

Médecins Sans Frontières/ Doctors Without Borders Written Submission to the Canadian House of Commons Standing Committee on International Trade for consideration in the study of the Trans-Pacific Partnership Agreement

December 2016

Executive Summary:

Doctors Without Borders/Médecins Sans Frontières (MSF) provides the following written submission regarding the impact that the Trans-Pacific Partnership (TPP) trade agreement will have on access to affordable medicines and biomedical innovation for consideration by the House of Commons Standing Committee on International Trade's study of the Trans-Pacific Partnership Agreement.

As a medical humanitarian organization working in nearly 70 countries, MSF is in need of both affordable access to and innovation for medical technologies. Through our work, MSF witnesses the everyday impacts on people of having limited or no access to medicines. Drug prices need to be affordable so that our patients — and millions of others waiting for treatment — can get the medicines they need.

In our experience, generic competition saves lives by reducing price and increasing access. Competition among medicines producers has consistently proven to be a critical tool to lower drug prices and help deliver effective medical care. Patients, ministers of health and treatment providers like MSF rely on affordable, quality generic medicines to treat many life-threatening diseases, including tuberculosis, malaria, HIV/AIDS and other infections that afflict the poorest and most vulnerable people in the world.

However, new intellectual property obligations and other protections for pharmaceutical companies that limit price-lowering generic competition are driving up drug prices and limiting access to medical innovations. Several provisions included in the TPP will further reduce the timely availability of affordable medicines needed by MSF and patients around the world. The TPP puts in place new, far-reaching government obligations that lengthen, strengthen and broaden patents and other mechanisms that extend market exclusivities for pharmaceutical products. It will require some countries to change their national laws to implement these harmful new rules and will lock countries like Canada in to provisions that keep medicine prices unnecessarily high. The effect will be to further delay access to generic medicines beyond current requirements of international trade law, undermining the public health safeguards that governments and others have to promote access to medicines and limit abuse of pharmaceutical market exclusivity mechanisms. If enacted, the TPP will undermine existing Canadian global health commitments towards developing countries (such as Canada's recent \$785 million commitment to the Global Fund to Fight AIDS, Tuberculosis and Malaria), making medicines less affordable and less accessible to patients and treatment providers who need them.

The TPP will exacerbate the global crisis of high drug prices. For example, the TPP will prohibit national regulatory authorities from using existing clinical trials data demonstrating a pharmaceutical product's safety and efficacy to authorize the sale of competitor products, even in the absence of patents by mandating data exclusivity periods. By 2014 the price to vaccinate a child had risen to 68 times more expensive than it was in 2001, with many countries unable to afford new high-priced vaccines that prevent countless deaths from diseases such as childhood pneumonia, which kills about one million children each year. The additional monopoly protections for biologic drugs and vaccines will keep already expensive products out of the hands of millions. The TPP will also force governments to extend existing patent monopolies beyond current 20-year terms at the request of

pharmaceutical companies, and to redefine what deserves a patent, including mandating the granting of new patents for modifications of existing medicines.

Instead of using trade deals to legislate protectionism for pharmaceutical companies through the TPP, Canada should seek to establish improved global norms to fix the world's broken research and development (R&D) system. The sole reliance on high medicine prices, backed by exclusivities and monopolies, is a flawed paradigm for funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases where patients have limited purchasing power, like neglected tropical diseases or where drugs have to be used sparsely like antibiotics. MSF supports the importance of rewarding innovators for undertaking the costs and risks of biomedical innovation. Alternative approaches could address some of the flaws in the current system of R&D by rewarding innovators for these efforts while prioritizing biomedical innovation in areas of public health importance. These approaches would not require people in need of lifesaving treatment to pay artificially high prices to fund this future work. Instead of doubling down on a broken model, the Canadian government should collaborate with other governments to introduce new approaches that promote both innovation and access.

The negative public health impacts of the TPP will be felt for years to come, and will not be limited to the more than 800 million people in the current 12 TPP countries. Other countries are already being invited to join or expressing interest to sign on. Additionally, by aiming to be a standard-setting agreement, it is a dangerous blueprint for future agreements and new global trade norms.

