicines when pharmaceutical companies can use their monopolies to charge high prices.

It is precisely the experience so far with the existing international rules on intellectual property, and the grave concern raised by the rules becoming even more restrictive for access to medicines through other international "free trade" agreements, that led the high-level **Global Commission on HIV and the Law** to take up this issue, among others, in its ground-breaking report a few years ago. The Global Commission included former presidents and judges, and other leading experts on HIV, law and/or human rights, and it received hundreds of submissions and heard testimony in regional dialogues held around the world. In its final report, **the Commission called for an immediate global moratorium on including any new provisions on intellectual property in any international treaty that would further restrict the policy options available to countries to improve access to medicines at affordable prices.**[8]

Most recently, similar concerns have been expressed in the long-awaited report of the **UN Secretary-General's High-Level Panel on Access to Medicines**, released last month.[9] Co-chaired by the former presidents of Switzerland and Botswana, with representation from eminent experts from various fields, the Panel was established out of concern that international and domestic rules on patents and other aspects of intellectual property—including more restrictive rules being negotiated in successive international trade agreements —are fuelling an ongoing public health and human rights crisis, particularly in low- and middle-income countries, and increasingly posing unsustainable burdens on high-income countries as well. The Panel was asked by the UN Secretary-General to recommend remedies for the "incoherence" between human rights and public health on the one hand, and on the other hand, rules on intellectual property (e.g., those further extending drug companies' patent and data monopolies).

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[7] B. Waning et al., "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries," *Journal of the International AIDS Society* 2010; 13: 35, online: www.jiasociety.org/index.php/jias/article/view/17573.

[8] Global Commission on HIV and the Law, *Risks, Rights & Health* (New York: UNDP, 2012), Chapter 6 (pp. 76-87), online: http://www.hivlawcommission.org/.

[9] *The United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies*, September 2016, online: http://www.unsgaccessmeds.org/final-report/. The High-Level Panel's report was released before Canada hosted in Montreal the 5th Replenishment Conference for the Global Fund to Fight AIDS, Tuberculosis and Malaria—the largest, most important multilateral body funding the global response to these three pandemics. Canada is a major donor to the Global Fund, and the funds it contributes, including for the purchase of life-saving medicines and other pharmaceutical products, are squandered unnecessarily to the extent that intellectual property policies, including those negotiated via trade agreements such as the TPP, restrict countries' ability to use those funds as cost-effectively as possible by purchasing lower-priced, generic medicines and products as much as possible.

Among other findings and recommendations, the High-Level Panel has called on countries to make full use of any "flexibilities" under international agreements such as the WTO's TRIPS Agreement, as part of fulfilling their human rights obligations to ensure access to medicines.[10] Underscoring the importance of preserving what flexibilities exist under TRIPS to promote equitable access to affordable medicines, the High-Level Panel outlines its concern with pressure on countries to not use those flexibilities.

It also explicitly stated its concern with "the proliferation of free trade agreements containing expansive patent and test data protections on health technologies" that exceed the requirements of TRIPS Agreement —and points to the TPP specifically as "emblematic" of such concerns. In the Panel's view, these endanger countries' efforts to ensure access to medicines and other health technologies and run counter to their human rights obligations. The Panel notes that countries concluding such agreements are in dereliction of their human rights obligations by doing so before undertaking a transparent, public assessment of its impact on access to medicines and public health. While civil society organizations and academic researchers have prepared some such analyses, the Canadian government does not appear to have undertaken any similar assessment to date.

Canada should heed these cautions and recommendations. In its potential impact on access to affordable medicines, domestically and globally, the TPP flies in the face of what is needed to respond to major public health challenge raised by both communicable diseases (including HIV, tuberculosis, malaria and others) and non-communicable diseases and health conditions (which represent an even greater, and growing, burden on the populations, health systems and economies of many countries, including both developing and high-income countries). Instead of accepting the provisions of the TPP as they stand, Canada should instead demonstrate international leadership in global health and honour its repeated commitments to global health, including access to medicines.

IMPACT ON DRUG FORMULARY PRICES AND CONTROLS ON DRUG COMPANY MARKETING

A second area of concern is the so-called annex in the TPP on "transparency and procedural fairness for pharmaceutical products and medical devices" (Annex 26-A). Its ambiguous wording could create new opportunities for pharmaceutical companies to challenge and undermine decisions on how drugs get listed for reimbursement, and at

[10] This includes a specific recommendation to apply stricter standards for granting patents on pharmaceutical products in the first place, and to adopt laws that facilitate quick implementation of compulsory licenses on patented products to address public health needs—including compulsory licensing in order to export supplies of lower-cost, generic medicines to other countries (as was supposed to be the case with the deficient CAMR).

what prices, in relation to “national health care programmes” operated by “national health authorities.”

With regard to Canada’s specific context, there is some ambiguity in the wording of the TPP provisions as to just whether this provision would currently be applicable to any of the insurance schemes maintained by the federal government covering regarding specific populations (i.e., current members of the RCMP and armed forces, veterans, federal prisoners, and First Nations and Inuit people). However, what is certainly clear is that any such provisions for challenging reimbursement decisions would create yet another complication in eventually introducing a truly national pharmacare program, something that has long been recommended for Canada by various experts and commissions so as to fill a disturbing gap in the country’s health care system.

In addition, this annex in the TPP could further undermine efforts—already weak in Canada—to limit drug companies directly marketing their products to consumers. The TPP would compel countries to allow drug companies to disseminate information online directly to health professionals and to consumers.

