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Submission for Study: Canada's International Trade and Investment Policy – Selected Considerations Concerning COVID-19 Vaccines

Doctors Without Borders/Médecins Sans Frontières (MSF) is a medical and humanitarian organization that needs both affordable access to and innovation for new lifesaving medical technologies, such as COVID-19 vaccines. Yet, for over 40 years, MSF teams have witnessed the deadly consequences of people being unable to access the lifesaving drugs, vaccines, diagnostics and other medical devices that they need, because they are too expensive, are not adapted to local health care settings, or simply do not exist.

MSF's full briefing paper on Canada and the TRIPS Waiver is available on our website[1]. In this submission we are responding to two aspects of the Committee's study concerning COVID-19 vaccines.

Canada's position with respect to a proposal at the World Trade Organization to provide "a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19"

Canada's conduct regarding the proposed TRIPS waiver has been widely viewed as obstructive. Canada has so far consistently maintained that it "has not rejected this proposal." At the same time, however, it has not supported progress on text-based negotiations – a necessary step for the waiver to be adopted by WTO members — and has instead insisted on dragging things out through measures like demanding to first hear about specific intellectual property challenges, rather than acting urgently on implementing solutions. Its support for an alternative approach relying upon voluntary participation by pharmaceutical companies is undermined by Canada's own failed attempts to get any company to manufacture a single dose in Canada. A subsequent arrangement with Novavax will not see any doses until late 2021 at best.

This is unacceptable. MSF has repeatedly witnessed how exclusive rights and monopolies granted to pharmaceutical corporations have negatively affected our work in different countries, allowing companies to control who receives access and at what price. This story has been repeated over and over, from HIV to tuberculosis. Now, it is happening again with COVID-19 — and Canada is among those impeding efforts by WTO member states to address the problem. The Waiver is not a complete solution. It is, however, an important part of the solution; the fact that other actions will be needed cannot be used as an excuse not to move forward with any of them. Canada should stop contributing to delays, and instead support the Waiver.

Point 1: Vaccines are not, and should not be, considered the sole focus of the proposed TRIPS Waiver.

Although vaccines have received the most attention in the context of the proposed waiver, and although they are the focus of this consultation, it must be recalled that the TRIPS waiver must be considered in a broader context, encompassing other elements of the COVID-19 response, ranging from drugs to medical devices (e.g., ventilator components). For example, several potentially promising medicines for COVID-19 prevention and treatment are currently in clinical trials, and if proven effective, could be a critical part of the ongoing response, especially in light of the slow and unequal global vaccine rollout and the emergence of virus variants. In Canada, hospitals are already rationing the use of one patented medicine – tocilizumab – which is owned and manufactured by only one company (Hoffman-LaRoche), which has struggled to meet global demand. There are no generic manufacturers authorized to produce it.

Point 2: Canada should apply the same evidentiary standards at home and abroad.

As pointed out by multiple countries, and by MSF, Canada appears to hold itself to a lower evidentiary standard when it comes to loosening intellectual property protections in the COVID-19 response. Canada has repeatedly asked other countries to supply evidence of situations where IP has been a barrier in the response. By contrast, it was very quick to pass time-limited changes greatly simplifying domestic mechanisms for issuing a compulsory license. As of the morning of March 25, 2020,[2] the day the amendment received assent, less than three thousand cases of COVID-19 had been detected in Canada, resulting in fewer than

[1] https://www.doctorswithoutborders.ca/sites/default/files/msf_canada_briefer_on_trips_waiver.pdf
[2] https://toronto.citynews.ca/2020/03/25/the-latest-numbers-of-covid-19-cases-in-canada-7/

thirty deaths. Furthermore, there were no COVID-19-specific patents in place. This demonstrates that Canada was not responding to a specific, concrete IP barrier requiring this intervention, but was instead preparing for potential barriers it might face via a time-limited (now expired) tool. This is what the similarly temporary TRIPS Waiver is also intended to do.

Canada has argued that the domestic and international situations are different, as the former is permitted under TRIPS. This is a false comparison; the WTO can, and has frequently, agreed to adapt TRIPS in response to existing circumstances; the repeated shift in timelines for least-developed countries to enact various measures under TRIPS is a clear example.

Point 3: If Canada argues existing TRIPS flexibilities are sufficient, it should take them seriously at home

Canada's assertions about the utility of compulsory-license-for-export provisions under TRIPS (per Article 31bis), and its own assertions of expertise as the only country to make use of such flexibilities as an exporting country (per Canada's Access to Medicines Regime, CAMR) are difficult to take seriously. While there is disagreement over how both CAMR and Article 31bis could be reformed to be more effective, or even whether such reform is possible, there is considerable agreement – from both industry and civil society – that they does not work in their existing form. Canada has not proposed any improvements, domestically or internationally.

This is underscored by media reports of a current attempt to use CAMR – made after Canada's statement in support of the mechanism at the WTO. As reported, this attempt to use CAMR for a COVID-19 vaccine has encountered barriers such as CAMR contact phone numbers no longer being in service. Similarly, Canada has asked fellow WTO members to identify unused vaccine production capacity. Now, when a Canadian company states it has unused production capacity, and wishes to utilize TRIPS flexibilities, the process seems to stall. If Canada wants to highlight TRIPS flexibilities as a reason not to support the waiver, it needs to demonstrate that it actually takes them seriously domestically.