It is not too late to prevent the further restrictions on access to affordable medicines that would be created through the TPP. MSF urges the Canadian government to protect the right to health of millions of people that will be negatively impacted if the TPP is approved in its current form. The TPP should be rejected as long as damaging provisions for access to medicines remain in the final agreement.

This submission complements the intervention made by MSF at the 2016 Parliament Hearing and available here: <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=8337011&File=0>

For more information on MSF's concerns with the TPP, please read our 2016 issue brief on TPP and Health: <https://www.msfaccess.org/content/issue-brief-trading-away-health-trans-pacific-partnership-agreement-tpp-2016>

Introduction

Doctors Without Borders/Médecins Sans Frontières (MSF) provides the following written submission regarding the impact that the Trans-Pacific Partnership (TPP) trade agreement will have on access to affordable medicines and biomedical innovation for consideration by the House of Commons Standing Committee on International Trade's study of the Trans-Pacific Partnership Agreement.

As a medical treatment provider that needs both affordable access to and innovation for medical technologies, MSF is able to speak about the relationship between trade, intellectual property and health, and about the role competition has played in enabling access to medical care for millions.

MSF urges the Standing Committee on International Trade and the Government of Canada to consider the negative impact the TPP will have on the health of millions of people before ratifying, implementing and encouraging additional countries to adopt to the TPP's restrictive provisions for pharmaceuticals.

Importance of competition for access to affordable medicines

Intellectual property monopolies negatively impact access to medicines by allowing pharmaceutical companies to charge high prices for longer, free from generic competition. That patents and other intellectual property monopolies can have a negative impact on access to medicines is widely recognized, including by the World Health Organization, the World Intellectual Property Organization, and the World Trade Organization.¹

MSF's medical operations have been challenged by the high price of medicines for many years. In 2001, high prices left MSF limited in our ability to save the lives of our patients with HIV, as pharmaceutical companies charged MSF and others an astronomical US \$10,000 per person, per year for antiretroviral medicines used to treat HIV. This meant that MSF and governments, in the face of thousands of people dying daily from AIDS-related illnesses, could only provide treatment to a very limited number of people. In response, affected governments and civil society applied legal safeguards to remove patent barriers and foster generic competition and HIV treatment costs fell, virtually overnight, to one US dollar a day per person.²

As a result of competition among generic medicines producers, prices for first-line HIV medicines have continued to fall and today almost 16 million people receive treatment,³ including through Canadian government-funded programs such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). In 2012, generics accounted for 96% of all treatments purchased by donor-funded programs like the Global Fund.⁴ The reliance on generic competition by MSF and by government-funded donor programs provides important savings that stretches investments in global health further, saving millions of lives. For Canada, this investment includes the \$785 million recently pledged by the Government of Canada to the Global Fund⁵ and more than \$1 billion contributed or pledged to Gavi, the Vaccine Alliance since 2000.⁶ Undermining access to medicines in countries also undermines the important contributions of Canadian taxpayer funding to these efforts.

Price-lowering generic competition remains critical to the ability to deliver effective care. We need generic competition for new HIV medicines that sustain the lives of patients on treatment and provide better medical outcomes. Currently patented HIV medicines can be 20 times more expensive, and because of patents no affordable generic alternatives can be sold in some countries.⁷

We also need access to affordable treatments for many other diseases. New medicines to treat hepatitis C, which chronically affects up to 150 million people worldwide⁸ and an estimated 220,000-246,000 people in Canada

alone,⁹ provide a critical illustration. These medicines, including Gilead's sofosbuvir and combination products, offer the potential for a cure. However, patents and other monopolistic protections have allowed pharmaceutical companies like Gilead to charge exorbitant prices.