EXPANDED RULES FOR CORPORATIONS TO SUE GOVERNMENTS REGULATING IN THE PUBLIC INTEREST

The potential negative impact of the TPP is exacerbated by the inclusion of an investor-state dispute settlement (ISDS) clause that allows businesses to sue member countries for significant sums of money for laws and policies that may have been adopted to safeguard human rights but have in some way limited free trade possibilities. Pharmaceutical companies would thus have the right to sue sovereign governments over “interference” with their “expectations” of future profit or merely reduce their (expected) value of their investment – including through various regulations aimed at protecting the public interest.

The TPP’s “investment” chapter contains language that allows a company that objects to the impact of local laws or regulations on its profits to mount a challenge through mechanisms created by the trade deal or through the International Centre for Settlement of Investment Disputes, a body associated with the World Bank. ISDS provisions are anomalous in that they provide protection for private investors but not for States or for the general public. They allow investors to sue governments but not vice-versa.

Such ISDS procedures have become a standard feature of many trade agreements, leading to hundreds of claims by corporations challenging a wide range of public interest regulations. They have been among the features provoking the strongest opposition to such deals, including most recently the *Comprehensive Economic and Trade Agreement* (CETA) between Canada and the European Union. Such provisions, which are not

primarily aimed at removing at-the-border barriers to trade but instead at disciplining governments for domestic regulatory measures aimed at protecting various legitimate public interests, undermine the very legitimacy of such "free trade" agreements—and the TPP would take an unprecedented step in further expanding the scope of such provisions, intensifying questions about its democratic legitimacy.

Based on research that has been conducted to date under similar investor-state clauses in other free trade agreements, we are concerned that the TPP's ISDS clause could create a chilling effect if member countries are penalized for adopting regulations that would increase equitable access to medicines. **Until the TPP, ISDS provisions in trade agreements have not generally extended to defining "investment" as including intellectual property rights. Now, under the TPP, they are explicitly included.** This opens up a whole new route for pharmaceutical companies to try to derail laws or regulations that interfere with their expected profits. In fact, Canada is already facing an unprecedented suit by Eli Lilly under this sort of chapter in an existing trade agreement (NAFTA), in which the company is attempting a novel re-interpretation of the NAFTA provisions to try to incorporate intellectual property claims. This only highlights the dangers of including yet more such measures in the TPP, and this time with the explicit extension of ISDS provisions to include intellectual property claims.[11]

CONCLUSIONS AND RECOMMENDATIONS

While the increased employment and prosperity that flows from growing trade and investment can boost the enjoyment of human rights, the contrary is true if such initiatives are not managed responsibly. As outlined above, the TPP text pushes beyond the rules of the WTO TRIPS Agreement—rules which are already proving challenging for many developing countries, and increasingly for high-income countries—with the effect of further limiting the room for manoeuvre that countries need in order to protect the public good, including by trying to achieve equitable, universal access to medicines.

Our concerns are widely shared by health and human rights advocates around the world. UN agencies have repeatedly expressed concern over provisions in trade agreements limiting access to affordable medicines (particularly in developing countries),[12] and earlier this year, the UNAIDS Executive Director called on the TPP negotiating countries to refrain

[11] D. Tencer, "Eli Lilly's NAFTA Lawsuit Threat Against Canada Prompts Calls For Review Of Investor Rights," *Huffington Post,* 4 September 2013, online: www.huffingtonpost.ca/2013/09/04/eli-lilly-lawsuit-nafta-canada_n_3861869.html. See also the documents available the website of the Department of Foreign Affairs, Trade and Development: http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng.

[12] UNDP & UNAIDS, *Issue Brief: The Potential Impact of Free Trade Agreements on Public Health* (2012), online: http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf.

from including such "TRIPS-plus" provisions in the agreement.[13] So, too, did 10 UN Special Rapporteurs on various human rights issues: in a joint statement they expressed concern over the impact of more stringent intellectual property rules and "investor-state dispute settlement" provisions allowing corporations to sue states for laws and regulations aimed at protecting the public interest. They specifically expressed concern about the TPP and called on states to revisit these treaties to ensure they do not undermine human rights and to ensure an assessment of the treaties' impact on human rights, both before and after they come into effect.[14]

In keeping with the recommendations of UN agencies, and numerous health and human rights experts, the Legal Network urges Canada to:

- **conduct an independent assessment of the impact of the TPP on human rights, including access to medicines;**

- **refuse to ratify the TPP as long as it contains any "TRIPS-plus" provisions that exceed the already-restrictive rules on intellectual property that have been adopted at the WTO; and**

- **reject any deal that extends the discredited, damaging "investor-state dispute settlement" system to cover intellectual property or other laws and regulations affecting pharmaceuticals, as this would enable pharmaceutical companies to impede regulation of this sector in the public interest.**

Antiretroviral drugs have a crucial role to play not only in saving millions of people from dying of AIDS, but also in preventing millions of new HIV infections and moving the world toward the goal of ending the epidemic, as has been agreed by all countries in the Sustainable Development Goals. But these goals will never be achievable as long as governments—including Canada's—continue negotiating new trade agreements that keep raising barriers to the realization of universal access to such medicines.

[13] UNAIDS, *Press statement: UNAIDS calls on trade negotiators to uphold governments' commitments to public health and access to medicines*, 28 July 2015, online: http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/july/20150728_trips_plus.

[14] Office of the UN High Commissioner for Human Rights, News release: "UN experts voice concern over adverse impact of free trade and investment agreements on human rights," Geneva, 2 June 2015, online: www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16031.