DON'T TRADE AWAY HEALTH:

BRIEF TO CANADA'S MINISTER OF INTERNATIONAL TRADE REGARDING THE TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS AND ACCESS TO MEDICINES

The Access Gap

Billions of people around the world lack access to life-saving medicines. While this is because of a number of synergistic causes, one critical factor is the prohibitively **high cost of patent-monopolized medications**. Provisions currently being negotiated for the Trans-Pacific Partnership agreement (TPP) risk exacerbating this situation, which for many is a matter of life and death.

In the ministerial *Declaration on the TRIPS Agreement and Public Health*, adopted in 2001, all Members of the World Trade Organization (WTO) recognized the serious threat that strict intellectual property measures pose to health, and particularly the health of people living in developing countries. Reflecting this unanimous agreement, **WTO Members affirmed that all countries subject to the WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) are entitled to use to the full the agreement's "flexibilities" to protect public health, and in particular "to promote access to medicines for all."** Among other things, this includes the use of compulsory licensing to enable generic competition in the pharmaceutical marketplace and thereby lower prices.

In addition, WTO Members explicitly recognized that countries with insufficient manufacturing capacity in the pharmaceutical sector could face difficulties in "making effective use" of compulsory licensing. For this reason, in 2003, WTO Members adopted an ostensible solution to this problem, with a view in particular to enabling developing and least developed countries to gain access to generic medicines produced elsewhere through compulsory licensing. In 2004, Canada became the first nation to make use of the WTO's decision to uphold this TRIPS flexibility when Parliament unanimously voted to create Canada's Access to Medicines Regime (CAMR). As a result, Canada was the first nation to export life-saving generic medicines produced under compulsory licence when a Canadian generic pharmaceutical company exported a shipment of antiretrovirals for HIV treatment to Rwanda. (It is unfortunate that CAMR is unlikely to be used again given the difficulties encountered in its single use and the failure to date of Parliament to enact proposed reforms to streamline and strengthen the regime.)

We also note that, in the past, Canada has made key contributions to the WHO's major initiative in 2002 to scale up access to HIV treatment globally. Canada has also been a key supporter of the Global Fund to Fight AIDS, Tuberculosis and Malaria, the single most important multilateral mechanism for preventing millions of new infections and millions of deaths from these three diseases while strengthening health systems in many developing countries – and we urge Canada to renew and enhance that commitment to

the Global Fund by the time of the upcoming replenishment meeting later this year. Furthermore, in 2008 Canada joined the rest of the Member States of the World Health Organization (WHO) in adopting another historic agreement to improve access to medicines (the *WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*), and in 2011 Canada endorsed the WHO's new, comprehensive strategy to combat HIV (*The Global Health Sector Strategy on HIV/AIDS, 2011-2015*) which reaffirms the goal of universal access to HIV treatment. The year before, at the G8 Summit in 2010, Canada launched the Muskoka Initiative aimed at protecting and promoting maternal, child and newborn health – which necessarily will require access to medicines to address HIV and other major health burdens particularly jeopardizing the health of women and their children.

Canada is, therefore, repeatedly on record as recognizing both the need to improve access to medicines and the need to ensure that intellectual property rules and international trade agreements not impede this urgent global health priority**. Yet the TPP negotiations threaten to put in place provisions that would go far beyond the existing WTO agreement and further limit the flexibilities stated therein. Including "TRIPS-plus" provisions in the TPP would set back commitments Canada has already made to promote global health, by undermining access to medicines for Canadians and for developing countries included in the TPP, and by setting a damaging global precedent that will be used in subsequent agreements to further impede universal access to medicines in even more countries**.

Lack of transparency in negotiations

Our first, overarching concern is the disconcerting secrecy of the TPP negotiations that have prevented any semblance of an open and fair process. The TPP will affect more than half a billion people in at least 11 countries, and potentially many more. Yet the only information available about what is being negotiated is that obtained through partial leaked texts of some countries' proposals – including the far-reaching, TRIPS-plus proposals being aggressively advanced by the US. The US Trade Representative has also made it clear that it sees the TPP as a precedent that will "set the standard for 21st-century trade agreements going forward." Yet these negotiations are being held behind closed doors, with only the final, agreed-upon text to be made public – after it is too late to evaluate the public health impact or change harmful provisions. **We urge the Canadian government to publicly state its support for releasing the negotiating texts under discussion, and to request that all countries negotiating the TPP agree.** Canadians and the people of other countries involved in the TPP negotiations deserve a transparent process and to have a say in ensuring that the negotiations do indeed deliver a new model agreement that broadly benefits people in the involved countries.

In addition to the question of transparency, as noted above, we have a number of concerns with the ***intellectual property***, ***pharmaceutical pricing*** and ***investment*** provisions under negotiation.