In Canada, the high price of the treatment has resulted in rationing for Canadians affected by hepatitis C, leaving some forced to wait until they become sicker before being able to receive treatment.¹⁰ At its highest price of \$84,000 USD per treatment course in the United States which has some of the most expansive intellectual property rules favouring pharmaceutical companies, this potential cure is marked up more than 83,000% over the cost of production given that it only costs an estimated US \$101 per person per treatment course (or slightly more than one US dollar per pill) to produce a key treatment, sofosbuvir¹¹. Economist Jeffrey Sachs has estimated that patent-holder Gilead's investments in research and development of this treatment could have been as low as \$300 million USD. With revenues of more than \$10 billion USD in one year, Gilead may have brought in 34 times its investment in just the first year of sales alone.

While new hepatitis C medicines are less expensive in other countries, they are still unaffordable, especially in developing countries considered 'middle-income' economies where most people with hepatitis C reside¹². As generic treatments are entering some markets where barriers to competition do not exist or are lifted, prices are falling¹³. However, if the TPP is implemented, the availability of affordable generic treatments for hepatitis and other important medical conditions will be further delayed, leading to higher prices for a longer period of time.

The TPP will exacerbate the global crisis of rising medicine prices

Intellectual property obligations for pharmaceuticals, now nearly fully implemented worldwide through the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) are already driving up drug prices by delaying competition globally, including in Canada. The TPP will exacerbate these challenges by unnecessarily strengthening pharmaceutical companies' monopolies and market power and making it more difficult to change national systems that protect these monopolies.

The price of medicines are already a concern to Canadians. In April 2016, the Hon. Jane Philpott, Canada's Minister of Health referred to the price of medicines in Canada as "extremely high" in her appearance to the Standing Committee on Health,¹⁴ while other experts have testified that the Comprehensive Economic Trade Agreement signed between Canada and the European Union will increase overall drug expenditures by up to 12%.¹⁵ In addition to the rationing of hepatitis C treatments due to price, as one 2014 study reported, "on a per capita basis, Canadian drug costs are already the second highest in the world after the United States and are among the fastest rising in the Organization for Economic Co-operation and Development."¹⁶

While the text has improved over initial proposals from the United States, mostly due to the widespread opposition of the rest of the TPP countries, the TPP will still go down in history as the worst-ever trade agreement for access to medicines. Our analysis of the now publicly released text shows that the TPP puts in place new, far-reaching obligations for governments that lengthen, strengthen and broaden patents and other pharmaceutical monopolies beyond international trade rules established by the TRIPS Agreement and restrict access to price-lowering generic competition. The provisions also undermine public health safeguards that governments and others have to limit abuse, affirmed by the 2001 WTO Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration) and the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA 61.21).

Developing countries currently part of the TPP negotiation, namely Vietnam, Malaysia, Mexico and Peru, will be forced to change their laws to incorporate abusive new monopoly protections for pharmaceutical companies that will limit access to price-lowering generic competition. For Canada and other countries where some of the TPP's

provisions already exist in national law, these countries will be locked in to rules that keep medicines prices high, limiting governments' ability to address challenges of unaffordable medicines.

For an additional analysis of these issues, please refer to MSF's issue briefs and analysis, available [online](#).¹⁷

The TPP's overall negative impact on health and access to medicines

The overall negative public health impact of the TPP has been recognized by many others, including but not limited to the World Health Organization,¹⁸ UNITAID,¹⁹ the Holy See²⁰ and the World Medical Association.²¹

The negative impact of TRIPS-plus provisions that expand protections for pharmaceutical companies at the expense of affordable access to medicines, beyond what is currently required by international trade rules through the WTO's TRIPS Agreement has been well documented.²² For example, a 2009 study evaluating the impact that just two TRIPS-plus provisions like those included in the TPP would have on Peru if implemented in a different trade agreement estimated that they "would lead to an increase of 459 million USD in Peru's total pharmaceutical expenditure in 2025 and a cumulative increase in expenditure of 1267 million dollars (at present value, PV) for the same year."²³

One analysis of the TPP's overall potential impact on the cost of health care found that in Vietnam HIV treatment access would be significantly affected. The results indicated that "82% of the HIV population eligible for treatment would receive ARVs under a full TRIPS flexibility scenario, while only 30% of Vietnam's eligible HIV patients would have access to ARVs under the US 2014 TPP proposals" as identified in leaked versions of TPP negotiating texts. That is less than half of the HIV-treatment eligible population receiving treatment in Vietnam as of November 2014, according to the study. As the study also highlighted, "similar price impacts can be expected for other countries participating in the TPP."²⁴

Below we highlight some of the specific provisions included in the TPP and their effects on access to medicines.

