The need to expand the scope to include treatments, not just vaccines.

Brief for the 'Vaccine Equity and Intellectual Property' Study for the **Standing Committee on Foreign Affairs and International Development (FAAE)**

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As the world considers different approaches to end this pandemic, one approach is to consider a ‘vaccines-only’ approach to temporarily suspending intellectual property, which is currently the draft text of the proposal currently under review at the World Trade Organization. This would be short-sighted, and will not provide the necessary tools to achieve the goals of saving lives. Specifically, we need to expand any conversation to include therapeutics, and the name of this committee being ‘Vaccine Equity’ is limiting in the scope of what is required to save the most lives.

Canada, even with its high level of population immunity due to access to mRNA vaccines, is dependent on effective therapeutics to save lives. From outpatients at high-risk to hospitalized patients to critically ill patients, Canada has spent billions of dollars in purchasing these products for the benefit of the Canadian population. Huge strides have been achieved, and we now know a tremendous amount about which drug to give to which patient, with the goal of saving lives and reducing impact to health systems.

For outpatients, we have monoclonal antibodies that target the virus, and direct acting antivirals that stop the virus from replicating. Both have shown to be very effective at reducing hospitalizations if given in the appropriate patient. For inpatients, we have antivirals, steroids, and other immune modulating therapies, in addition to high-quality supportive care. Most of these medications are not available around the world, and it has been shown that risk-adjusted mortality rates for hospitalized patients in Sub-Saharan Africa is much higher than mortality rates for hospitalized patients in Canada.[1] Much of this difference is due to the inaccessibility of therapeutics, where patients in Canada will receive very different therapies than patients in other parts of the world.

The value of these therapeutics is apparent in a highly vaccinated population, such as Canada, but is even greater in a largely unvaccinated population, where the risk for severe disease is higher, and the rates of hospitalization are large. In this context, limited access to therapeutics compounds the inequities apparent with vaccine inequity, further prolonging the pandemic and causing more lives lost.

I am a critical care physician and a Research Chair in pandemic preparedness at the University of British Columbia and have received funding from CIHR to help evaluate COVID19 therapeutics. I also chair clinical guidelines in Canada and the World Health Organization for clinical management of COVID19. Having managed many patients with COVID19, and evaluated the evidence for their benefit very closely, I am very aware of the value they add to overall pandemic control. If they were removed from our management armamentarium in Canada, we would be very limited in our ability in making our patients better. I am on daily calls with colleagues in less-resourced hospitals around the world, where the medications that I have access for managing my patients are inaccessible to them.

Specifically, as it relates to therapeutics, the agents currently proven to be useful have manufacturing that is very feasible by hundreds of manufacturers around the world. This is particularly true for the small molecules such as baricitinib or nirmatrelivir, which are on-patent medications that are either unavailable or have very restricted access in many regions of the world. These have clear pathways for scale-up of manufacturing at reasonably low-costs.[2] Removing patent restrictions, globally, on therapeutic products for this pandemic, has a high likelihood of leading to manufacturing scale-up and increased accessibility, many lives saved, and huge economic impacts. For example, the availability of corticosteroids, another life-saving therapy that is more accessible and off-patent, has been shown to save a million lives in 2020 alone.[3]

Relying on donations of therapeutics from Canada, as evidenced by our experience with vaccine donations, will never suffice for the large amounts of products required. This is especially true given the limited supply of these products in Canada currently, and the only solution is a massive scale-up of production by all available manufacturing capacity, with local control that is not susceptible to relying on

charity from richer countries. Licensing agreements have been made by the manufacturers, which still limit access to many parts of the world, particularly those with high burden of disease. Current flexibilities in intellectual property are also inadequate – for example, the recent application for a compulsory license by the Dominican Republic for production of Paxlovid (nirmatrelivir/ritonavir) is being actively opposed by Pfizer, causing undue delays.

Other submissions and witnesses to this committee have spoken to the need for improved vaccine and diagnostics access around the world through local control of production, which cannot be overstated. This brief is focused on **ensuring that local production of therapeutics is part of any global intellectual property policy,** as part of any pandemic preparedness program. This is in contrast to the current language at the World Trade Organization, that is specific only to vaccines. I will be happy to speak further to the committee on the importance for global access to life-saving therapeutics.

1. African C-CCOSI. Patient care and clinical outcomes for patients with COVID-19 infection admitted to African high-care or intensive care units (ACCCOS): a multicentre, prospective, observational cohort study. *Lancet* 2021; **397**(10288): 1885-94.
2. . https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments.
3. Aguas R, Mahdi A, Shretta R, et al. Potential health and economic impacts of dexamethasone treatment for patients with COVID-19. *Nat Commun* 2021; **12**(1): 915.