April 30, 2021

Standing Committee on International Trade
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Re: Standing Committee on International Trade study of Canada's International Trade and Investment Policy: Selected Considerations Concerning COVID-19 Vaccines

On behalf of Innovative Medicines Canada (IMC), thank you for the opportunity to appear before the Standing Committee on International Trade (CIIT) on April 16, 2021 in support of the CIIT's study of Canada's trade and investment policy, and trade agreements in respect of how they may help or hinder the production and distribution of COVID-19 vaccines in Canada and across the world.

IMC represents Canada's research and development biopharmaceutical industry. Our 47 member companies range from established organizations to emerging small biotechnology companies, all of whom are dedicated to improving healthcare through the discovery and development of new medicines and vaccines. Our mission is to ensure that Canadians have access to the innovative treatments they need.

In response to some of the questions raised and ensuing discussions during our CIIT appearance, we would like to take this opportunity to clarify and expand upon certain points – in particular with respect to the motion regarding 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". We also note that, subsequent to our appearance, the sponsor of this motion has been quoted as continuing to question why the TRIPS waiver would be damaging[1].

As noted before the CIIT, IMC would stress that the potential harm to the innovative biopharmaceutical industry of essentially waiving countries' core obligations under the TRIPS agreement to protect intellectual property (IP) for a broad range of technologies related to COVID-19 would be both significant and detrimental to ongoing international efforts to contain and defeat the pandemic.

In particular, we wish to reiterate the critical role that globally agreed upon IP standards play in fostering the stability of the global innovation ecosystem. IP is a key factor for businesses in deciding when and where to invest in biopharmaceutical research and development. Without having had certainty that IP rights would be protected in a stable and predictable manner leading up to the current pandemic, industry would not have at

[1] Moss, Neil. "Canada continues to delay decision on COVID vaccines IP waiver". *The Hill Times*. 21 April, 2021. Available at https://www.hilltimes.com/2021/04/21/canada-continues-to-delay-decision-on-covid-vaccines-ip-waiver/294146.

the ready the advanced processes and technologies required to develop new vaccines in such an unprecedented timeframe and at such an extraordinary scale.

Not only was IP a driving force behind rapid COVID-19 vaccine development in support of the current COVID-19 crisis, it will also continue to be relied upon moving forward as new variants emerge and as ongoing disease management relies upon treatments and vaccine boosters. In view of this ongoing and adapting response, we need collectively to ensure that innovation continues and is appropriately incentivized. The reality is that the business model driving innovation is based on some sort of return on investment, and the IP protections enshrined within TRIPS and Canadian trade agreements, and as incorporated within Canada's domestic IP laws, provide key incentives for innovative biopharmaceutical companies to constantly strive to innovate.

In addition to the above, we wish to reemphasize that the proposed TRIPS waiver is misplaced in directing WTO members' attention to IP rights as the source of vaccine supply issues. Proponents argue that revoking IP rights would lead to an increase in the supply of new vaccines in developing nations. Let us be very clear: there is no credible evidence validating this assumption. We must look at the nature of vaccines themselves; effective manufacturing capacity expansion needs to overcome major challenges, tackling such bottlenecks as the need for highly specialized equipment, qualified and trained personnel, difficult and time-consuming technology transfers, and the management of complex international supply chains frequently involving more than 100 components[2]. With these global supply chain constraints in mind, it important that we reiterate that the TRIPS waiver – through its proposed dilution of IP rights – is not a viable mechanism by which to efficiently increase COVID-19 vaccine production and supply in Canada or elsewhere. Moreover, vaccine manufacturers are already collaborating worldwide to expand production. Despite the challenges of increasing manufacturing on an expedited basis, it is estimated that COVID-19 vaccine producers will produce approximately 10 billion doses by the end of 2021. It has been reported that, pre-pandemic, annual output of the major vaccine producers was in the region of 5 billion (including seasonal flu) – the swift scale-up has been unprecedented[3].

In fact, several biopharmaceutical companies have already entered into agreements with manufacturers of COVID-19 vaccines and therapies to help provide additional manufacturing support – including state-of-the-

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[2] International Federation of Pharmaceutical Manufacturers and Associations. *Meeting discusses COVID-19 vaccine manufacturing bottlenecks that must be urgently tackled for C19 vaccine output to reach its full potential*. 9 March, 2021. Available at: https://www.ifpma.org/resource-centre/meeting-discusses-covid-19-vaccine-manufacturing-bottlenecks-that-must-be-urgently-tackled-for-c19-vaccine-output-to-reach-its-full-potential/. There is strong global consensus amongst vaccine manufacturers and suppliers of vaccine components of the non-IP-related challenges to effective COVID-19 vaccine manufacturing capacity expansion.