The TPP lowers standards of patentability

Under the WTO's TRIPS Agreement governing global intellectual property obligations, governments have to grant 20-year patents on pharmaceutical products but also have important flexibility to define the specific patentability criteria of what does and does not deserve a patent in a way that addresses the needs of their own citizens and innovation system and prevents abuse of the patent system, as long as they abide by the general patentability criteria and patentable subject matter agreed as international norms.

It is in the public interest for governments to retain these flexibilities, including the ability to strengthen patentability criteria and limit patent "evergreening" (the granting of additional 20-year patents on the same medicine) and other abusive practices exercised by the pharmaceutical industry. Allowing for stricter patentability curtails the worst excesses of the patent system, ensuring that innovators focus their energies on truly useful and new drugs and other medical technologies, rather than business strategies that extend existing patent monopolies with low or no inventive, technological and societal contributions. Canada has recognized this in its own laws by applying patent "utility" requirements to pharmaceutical patent applications.

Governments should continue to make adjustments to their patent systems to achieve a better balance between rewarding innovation and providing for health and other public needs. The TPP should not prohibit signatory countries from doing the same. However, the current text of the TPP mandates the granting of secondary patents on modifications of existing drugs. The relevant section is Article 18.37 Patentable Subject Matter of Chapter 18 (Intellectual Property) that reads as following:

2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.

The obligation to grant new patents on modifications of known products is not required under international trade law, and it threatens to restrict or delay access to price-lowering generic competition by extending patent monopolies beyond the 20-year original patent term. It is difficult to completely estimate how long monopolies will be extended, and most likely the effects will differ drug by drug and country by country, but a recent study found that granting secondary pharmaceutical patents extends the life of monopoly protections by an average of more than six years in the U.S.²⁵

The TPP mandates additional data regulatory protection

The TPP mandates that clinical trials data be protected with a period of exclusivity, which is a specially-extended period of protection for biologic products, independent from and additional to patent protection.

Biologics are a class of medical product that include many drugs and vaccines that are already very expensive and in too many instances unavailable as a prevention and treatment option in many of the countries where MSF works due to high prices and reduced competition²⁶. Examples of biologics products include medicines for the treatment of cancer, arthritis, and diabetes and vaccines like the pneumococcal conjugate vaccine (PCV) for the prevention of pneumonia. MSF currently has an ongoing public campaign to reduce the price of pneumonia vaccines to increase access for children living in developing countries, where pneumonia is a leading cause of death: <http://www.afairshot.org>

This regulatory exclusivity prevents drug safety authorities from using existing clinical trials data to grant market approval to generic or biosimilar medicines, delaying price-lowering competition and keeping medicines prices high for longer.

Protection of data with exclusivity for any class of drugs is not required by the TRIPS Agreement or any other international law, and the United Nations recommends against implementation of data exclusivity, especially in developing countries.²⁷ An evaluation of the impact of ten years of implementation of data exclusivity rules in Colombia from 2003-2011 found that they resulted in an increase of more than US \$396 million in additional expenses for the public health care system.²⁸ Another study found that once Guatemala enacted data exclusivity due to DR-CAFTA obligations, some medicine prices rose as much as 846 percent.²⁹ In Jordan, data exclusivity enacted due to the US-Jordan trade agreement delayed the introduction of cheaper generic versions of 79% of medicines between 2002 and 2006. Prices of medicines under data exclusivity in Jordan were up to 800% higher than in neighbouring Egypt.³⁰

