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June 08, 2021

Hon. François-Philippe Champagne, P.C., M.P.
Minister of Innovation, Science and Industry
C.D. Howe Building
235 Queen Street
Ottawa, Ontario K1A 0H5

Hon. Patty Hajdu, P.C., M.P.
Minister of Health
House of Commons
Ottawa, Ontario K1A 0A6

RE: Utilizing TRIPS flexibilities and Canada's Access to Medicines Regime (CAMR) for COVID-19

Dear Honourable Ministers,

The international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF) is calling upon the Government of Canada to make use of existing flexibilities within the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property (TRIPS) Agreement to increase the scale-up and diversification of pharmaceutical manufacturing capacity in Canada as part of the global response to COVID-19. Specifically, MSF is asking the Canadian government to add pharmaceuticals (including vaccines) for COVID-19 to Schedule 1 of the *Patent Act*, making them eligible for compulsory license, manufacture, and export under Canada's Access to Medicines Regime (CAMR).

Schedule 1 is the list of patented products eligible for export under CAMR. Per s.23.03(1) of the *Patent Act*, this list can be amended via an order by the Governor-in-Council, based on the recommendation of the Minister of Health and the Minister of Innovation, Science & Industry. As such, MSF asks both of you, Ministers, to issue such a recommendation for pharmaceuticals, including vaccines and therapeutic medicines, used in the global COVID-19 response.

Under the *Patent Act,* a product is eligible to be added to Schedule 1 if it is a "patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". Products used to address the global COVID-19 pandemic clearly meet these criteria.

Canada has repeatedly referenced Article 31bis of the TRIPS agreement, and Canada's domestic

operationalization of it via CAMR, as an example of an existing flexibility that countries could use in the context of the COVID-19 pandemic. In turn, Canada has used TRIPS flexibilities and CAMR as a rationale for delaying its support of a waiver on intellectual property rules proposed by India and South Africa.

For instance, in its December intervention at the WTO regarding the TRIPS Waiver, Canada stated "Canada remains the only Member to have used the special compulsory licensing system under Article 31*bis*, and can thus observe, on the basis of concrete experience, that the system worked as intended." This statement is misleading, both in terms of its past use and in its demonstrated utility thus far in response to the COVID-19 pandemic.

Technically speaking, it is correct that Canada remains the only country to have utilized Article 31bis flexibilities to export pharmaceuticals produced under a compulsory license, which it did using CAMR. The only time Article 31bis flexibilities have been used in Canada, and therefore the only time they have ever been used anywhere in the world, was in 2008, for two shipments of an antiretroviral therapy drug for HIV that were sent to Rwanda. The company that made and exported the drug said it would never go through the process again. Numerous other parties, including MSF, have tried to use CAMR to increase access to other vital medicines; none have ever been successful.

As such, it is hard to call Article 31bis or CAMR a success. Nonetheless, Canada's clear suggestion at the WTO is that such tools not only remain potentially valuable in the response to the current COVID-19 pandemic, but that they render the proposed TRIPS waiver unnecessary. In practice, however, it is Canada that has proven the greatest roadblock in even attempting to use Article 31bis in response to COVID-19. Canada cannot credibly claim that existing TRIPS flexibilities such as Article 31bis work, only to turn around and obstruct those very same flexibilities when an attempt is made to use them at home.

As widely reported in national and international media, a Canadian company has made efforts to use CAMR to produce COVID-19 vaccines. Furthermore, Bolivia has signed an agreement with this company to purchase millions of doses of vaccines. Bolivia is eligible to purchase Canadian exports under CAMR; it has also notified the WTO of its intent to make use of TRIPS flexibilities as an importing country. As such, there is a willing buyer and a willing seller; Canada remains the obstacle. The company in question has been unable to get COVID-19 vaccines added to Schedule 1. MSF is not party to this process and cannot comment on the merits of this specific attempt. However, reports have surfaced of the barriers encountered thus far, which do not inspire confidence in the process, including a listed phone number for CAMR being out of service and a general lack of clarity on steps required to move the process forward.

To be clear, MSF Canada does not believe that existing TRIPS flexibilities are sufficient to respond to the COVID-19 pandemic. It also does not believe that CAMR, in its current form, is an effective means of exercising those TRIPS flexibilities. However, MSF believes that Canada should follow its own statements at the WTO to their logical conclusion, and ensure that COVID-19 vaccines and other pharmaceuticals are quickly added to Schedule 1 of the *Patent*

Act. The continued failure to enable the very TRIPS flexibilities it endorses does not aid Canada's credibility or provide assurances that it is acting in good faith in response to the COVID-19 pandemic.

Yours sincerely,

Joseph Belliveau,
Executive Director,
Doctors Without Borders/Médecins Sans Frontières (MSF)

CC: Hon. Mary Ng, M.P., Minister of Small Business, Export Promotion and International Trade;
Hon. Marc Garneau, M.P., Minister of Foreign Affairs;
Hon. Karina Gould, Minister of International Development.