Intellectual property provisions

The proposed intellectual property measures include a number of provisions which would surpass the level of patent protection already granted y TRIPS. **Among other things, we are particularly concerned about proposals to: (1) *extend patent terms*, (2) impose *stricter rules on data exclusivity* and (3) *impede legitimate trade in generic medicines.***

Patent term extension

Currently, Canada does not provide extensions of patents beyond the 20-year term required by the WTO TRIPS Agreement, and for good reason. Yet proposals put forward for the TPP would allow pharmaceutical companies to request extensions for years more if examination of the patent application or review by Health Canada for marketing approval exceeds a certain period of time. But increased patent protection time delays the ability of generic pharmaceutical companies to compete by keeping their products off the market longer. Longer patent protection times on medicines mean that patients and governments – including Canada's federal and provincial governments – would have to pay for expensive, brand-name medications for a longer period of time. Patent term extensions are unnecessary and would simply represent an additional windfall for patent-holding pharmaceutical companies (which are already among the most profitable of companies under the existing regime), and impose further costs on patients and payers (including publicly-funded insurance plans). With **drug costs recently surpassing physicians' salaries as the second-largest component of health care spending in Canada**, further increasing drug costs by including such provisions in the TPP is simply an unsustainable course for Canada, and certainly for developing countries with even more limited resources, such as Vietnam, Malaysia or Peru. If **the TPP includes such provisions, it would further restrict many people's access to affordable medicines.**

Data exclusivity

Similarly, aggressive new requirements on "data exclusivity" would further hinder the production of less expensive generic medicines, certainly for domestic use in Canada and potentially for export to eligible countries under a mechanism such as CAMR. Indeed, the WHO and other UN agencies have strongly recommended developing countries not adopt data exclusivity regimes. The TPP runs directly counter to this public interest of developing countries in the TPP negotiations, as well as Canada's stated concern for access to medicines in developing countries. Domestically, Canada currently already provides extensive protection to clinical test data of an "innovative drug." Yet the US proposal would have the TPP go even further in expanding protection to any information submitted in an application for any pharmaceutical product (whether innovative or not), even if the information is in the public domain and the product is not marketed in Canada. In addition, minor changes to an existing product (e.g., new uses or indications) would also benefit from at least 3 years of additional data exclusivity. Furthermore, the US is pushing for even longer data exclusivity periods for biologic pharmaceutical products – which Canada currently does not provide with this enhanced, preferential treatment. Such new data exclusivity requirements would not only affect local manufacturing and the export interests of Canadian generic manufacturers but also increase the costs of pharmaceuticals for healthcare payers in Canada – i.e., the federal and provincial governments, private insurers and patients.

Enforcement measures impeding supply of medicines

We also are concerned that "enforcement" provisions proposed for inclusion in the TPP would impede the free transit of generic pharmaceutical products, particularly to developing countries. Proposals from the US, often couched in the guise of combating "counterfeit" or substandard medicines, include TRIPS-plus measures to allow customs officials to detain shipments of medicines at borders on the mere suspicion of infringement of intellectual property rights, as well as requiring mandatory injunctions for alleged violations of intellectual property rights. We have already witnessed, with actions of some European Union countries, how such rules disrupt legitimate trade in generic medicines destined for developing countries – an experience which has contributed to a large majority of the European

Parliament voting to reject such measures in the existing Anti-Counterfeiting Trade Agreement (ACTA). The proposals in the TPP negotiations appear to be a further attempt to advance such measures in this new treaty, with a further chilling effect on access to medicines.

We therefore urge Canada to reject the inclusion of any provisions on patent term extension, data exclusivity rules or enforcement measures in the TPP.

Pharmaceutical pricing and marketing provisions

The US has proposed a chapter in the TPP aimed at regulating how countries manage their pharmaceutical reimbursement programs and removing limits on the marketing of pharmaceutical products to health professionals and directly to consumers. These are matters which are entirely questions of public health policy and have nothing to do with international trade. Although the leaked provisions of this proposed chapter present these as provisions to increase "transparency," they are being negotiated in secret.

Furthermore, the clear objective of such provisions is not transparency but rather to regulate countries' drug pricing programs to the benefit of patented, brand-name pharmaceutical companies, undermining the ability of governments' public insurance programs to negotiate reduced prices from manufacturers, including using evidence-based pricing that assesses the safety, efficacy and cost-effectiveness of new medicines against existing therapeutic equivalents. Undermining governments' ability to manage costs of its public insurance schemes by ensuring value-for-money when it comes to pharmaceutical reimbursement is obviously of grave concern to Canadians, given the significant percentage of people – and particularly and disproportionately seniors, those on social assistance, those with 'catastrophic' drug costs and Aboriginal people – who depend upon such programs, whether provincial or federal, for coverage of prescription medications that would otherwise simply be unaffordable.

In addition, the proposals being pursued by the US would require countries to allow greater marketing by pharmaceutical companies of their products to health professionals and directly to consumers. Most countries regulate or prohibit direct-to-consumer advertising of pharmaceutical advertising in the public interest, because evidence shows little or no benefit – and even harm in some cases – to consumers and to payers, while increasing spending on expensive, brand-name products marketed by pharmaceutical companies. Canada's already weak regime of limiting direct-to-consumer advertising would be further undermined by such provisions if they are included in the TPP.