An assessment by the US Federal Trade Commission found that additional exclusivity for biologics is not warranted to promote innovation, and it imperils the public health and budgetary benefits to accelerate the entry of follow-on biologics.³¹ In the United States, the Obama Administration estimates that reducing data exclusivity for biologics from the current twelve to a proposed seven, would result in savings of nearly US \$7 billion over ten years.³²

Additional provisions of concern for access to medicines

MSF is also concerned about other provisions included in the TPP, including provisions in the “Transparency and Procedural Fairness Chapter” that could restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs and provisions, and in the “Investment Chapter” that give pharmaceutical companies the right to sue governments for laws, regulations, judicial practices and decisions that reduce their expected profits in private, supra-national investor-state dispute settlement (ISDS) tribunals, the decisions of which can usually not be appealed.

A salient example of how ISDS provisions pose a threat to national public health objectives is the case Canada is currently facing under ISDS provisions in the North American Free Trade Agreement (NAFTA). US pharmaceutical company Eli Lilly is currently in dispute with the Government of Canada, claiming \$500 million in compensation over Canada’s legitimate exercise of its national patent laws that resulted in the invalidation of two of Eli Lilly’s patent applications which did not meet Canada’s standards of disclosing the promised utility in patent applications.

As a TRIPS and NAFTA compliant measure, Canada’s doctrine of promised utility has been implemented consistently in Canada’s patent law system as an important sovereign discretion and flexibility in ensuring that its national patent system does not get abused by private entities, including those concerning pharmaceuticals. Eli Lilly’s current attempt of using ISDS as a de facto appeal procedure to manage its frustrated ‘expectation’, after it had failed all levels of domestic court in Canada, sets up a negative precedent for pharmaceutical industries that could further use ISDS to undermine legitimate public health safeguard in national laws and policies.

The TPP is bad for biomedical innovation

MSF recognizes the need to reward innovation and finance research and development (R&D). We are a humanitarian medical organization that welcomes innovations that improve medical outcomes. However, the TPP also fails to address the urgent need for reform in the biomedical innovation system. The sole reliance on high medicine prices, backed by monopolies expanded and further entrenched by the TPP, is a flawed paradigm for funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases disproportionately affecting developing countries, where patients have limited purchasing power, or that are not considered profitable enough.

In fact, the current innovation model is failing patients in all countries. For example, in Canada, a review of new drugs approved between 1990 and 2003 found less than 6% “met the regulatory criterion of being a breakthrough drug (‘the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drug products’).” From 2010 to 2014, only about 2% of new drugs reported to the Patented Medicine Prices Review Board (PMPRB) were the first drug product to be sold in Canada that effectively treats a particular illness or effectively addresses a particular indication.³³ Despite this, prescription drug spending grew rapidly in the 2000s when the use of many classes of on-patent drugs expanded in terms of use and cost. More recently, generic competition has successfully led to slower growth rates in prescription drug spending, as patents expired and subsequent entrants entered the market.³⁴

Despite the urgent need for new antibiotics that must be affordable and used sparingly, many pharmaceutical companies have abandoned antibiotic drug development altogether. We are now facing a crisis of growing antibiotic resistance that outpaces the development of new antibiotics. Canada has recognized the serious threat AMR presents with its own “Federal Action Plan on Antimicrobial Resistance and Use in Canada,” describing concretely how Canada will implement the Federal Framework for Action on AMR. This plan names among other

priorities, to “promote innovation through funding collaborative research and development efforts on antimicrobial resistance both domestically and internationally.”

Governments are already funding medical innovation and providing drug companies with tax incentives and subsidies to promote innovation while paying record prices. In some cases, governments are paying twice – first by paying a significant percentage of the R&D costs and second by paying high prices. Furthermore, even where government funding does lead to important advances in biomedical innovation, these investments still do not lead to effective prioritization of further research and development according to public health need. For example, it was thanks to initial studies at a Canadian government laboratory that the VSV-EBOV vaccine was confirmed as potentially effective against Ebola. Despite the fact that the government licensed this vaccine to a small US company, NewLink, four years before the West African Ebola outbreak, the project stalled and the vaccine was not made available to people at risk for more than five years. If clinical trials had been conducted sooner the vaccine could have potentially helped save lives. This wasted opportunity and failure to advance the vaccine’s development nevertheless netted NewLink a more than \$63.5M profit when they sold the rights to the pharmaceutical company Merck.