[3] McCarthy, Niall. "The Number of Covid-19 Vaccine Doses Produced In 2021 Will be Twice as High as Pre-Covid-19 Vaccine Output". *Forbes*. 24 March, 2021. Available at: https://www.forbes.com/sites/niallmccarthy/2021/03/24/the-number-of-covid-19-vaccine-doses-produced-in-2021-will-be-twice-as-high-as-pre-covid-19-vaccine-output/?sh=6941e780462b.

art manufacturing facilities, technology and expertise[4]. These agreements demonstrate a shared commitment across the industry to increase global supply of, and access to, COVID-19 vaccines and treatments. These agreements also demonstrate that, despite having existing infrastructure and expertise, the shift to manufacturing COVID-19 products cannot occur instantly. Rather, it takes significant time and resources to adapt long-standing capacity and technology to produce safe and high quality COVID-19 products.

In summary, it is IMC's position that weakening IP protections through a TRIPS waiver would only undermine the confidence in what has proven to be a functioning IP system; one that has allowed industry to confidently partner with academia, research institutes, foundations, and other private companies in responding to COVID-19. Moving forward, it would also create uncertainty in the business ecosystem that will inevitably delay research and innovation. While we are open and receptive to policy measures that would improve on current vaccine development processes and timelines, they must be evidence-based and we caution against making decisions without substantively analyzing their anticipated efficacy and potential consequences. In view of the very real potential for negative consequences for production of vaccines, IMC recommends that Canada stand with leading innovative jurisdictions to oppose the TRIPS waiver proposal.

At the same time, there are constructive improvements to our current processes that can be implemented. We can continue to increase manufacturing capacity with technology transfer, voluntary licences, and partnerships between companies. We can also identify and address regulatory inefficiencies while

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[4] See, e.g., Merck. *Amid Humanitarian Crisis in India, Merck Announces Voluntary Licensing Agreements with Five Indian Generics Manufacturers to Accelerate and Expand Global Access to Molnupiravir, an Investigational Oral Therapeutic for the Treatment of COVID-19.* 27 April, 2021. Available at: https://www.merck.com/news/amid-humanitarian-crisis-in-india-merck-announces-voluntary-licensing-agreements-with-five-indian-generics-manufacturers-to-accelerate-and-expand-global-access-to-molnupiravir-an-investigational-ora/; Merck. *Merck to help produce Johnson & Johnson's COVID-19 vaccine; BARDA to provide Merck with funding to expand Merck's manufacturing capacity for COVID-19 vaccines and medicines.* 2 March, 2021. Available at: https://www.merck.com/news/merck-to-help-produce-johnson-barda-to-provide-merck-with-funding-to-expand-mercks-manufacturing-capacity-for-covid-19-vaccines-and-medicines/; Novartis. *Novartis signs initial agreement with CureVac to manufacturer COVID-19 vaccine candidate.* 4 March, 2021. Available at: https://www.novartis.com/news/media-releases/novartis-signs-initial-agreement-curevac-manufacture-covid-19-vaccine-candidate;
Novartis. *Novartis signs initial agreement to provide manufacturing capacity for Pfizer-BioNTech COVID-19 vaccine.* 29 January, 2021. Available at https://www.novartis.com/news/media-releases/novartis-signs-initial-agreement-provide-manufacturing-capacity-pfizer-biontech-covid-19-vaccine;
Sanofi. *Sanofi to help manufacture Moderna COVID-19 vaccine, supporting global supply demands.* 26 April, 2021. Available at: https://www.sanofi.com/en/media-room/press-releases/2021/2021-04-26-13-00-00-2216648; Sanofi. *Sanofi to provide manufacturing support to Johnson & Johnson for their COVID-19 vaccine to help address global supply demands.* 22 February 2021. Available at: https://www.sanofi.com/en/media-room/press-releases/2021/2021-02-22-11-40-00-2179318; Sanofi. *Sanofi to provide support to BioNTech in manufacturing their COVID-19 vaccine to help address public health needs.* 27 January, 2021. Available at: https://www.sanofi.com/en/media-room/press-releases/2021/2021-01-27-07-30-00.

maintaining strict safety standards. We can eliminate export barriers, to mitigate situations like what recently occurred in the European Union, where vaccine shipments for other countries have been delayed or blocked. We encourage the Government of Canada to continue to focus on these types of meaningful and progressive initiatives in order to foster biopharmaceutical innovation.

Finally, and as noted in our comments to the Committee on April 16th, we would reiterate that there is an urgent need to suspend the July 2021 implementation of changes to the Patented Medicine Prices Review Board (PMPRB) until the COVID-19 pandemic has abated. The PMPRB changes are having a destabilizing impact and are strongly opposed by industry, patient groups and life sciences stakeholders due to concerns about impacts on access to new innovative medicines and Canada's future domestic life sciences capacity. The federal government has previously cited COVID-19 as the rationale for suspending these changes, and there is no scenario in which the pandemic will have abated by the implementation date.

Thank you for your consideration of this information. IMC would be pleased to address any questions that you may have with respect to this issue.