

November 13, 2015

The Right Hon. Justin Trudeau
Prime Minister of Canada

The Hon. Chrystia Freeland
Minister of International Trade

The Hon. Jane Philpott
Minister of Health

The Hon. Marie-Claude Bibeau
Minister of International Development



Dear Prime Minister and Ministers:

Re: Access to medicines and the Trans-Pacific Partnership

We write to you as Canadian civil society organizations concerned about access to medicines, in Canada and globally. A number of us are members 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 congratulate you on your success in the recent federal election and look forward to working with your government on this shared concern. We know you share this concern partly as a result of your party's response to inquiries during the election, as follows:

There is no question that we need to get more low-cost medicines and other essential medical supplies and equipment to people in developing countries. The Liberal Party believes that the government should commit itself to the procurement of quality medicines wherever they are available to help those countries most in need roll back the advance of devastating diseases like HIV/AIDS, malaria, and tuberculosis that are ravaging their populations, as well as to assist in creating lasting health infrastructure in their countries. It is for these reasons that the Liberal Party supported Bill C-398 in Parliament, and a future Liberal government is committed to these same goals.

The Liberal Party supports free trade and the Trans Pacific Partnership (TPP) in principle. The TPP stands to remove trade barriers, widely expand free trade for Canada, and increase opportunities for our middle class. This is why Canada must be at the negotiating table. However, the federal government must also keep its word and defend Canadian interests, including supply management, during these negotiations.¹

¹ Letter from Liberal Party of Canada to Canadian HIV/AIDS Legal Network, dated September 19, 2015, online via www.aidslaw.ca/election2015.

At this juncture, we write to you to express our deep concerns with numerous provisions included in the *intellectual property, pharmaceutical pricing and investment* chapters of the Trans-Pacific Partnership agreement (TPP).

As we had communicated to the previous government, in correspondence shared with all Members of the previous Parliament, we have long been concerned about the measures reportedly being negotiated in the TPP that would hamper the ability of millions of people worldwide, including Canadians, to receive necessary medications at prices that they can afford. Now that the full text of the agreement has been released last week, those fears have been confirmed. 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.”

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) and the flexibilities ostensibly preserved therein for countries to make policy in the public interest such as “promoting access to medicines for all” (as agreed unanimously by WTO Members in their 2001 “Doha Declaration”). Adopting the “TRIPS-plus” provisions currently found in the TPP would set back commitments Canada has already made to promote global health and undermine access to medicines – not just for Canadians and the 800 million people living here and in the other TPP negotiating countries, but ultimately for many member, since the TPP is being billed as a model for future trade agreements across the globe.

We wish to outline for you a number of specific concerns about how the provisions in the TPP will undermine equitable access to affordable medicines:

1. *Stricter rules on intellectual property*

First, the 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:

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

- 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 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.

These provisions in the TPP’s intellectual property chapter will 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.² 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.

² 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.

2. Challenging drug formulary prices, weakening controls on drug company marketing

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

3. Expanded rules for corporations to sue governments for regulating in public interest

Finally, the TPP includes a chapter on “investment” that would give pharmaceutical companies rights 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 public interests.

Such chapters, setting up “investor-state dispute settlement” 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. But until the TPP, they have not generally extended to define “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), which only highlights the dangers of including yet more such measures in the TPP.³

³ 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. 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>.

Our concerns are widely shared by health and human rights advocates around the world.

As outlined above, the TPP text pushes beyond the rules of the WTO TRIPS Agreement – which rules are already proving challenging for many developing 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. UN agencies have repeatedly expressed concern over provisions in trade agreements limiting access to affordable medicines (particularly in developing countries),⁴ and earlier this year, the UNAIDS Executive Director called on the TPP negotiating countries to refrain from including such “TRIPS-plus” provisions in the agreement.⁵ 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 another major trade agreement under negotiation, the Transatlantic Trade and Investment Partnership, TTIP), and they 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.⁶

In fact, 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 groundbreaking 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 their final report, the Commissioners 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.⁷

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

⁴ 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.

⁵ 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.

⁶ 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.

⁷ Global Commission on HIV and the Law, *Risks, Rights & Health* (New York: UNDP, 2012), Chapter 6 (pp. 76-87), online: <http://www.hivlawcommission.org/>.

represent an even greater, and growing, burden on the populations, health systems and economies of many countries, including developing 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.

As noted above, during the recent election, your party declared that “it must keep its word and defend Canadian interests during these negotiations” regarding the TPP.

Those interests clearly include access to affordable medicines. 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.⁸ 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 care.⁹ It is no wonder, then, that Canadians have repeatedly expressed their opposition to longer patents for drug companies, including in the context of the not-yet-ratified Comprehensive Economic and Trade Agreement (CETA) with the European Union.¹⁰

“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. This commitment was reflected in the widespread support – including from 80% of Canadians polled – for legislative proposals (e.g., Bill C-398) in front of the last Parliament that were aimed at fixing the flaws in Canada’s Access to Medicines Regime (CAMR).¹¹ 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).

In the meantime, the immediate question before you as a new government is that of the TPP. As we and other health advocates around the world have outlined, the agreement’s current provisions stand in direct contradiction to the goals of improving access to medicines, for Canadians and for people in developing countries. Therefore, in keeping with the recommendations of UN agencies, and numerous health and human rights experts, Canada should:

⁸ 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>.

⁹ 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.

¹⁰ L. Vogel, “Canadians balk at longer brand-name drug patents,” *CMAJ* 2014; 186(2): E69, online: <http://www.cmaj.ca/content/186/2/E69.full.pdf+html>.

¹¹ 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.

- **commit to a full public consultation on the TPP, including an independent assessment of its impact on human rights (including access to medicines), among other concerns;**
- **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.**

Earlier this year, more than 500 researchers, clinicians and civil society experts from around the world issued the “Vancouver Consensus” at the international AIDS conference held there.¹² They highlighted the wealth of scientific evidence demonstrating the crucial role that antiretroviral drugs have 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. But such goals will never be achievable as long as governments – including Canada’s – continue negotiating new trade agreements that keep raising barriers to actually achieving universal access to such medicines.

As so much is at stake, for Canadians and for developing countries, we would like to request a meeting with you at your earliest convenience to discuss Canada’s role and access to medicines positions as a party to the TPP negotiation. You may find our contact information at the end of this letter.

We look forward to hearing back from you soon.

Sincerely,



Richard Elliott

On behalf of the following:
Canadian HIV/AIDS Legal Network
Canadian Centre for Policy Alternatives
Grandmothers Advocacy Network
CATIE
Canadian Treatment Action Council
Global Fund Advocates Network

¹² International AIDS Society, “The Vancouver Consensus” from the International AIDS Conference, 2015, online: <http://vancouverconsensus.org/>.

Interagency Coalition on AIDS and Development
Canadian Working Group on HIV and Rehabilitation
Canadian Aboriginal AIDS Network
Canadian Association of Nurses in AIDS Care

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