Canada makes many other important contributions to medical innovation. In Canada’s Budget 2016, the government “defined a new vision for Canada’s economy: Canada as a centre of global innovation,” and acknowledged the important role the government can play in advancing science, research and innovation.³⁵ The budget commits over \$300M to health research, including \$32M directly to drug research and development through the Canadian Centre for Drug Research and Development.

Yet, seeking longer and stronger monopoly protection for pharmaceutical companies not only does little for innovation, but it perpetuates a failed innovation business model that is hurting Canadian patients as well as patients abroad. We believe new approaches to promote medical innovation, including approaches that MSF and others have supported, are demonstrating that significant medical breakthroughs with access are possible – in particular, when incentives break the link between the cost of R&D and the price of the end product.³⁶ Instead of doubling down on a broken model, the Canadian government should collaborate with other governments to introduce new approaches that promote both innovation and access. In this sense, TPP is a missed opportunity to promote public health driven biomedical innovation.

MSF has recently published a report on biomedical innovation, “Lives on the Edge,” that provides an overview of some the challenges with the current innovation system and our proposals on steps governments need to take to amend it. The full report is available here: <http://www.msfacecess.org/content/report-lives-edge-time-align-medical-research-and-development-people%E2%80%99s-health-needs>

Conclusion: the TPP is a bad deal for medicine

The TPP is a bad deal for medicine; it is bad for humanitarian medical treatment providers such as MSF, and it is bad for people who need access to affordable medicines around the world, including in Canada.

MSF has for years raised the alarm about the challenges of high prices and lack of needs-driven incentives to promote innovation for our medical operations. Governments around the world are under increasing pressure from patients, payers and medical providers in their own countries to address exorbitant drug pricing as barriers to effective medical care, the sustainability of health programs, and the emergency of antimicrobial resistance with a nearly dry pipeline for new antibiotics. Yet, at the same time, the TPP will lock in high prices and monopolies as the dominating incentive mechanism for biomedical innovation and keep price-lowering generic competition off the market for years to come, worsening these very problems.

At a time when the high price of life-saving medical tools, including hepatitis drugs, biologics and vaccines is becoming a barrier to effective medical care worldwide and access to medicines are being rationed because of high prices, MSF is concerned to see governments considering locking in rules that will keep prices high for longer and will do little to advance the fundamental changes that are needed in the biomedical innovation system. Instead, countries should tune in to the growing recognition that high prices are a global and unsustainable challenge and consider alternative ways to incentivize innovation which do not require a trade-off between tomorrow's innovations and the lifesaving medicines we need today.

There are ongoing efforts in international fora about how this could be achieved, including in the commitments made by Canada and all UN Member States on new models for biomedical innovation that de-link research and development costs from prices and sales to ensure both affordability and stewardship at the 2016 UN Political Declaration on Antimicrobial Resistance.

In the same direction, the recently released report of the UN Secretary General Ban Ki-Moon's High Level Panel on Access to Medicines acknowledges the failings of today's system of monopoly protections and high prices both for access and innovation and made a variety of recommendations³⁷ including increase transparency, accelerating competition, reforming incentives for innovation and preserving rules that help governments bring prices down. The Report also alerts against the negative public health impact of provisions included in the TPP and recommends a full public health assessment.

Every country has the right and the obligation to take steps to increase access to medicines and implement a patent and regulatory system in line with its public health needs; the TPP will take away key components of that flexibility and limit the tools that governments and civil society have to try to ensure access to affordable medicines.