We therefore urge Canada to reject the inclusion of any provisions in the TPP that would limit countries' options for regulating prices on pharmaceutical products or regulating marketing of such products.

Investment chapter

The partial TPP texts that have been leaked last year reveal that negotiators have already provisionally agreed to many "investor-state" provisions that create even greater rights for private corporations the right to sue governments for billions of dollars if their regulations negatively affect those corporations'

"investments", including their "expectations" of profit. The draft text expands the definition of "investments" to include intangible investments, including intellectual property.

The expansion of these provisions as envisioned in the TPP goes far beyond any established notion of government expropriation of real property for which compensation may be payable and instead creates a regulatory chill that undermines the ability of sovereign governments to act or regulate in the interest of public health and access to medicines – including, for example, through their rules for government procurement of goods and services or the regulation of drug prices, as currently done in Canada and many other countries.

Furthermore, such investor-state provisions give special privileges and protection to foreign corporations to sue governments outside of national court systems, unconstrained by the rights and obligations of countries' constitutions, other laws and domestic court procedures. Instead, corporations alleging some negative effect of a government regulation on their expected profits would take such complaints before private, closed-door tribunals composed of "judges" who are largely private sector lawyers who regularly act for such corporations. This poses obvious, insurmountable, unethical conflicts of interest, and such a system of privileged, secret adjudication for corporations is antithetical to a transparent, democratic society.

Our concern with the inclusion of investor-state provisions in the TPP is amply warranted by Canada's own experience to date with such provisions in the North American Free Trade Agreement (NAFTA). Under NAFTA, the Canadian government has already paid out hundreds of millions of dollars to private corporations in the face of challenges to rules aimed at protect public health, such as banning toxic substances (e.g. a carcinogenic gasoline additive).

Indeed, the multi-national company Eli Lilly, the fifth-largest US pharmaceutical corporation, notified Canada in November 2012 that it intends to sue Canada for "not less than CDN $100 million" because of a decision of the Federal Court of Appeal to invalidate its patent for a drug used to treat attention deficit hyperactivity disorder (ADHD). The Court had applied settled Canadian patent law principles in concluding that the drug failed to deliver the benefits the company had promised when it applied for the patent to obtain its monopoly rights, and therefore the claimed patent was invalid. As a result, Canadian producers are free to produce a less expensive, generic version of the drug, which benefits Canadian consumers and other public and private insurers paying for such medications. Eli Lilly is arguing that Canada's law for determining the validity of a patent – namely, that a pharmaceutical company is required to deliver on its promises of the drug's utility in order to get and maintain its patent monopoly – is "discriminatory, arbitrary, unpredictable and remarkably subjective."

Eli Lilly's claim is unprecedented. To the best of our knowledge, it is a new effort by patent-holding pharmaceutical companies to use investor-state provisions in a trade treaty to strike down national laws aimed at protecting the public interest. It is another stark illustration of why the inclusion of investor-state provisions in the TPP, and especially its potential application to pharmaceutical products and regulations, should be firmly rejected by Canada. We note that Australia, one of the other TPP negotiating partners and a country that has experienced a similar challenge under another trade treaty to its tobacco control measures by multinational cigarette manufacturer Philip Morris, has already publicly stated that it will not agree to any investor-state provisions in the TPP.

We urge Canada to refuse the inclusion of any investment chapter in the TPP.

In conclusion, we are gravely concerned that the TPP risks going far beyond any existing trade treaty in undermining access to affordable medicines, in Canada and in developing countries.

We submit that the TPP should not include any provisions exceeding those already outlined by the WTO's TRIPS Agreement.

The TPP should not undermine public health flexibilities included in the TRIPS agreement by adopting even more stringent strengthening intellectual property measures (e.g., patent term extension or data exclusivity rules).

The TPP should not further undermine Canada's ability to export essential medicines under the already complicated CAMR.

The TPP should not include similar provisions to the ones incorporated in the stalled Anti-Counterfeiting Trade Agreement (ACTA), which would potentially thwart access to medicines by introducing new rules on damages and injunctions, and limit the free transit and international supply of affordable generic medicines.

The TPP should not impose procedural or substantive restrictions on the ability of government agencies to protect the public interest by regulating pharmaceutical prices and reimbursement programs and by regulating drug companies' marketing practices.

The TPP should not include intellectual property in the definition of investment, as this would enable pharmaceutical companies to impede regulation of the pharmaceutical sector in the public interest. In fact, given Canada's experience under NAFTA, the TPP should contain no investment chapter at all.

Instead, the TPP should provide an opportunity for Canada to demonstrate further its international leadership in global health. **Canada should ensure that the TPP is written in such a way that it is in accordance with the WTO Doha Declaration on the TRIPS Agreement and Public Health and the WHO Global Strategy and Plan of Action. Canada must honour its repeated commitments to global health, including access to medicines.**