Point 4: Canada does not have to apply the TRIPS Waiver domestically, but should not prevent other countries from doing so.

If Canada feels that the TRIPS waiver is unnecessary, it does not have to apply it domestically. However, given the majority of WTO member states feel differently, Canada should not prevent other countries from doing so.

Furthermore, Canada must remember that not all countries have the same capacity. Simply attempting to use compulsory licenses under existing measures requires resources that may pose serious obstacles for many countries, particularly in overburdened health ministries who have little capacity to spare to search the patent status of each product to request compulsory licenses to be issued for government use, and who face protracted litigation from patent holders. This is coupled with serious political pressures that undermine the practical feasibility of such measures; for instance, even in the midst of the COVID-19 pandemic, the office of the United States Trade Representative [USTR] issued its Special 301 Report criticizing actions of trading partners for using or threatening to use TRIPS flexibilities. In any case, Canada's lack of success in negotiating voluntary licenses for the domestic production of COVID-19 vaccine suggests that Canada too might benefit from the waiver.

Whether Canada's current trade position should motivate accelerated capacity in domestic vaccine manufacturing capability;

Canada's recent nine-figure investment in the new Sanofi vaccine production plant underscores the significant role of public funding, and the potential for governments to exert leverage to secure affordable and accessible access to medicines and vaccines produced by pharmaceutical companies supported by public funds. As has been widely reported, Sanofi is the current owner of what was once Connaught Laboratories – a publicly owned, world-renowned laboratory known not only for important discoveries (such as insulin) but also for supplying Canada and other countries with high-quality vaccines for diseases like smallpox and diphtheria. Following the privatization of Connaught, Canada now must rely on other sources; in March 2021, for example, PHAC ordered $31.2 million (USD) of smallpox vaccine from a Danish company.

While the terms of the Sanofi agreement remain private, it must be emphasized that simply subsidizing companies like Sanofi with no strings attached does not by default secure access to medical tools like drugs or vaccines at fair prices. Consider Canada's investment in AbCellera, makers of the COVID-19 treatment bamlanivimab. Canada spent $176 million to support

AbCellera. In exchange, AbCellera got a record-breaking stock market valuation, while Canada subsequently spent over $30 million on bamlanivimab, with no evidence that the treatment was received at cost or with any favourable pricing.

Point 1: Canada needs to place conditions on any investments in private domestic manufacturing capacity. For instance, what guarantees have been made that a) such facilities will be used to respond to public health priorities rather than commercial priorities, particularly in a pandemic situation; and b) that Canada will receive favourable pricing – not merely for Canadians, but also for patients around the world – in recognition of its investment?

Point 2: Canada must be transparent about the terms of these investments. The public should be informed about where public funding is going, and how it protects their health. The terms of such funding agreements, particularly those terms that safeguard the public interest rather than private corporations, should be public. A recent resolution at the World Health Assembly[3] provides guidance on the nature of transparency that should be expected.

Point 3: Canada needs to fund domestic vaccine manufacturing capacity, including end-to-end development. Canada, and the Canadian government itself, boasts considerable expertise in vaccinology. Consider the National Microbiology Lab in Winnipeg, which has created vaccines for diseases like Ebola Virus and Lassa Fever. Unfortunately, Canada lacks options for getting these important innovations out of the lab and into the arms of people who need them, particularly for diseases that lack commercial interest. The failures of private partner commercialization are readily on display with the well-documented saga of the Ebola vaccine.[4] After being licensed to a private partner, it languished on a shelf for years; the result was that it was not ready for the West Africa Ebola outbreak of 2014-2015. A Canadian innovation could have saved lives; because Canada does not currently have capacity for end-to-end vaccine development, it was not available until it was too late for many people. The same situation currently faces a promising Lassa Fever vaccine, in which a Canadian innovation once again languishes because of lack of commercial interest.

Point 4: Public Canadian development and manufacturing capacity will help attract, train and maintain global expertise. As noted, Canada already boasts expertise in this area; ensuring end-to-end development, and ongoing production, will capitalize on this expertise. This will also assist in training of the next generation of experts and attracting experts from elsewhere.

Point 5: Canadian vaccine capacity can be a powerful force with a positive impact. Canada's reputation has suffered because of its conduct in the current pandemic. Despite generous financial contributions to mechanisms like COVAX and the ACT Accelerator, its other actions have made Canada a go-to example of "Vaccine Nationalism" around the world. These actions include using bilateral deals to secure the most vaccine doses per capita of any country despite limited global supply, entering into new bilateral deals (as with Serum Institute of India) even after the WHO had explicitly requested countries refrain from doing so, and being the only G7 country to take vaccines from the first round of COVAX, at a time when many countries had received zero doses of vaccines. Imagine instead if Canada were able to return to the era when it was able to not only meet its own domestic needs, but export to other countries in need. This applies both to made-in-Canada innovations, and the production of existing vaccines.

[3] https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf

[4] Matthew Herder, Janice E Graham, Richard Gold, From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine, Journal of Law and the Biosciences, 2020; https://doi.org/10.1093/jlb/lsz019