The negative impact of the TPP on public health will be enormous, be felt for years to come, and will not be limited to the 800 million people living in the current 12 TPP countries. Other countries are already being invited to join or expressing interest to sign on, including other developing countries. It is a dangerous blueprint for future agreements and aims at being a standard-setting agreement and to create new global trade norms.

Pharmaceutical companies already enjoy some of the highest profit margins and strongest monopoly protections of any industry. Granting them extended and additional market exclusivity and power is unnecessary to promote innovation and will cause needless death and suffering.

It is not too late to prevent further restrictions on access to affordable medicines that would be created through the TPP. MSF urges the Canadian government to protect the right to health of millions of people that will be negatively impacted if the TPP is approved in its current form. The TPP should be modified or rejected as long as damaging provisions for access to medicines are included. We are joined by the more than 40,000 people who signed our petition asking Canada to reject provisions in the TPP that threaten access to medicines for millions.³⁸

¹ WHO, WIPO, WTO. Promoting Access to Medical Technologies and Innovation. World Health Organization, World Intellectual Property Organization and World Trade Organization, 2012. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf

² Médecins Sans Frontières. Untangling the Web of Antiretroviral Price Reductions, 17th edition. July 2014. Available from: http://www.msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf

³ UNAIDS. Fact sheet 2015. June 2015. Available from: <http://www.unaids.org/en/resources/campaigns/HowAIDSchangedeverything/factsheet>

⁴ UNITAID. HIV Medicines Technology and Market Landscape. March 2014. Available from: <http://www.unitaid.eu/images/marketdynamics/publications/HIV-Meds-Landscape-March2014.pdf>

⁵ <http://www.cbc.ca/news/politics/justin-trudeau-global-fund-1.3573142>

⁶ <http://www.gavi.org/funding/donor-profiles/canada/>

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⁸ World Health Organization. Hepatitis C, factsheet no. 164 Updated July 2015. Available from: <http://www.who.int/mediacentre/factsheets/fs164/en>

⁹ <http://healthycanadians.gc.ca/diseases-conditions-maladies-affections/disease-maladie/hepatitis-c-hepatite/surveillance-eng.php>

¹⁰ See for example, <http://www.cbc.ca/news/health/hepatitis-c-medication-expensive-cure-1.3359149> and <https://news.vice.com/article/hepatitis-c-can-be-cured-in-canada-but-this-life-saving-drug-is-outrageously-expensive>

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¹² Swathi Lyengar, et al., 'Prices, Costs and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis', *PLoS Med* 13(5): e1002032. doi: 10.1371/journal.pmed.1002032, available at: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002032>

¹³ For example, Pricing of Indian generic sofosbuvir (30th Jan, 2016) <http://hepcasia.com/2016/02/16/pricing-of-indian-generic-sofosbuvir-30th-jan2016/>

¹⁴ <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=e&Mode=1&Parl=42&Ses=1&DocId=8174744>

¹⁵ <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=e&Mode=1&Parl=42&Ses=1&DocId=8273284&File=0#int-8923132>

¹⁶ Lexchin J, Gagnon M. CETA and pharmaceuticals: impact of the trade agreement between Europe and Canada on the costs of prescription drugs. [Online] *Globalization and Health* 2014; 10(30): doi:10.1186/1744-8603-10-30 [Cited 2015 June 8]. Available from:

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¹⁸ Chan, M. WHO Director-General asks think tanks to explore health challenges under the Sustainable Development Goals. 12 Nov 2015. Available from: <http://www.who.int/dg/speeches/2015/sustainable-development-goals/en/>.

¹⁹ UNITAID Report. The Trans-Pacific Partnership Agreement: Implications for access to medicines and public health. 2014 March. Available from:

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²⁰ Statement by H.E. Archbishop Silvano M. Tomasi, Apostolic Nuncio, Permanent Observer of the Holy See to the United Nations and Other International Organizations in Geneva at the 9th Session of the Ministerial Conference of the World Trade Organization, Bali, 3-6 December 2013. Available from:

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²¹ World Medical Association. WMA Council Resolution on Trade Agreements and Public Health. 2015

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